FORM 20-F

2020

SANOFI

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

(Mark One)

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

Or

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2020

Or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Or

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of event requiring this shell company report

For the transition period from to

Commission File Number: 001-31368

Sanofi

(Exact name of registrant as specified in its charter)

N/A

(Translation of registrant's name into English)

France

(Jurisdiction of incorporation or organization)

54, Rue La Boétie, 75008 Paris, France

(Address of principal executive offices)

Karen Linehan, Executive Vice President Legal Affairs and General Counsel
54, Rue La Boétie, 75008 Paris, France. Fax: 011 + 33 1 53 77 43 03. Tel: 011 + 33 1 53 77 40 00
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class:	Name of each exchange on which registered:
American Depositary Shares, each representing one half of one ordinary share, par value €2 per share	NASDAQ Global Select Market
Ordinary shares, par value €2 per share	NASDAQ Global Select Market*

Securities registered pursuant to Section 12(g) of the Act: None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None

The number of outstanding shares of each of the issuer's classes of capital or common stock as of December 31, 2020 was:

Ordinary shares: 1,250,690,553

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐.

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes ☐ No ☒.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐.

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or an emerging growth company. See definition of "large accelerated filer," "accelerated filer" or "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Emerging growth company ☐

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act. ☐

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report ☒

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐ International Financial Reporting Standards as issued by the International Accounting Standards Board ☒ Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒.

*Not for trading but only in connection with the registration of American Depositary Shares representing such ordinary shares.

Presentation of financial and other information

The consolidated financial statements contained in this annual report on Form 20-F have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and with IFRS as endorsed by the European Union, as of December 31, 2020.

Unless the context requires otherwise, the terms "Sanofi," the "Company," the "Group," "we," "our" or "us" refer to Sanofi and its consolidated subsidiaries.

All references herein to "United States" or "US" are to the United States of America, references to "dollars" or "$" are to the currency of the United States, references to "France" are to the Republic of France, and references to "euro" and "€" are to the currency of the European Union member states (including France) participating in the European Monetary Union.

Brand names appearing in this annual report are trademarks of Sanofi and/or its affiliates, with the exception of:

- trademarks used or that may be or have been used under license by Sanofi and/or its affiliates, such as Actonel®, a trademark of Actavis; Aldurazyme®, a trademark of the Biomarin/Genzyme LLC Joint Venture; Cialis® OTC, a trademark of Eli Lilly; Libtayo®, a trademark of Regeneron in the United States; Vaxelis®, a trademark of MCM Vaccine Co (USA) and MCM Vaccine B.V. (Netherlands); and Zaltrap®, a trademark of Regeneron in the United States;
- trademarks sold by Sanofi and/or its affiliates to a third party, such as Altace®, a trademark of King Pharmaceuticals in the United States; Hyalgan®, a trademark of Fidia Farmaceutici S.p.A.; StarLink®, a trademark of Bayer; and
- other third party trademarks such as Humalog®, a trademark of Eli Lilly; Eylea®, a trademark of Regeneron; Revlimid®, a trademark of Celgene Corporation; Velcade®, a trademark of Millennium Pharmaceuticals Inc; and Zantac®, a trademark of Glaxo Group Limited.

Not all trademarks related to products under development have been authorized as of the date of this annual report by the relevant health authorities.

The data relating to market shares and ranking information for pharmaceutical products, in particular as presented in "Item 4. Information on the Company — B. Business Overview — B.6. Markets — B.6.1. Marketing and distribution," are based mainly on sales data excluding vaccines and in constant euros (unless otherwise indicated) on a September 2020 MAT (Moving Annual Total) basis. The data are mainly from IQVIA local sales audit, supplemented by country-specific sources.

Product indications described in this annual report are composite summaries of the major indications approved in the product's principal markets. Not all indications are necessarily available in each of the markets in which the products are approved. The summaries presented herein for the purpose of financial reporting do not substitute for careful consideration of the full labeling approved in each market.

Cautionary statement regarding forward-looking statements

This Annual Report contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. We may also make written or oral forward-looking statements in our periodic reports to the Securities and Exchange Commission on Form 6-K, in our annual report to shareholders, in our offering circulars and prospectuses, in press releases and other written materials and in oral statements made by our officers, directors or employees to third parties. Examples of such forward-looking statements include:

- projections of operating revenues, net income, business net income, earnings per share, business earnings per share, capital expenditures, cost savings, restructuring costs, positive or negative synergies, dividends, capital structure or other financial items or ratios;
- statements of our profit forecasts, trends, plans, objectives or goals, including those relating to products, clinical trials, regulatory approvals and competition; and
- statements about our future events and economic performance or that of France, the United States or any other countries in which we operate.

This information is based on data, assumptions and estimates considered as reasonable by Sanofi as at the date of this annual report and undue reliance should not be placed on such statements.

Words such as “believe,” “anticipate,” “plan,” “expect,” “intend,” “target,” “estimate,” “project,” “predict,” “forecast,” “guideline,” “should” and similar expressions are intended to identify forward-looking statements but are not the exclusive means of identifying such statements.

Forward-looking statements involve inherent, known and unknown risks and uncertainties associated with the regulatory, economic, financial and competitive environment, and other factors that could cause future results and objectives to differ materially from those expressed or implied in the forward-looking statements.

Risk factors which could affect future results and cause actual results to differ materially from those contained in any forward-looking statements are discussed under “Item 3. Key Information — D. Risk Factors”. Additional risks, not currently known or considered immaterial by the Group, may have the same unfavorable effect and investors may lose all or part of their investment.

Forward-looking statements speak only as of the date they are made. Other than required by law, we do not undertake any obligation to update them in light of new information or future developments.

Abbreviations

Principal abbreviations used in the Annual Report on Form 20-F

ADR	American Depositary Receipt
ADS	American Depositary Share
AFEP	*Association française des entreprises privées* (French Association of Large Companies)
AMF	*Autorité des marchés financiers* (the French market regulator)
ANDA	Abbreviated New Drug Application
BLA	Biologic License Application
BMS	Bristol-Myers Squibb
CEO	Chief Executive Officer
CER	Constant exchange rates
CGU	Cash generating unit
CHC	Consumer Healthcare
CHMP	Committee for Medicinal Products for Human Use
COVALIS	Sanofi committee for internal occupational exposure limits (Comité des Valeurs Limites Internes Sanofi)
CVR	Contingent value right
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
EU	European Union
FCF	Free cash flow
FDA	US Food and Drug Administration
GAVI	Global Alliance for Vaccines and Immunisation
GBU	Global Business Unit
GCP	Good clinical practices
GDP	Good distribution practices
GLP	Good laboratory practices
GLP-1	Glucagon-like peptide-1
GMP	Good manufacturing practices
Hib	Haemophilus influenzae type b
HSE	Health, Safety and Environment
IASB	International Accounting Standards Board
ICH	International Council for Harmonization
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IFRIC	International Financial Reporting Interpretations Committee
IFRS	International Financial Reporting Standards
IPV	Inactivated polio vaccine
ISIN	International Securities Identification Number
J-MHLW	Japanese Ministry of Health, Labor and Welfare
LSD	Lysosomal storage disorder
MEDEF	*Mouvement des entreprises de France* (French business confederation)
MS	Multiple sclerosis
NASDAQ	National Association of Securities Dealers Automated Quotations
NDA	New Drug Application
NHI	National Health Insurance (Japan)
NYSE	New York Stock Exchange
OECD	Organisation for Economic Co-operation and Development
OPV	Oral polio vaccine
OTC	Over the counter
PhRMA	Pharmaceutical Research and Manufacturers of America
PMDA	Pharmaceuticals and Medical Devices Agency (Japan)
PRV	Priority Review Voucher
PTE	Patent Term Extension
QIV	Quadrivalent influenza vaccine
R&D	Research and development
ROA	Return on assets
SA	*Société anonyme* (French public limited corporation)
SEC	US Securities and Exchange Commission
SPC	Supplementary Protection Certificate
TRIBIO	Sanofi Committee for Biological Risk Prevention (Biosafety, Biosecurity, Biosurveillance)
TSR	Total shareholder return
UNICEF	United Nations Children's Emergency Fund
US	United States of America
WHO	World Health Organization

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Part I

Item 1. Identity of Directors, Senior Management and Advisers

N/A

Item 2. Offer Statistics and Expected Timetable

N/A

Item 3. Key Information

A. Selected financial data

N/A

B. Capitalization and indebtedness

N/A

C. Reasons for offer and use of proceeds

N/A

D. Risk factors

Important factors that could cause actual financial, business, research or operating results to differ materially from expectations are disclosed in this annual report, including without limitation the following risk factors. Investors should carefully consider all the information set forth in the following risk factors and elsewhere in this document before deciding to invest in any of the Company's securities. In addition to the risks listed below, we may be subject to other material risks that as of the date of this report are not currently known to us or that we deem immaterial at this time.

Risks relating to legal and regulatory matters

Product liability claims could adversely affect our business, results of operations and financial condition.

Product liability is a significant risk for any pharmaceutical company and our product liability exposure could increase, given that liability claims relating to our businesses may differ – with regard to their nature, scope and level – from the types of product liability claims that we have handled in the past. Substantial damages have been awarded by some jurisdictions and/or settlements agreed – notably in the United States and other common law jurisdictions – against pharmaceutical companies based on claims for injuries allegedly caused by the use of their products. Such claims can also be accompanied by consumer fraud claims by customers or third-party payers seeking reimbursement of the cost of the product.

We are currently defending a number of product liability claims (see Note D.22.a) to the consolidated financial statements included at Item 18. of this annual report) and there can be no assurance that we will be successful in defending these claims, or that we will not face additional claims in the future.

Often, establishing the full side effect profile of a pharmaceutical drug goes beyond data derived from preapproval clinical studies which may only involve several hundred to several thousand patients. Routine review and analysis of the continually growing body of post-marketing safety data and clinical trials provide additional information – for example, potential evidence of rare, population-specific or long-term adverse events or of drug interactions that were not observed in preapproval clinical studies. This may cause product labeling to evolve over time following interactions with regulatory authorities, including restrictions of therapeutic indications, new contraindications, warnings or precautions and occasionally even the suspension or withdrawal of a product marketing authorization. For example, in October 2019, we decided to voluntarily recall all Zantac® OTC in the US and Canada following inconsistencies in preliminary test results on the active ingredient used in the US products. Following any of these events, pharmaceutical companies can face significant product liability claims (see Note D.22.a) to the consolidated financial statements included at Item 18 of this annual report).

Furthermore, we commercialize several devices (some of which use new technologies) which, if they malfunction, could cause unexpected damage and lead to product liability claims (see "– Breaches of data security, disruptions of information technology systems and cyber threats could result in financial, legal, business or reputational harm" below).

Although we continue to insure a portion of our product liability with third-party carriers, product liability coverage is increasingly difficult and costly to obtain, particularly in the United States. In the future, it is possible that self-insurance may become the sole commercially reasonable means available for managing the financial risk associated with product liability in our pharmaceuticals and vaccines businesses (see "Item 4. Information on the Company — B. Business Overview — B.9. Insurance and Risk Coverage"). In cases where we self-insure, the legal costs that we would bear for handling such claims, and potential damage awards to be paid to claimants, could

have a negative impact on our financial condition. Due to insurance conditions, even when we have insurance coverage, recoveries from insurers may not be totally successful due to market-driven insurance limitations and exclusions. Moreover, insolvency of an insurer could affect our ability to recover claims on policies for which we have already paid a premium.

Product liability claims, regardless of their merits or the ultimate success of the Company's defense, are costly, divert management's attention, may harm our reputation and can impact the demand for our products. Substantial product liability claims could materially adversely affect our business, results of operations and financial condition.

Claims and investigations relating to compliance, ethics, competition law, marketing practices, pricing, human rights of workers, data protection and other legal matters could adversely affect our business, results of operations and financial condition.

Our industry is heavily regulated and legal requirements vary from country to country, and new requirements are imposed on our industry from time to time. Governments and regulatory authorities around the world have been strengthening implementation and enforcement activities in recent years, including in relation to anti-bribery, anti-corruption and ethical requirements with respect to medical and scientific research, interactions with healthcare professionals and payers, respect of the human rights of workers, and data protection legislation.

We have adopted a Code of Ethics that requires employees to comply with applicable laws and regulations, as well as the specific principles and rules of conduct set forth in the Code. We also have policies and procedures designed to help ensure that we, our officers, employees, agents, intermediaries and other third parties comply with applicable laws and regulations (including the US Foreign Corrupt Practices Act ("FCPA"), the UK Bribery Act, the OECD Anti-Bribery Convention, the French Anti-Corruption measures law ("Sapin II"), the French duty of vigilance law and other anti-bribery laws and regulations).

Notwithstanding these efforts, failure to comply with laws and regulations (including as a result of a business partner's breach) may occur and could result in liabilities for us and/or our management.

With respect to data protection legislation, the European General Data Protection Regulation ("GDPR") has created a range of compliance obligations since 2018, when it came into force. Violations of the GDPR carry financial risks due to penalties for data breach or improper processing of personal data (including a possible fine of up to 4% of total worldwide annual turnover for the preceding financial year for the most serious infringements) and may also harm our reputation and those of our activities that rely on personal data processing. Furthermore, significant new privacy legislation has entered into force in many jurisdictions, including in the United States with the California Consumer Privacy Act ("CCPA") among others, violations of which may also result in financial sanctions and reputational consequences. In addition, some uncertainty remains with respect to the legal and regulatory environment for these evolving privacy and data protection laws in the absence of clear guidance or case law.

Sanofi and certain of its subsidiaries are under investigation or could become the subject of additional investigations or proceedings by various government entities. We are currently defending ourselves in a number of lawsuits relating to pricing and marketing practices (including, for example, "whistleblower" litigation in the United States). We also face litigation and government investigations or audits, including allegations of corruption, claims related to employment matters, patent and intellectual property disputes, consumer law claims and tax audits. With respect to tax issues, the complexity of the fiscal environment is such that the ultimate resolution of any tax matter may result in payments that are greater or less than the amounts we have accrued. See "Item 8. Financial Information — A. Consolidated Financial Statements and Other Financial Information — Information on Legal or Arbitration Proceedings" and Note D.22. to our consolidated financial statements included at Item 18. of this annual report. In addition, responding to such investigations is costly and may divert management's attention from our business.

Unfavorable outcomes in any of these matters, or in similar matters that may arise in the future, could preclude the commercialization of our products, harm our reputation, negatively affect the profitability of existing products and subject us to substantial fines, punitive damages, penalties and injunctive or administrative remedies, potentially leading to the imposition of additional regulatory controls, monitoring or self-reporting obligations, or exclusion from government reimbursement programs or markets, all of which could have a material adverse effect on our business, results of operations or financial condition.

As the outcomes of such proceedings are unpredictable, we may, after consideration of all relevant factors, decide to enter into settlement agreements to settle certain claims. Such settlements may involve significant monetary payments and/or potential criminal penalties, and may include admissions of wrongdoing and may require entering into a Corporate Integrity Agreement ("CIA") or a Deferred Prosecution Agreement (in the United States), which is intended to regulate company behavior for a specified number of years. For example, on February 28, 2020, Sanofi US entered into a civil settlement with the United States Department of Justice and agreed to pay approximately $11.85 million to resolve allegations regarding certain charitable donations Sanofi US made to an independent patient assistance foundation that assisted patients being treated for Multiple Sclerosis. In connection with this settlement, Sanofi US also entered into a CIA with the Office of the Inspector General for the United States Department of Health and Human Services effective the same day, which will require the Company to meet and maintain certain compliance requirements in the United States.

In September 2018, Sanofi reached a civil settlement with the US Securities and Exchange Commission (SEC) fully resolving the SEC's investigation into possible violation of the US FCPA. Sanofi did not admit any wrongdoing in connection with the settlement but agreed to pay $25 million in penalties and to a two-year period of self-reporting on the effectiveness of its enhanced internal controls, which ended in January 2021.

Our activities (including our products and manufacturing activities) are subject to significant government regulations and approvals, which are often costly and could result in adverse consequences to our business if we fail to anticipate the regulations, comply with them, maintain the required approvals, and/or adapt to changes in applicable regulations.

Obtaining a marketing authorization for a product is a long and highly regulated process requiring us to present extensive documentation and data to the relevant regulatory authorities either at the time of the filing of the application for a marketing authorization or later during its review. Each regulatory authority may impose its own requirements which can evolve over time. Each regulatory authority may also delay or refuse to grant approval even though a product has already been approved in another country. Regulatory authorities are increasingly strengthening their requirements on product safety and risk/benefit profile. All of these requirements, including post-marketing

requirements, have increased the costs associated with maintaining marketing authorizations and achieving reimbursement for our products.

Moreover, to monitor our compliance with applicable regulations, the FDA, EMA, WHO and comparable national agencies in other jurisdictions routinely conduct inspections of our facilities, distribution centers, commercial activities and development centers and may identify potential deficiencies. For example, in November 2020, the FDA issued a Complete Response Letter (CRL) regarding the Biologics License Application (BLA) for sutimlimab, an investigational monoclonal antibody for the treatment of hemolysis in adults with cold agglutinin disease, referring to certain deficiencies identified by the agency during a pre-license inspection of a third-party facility responsible for manufacturing. More generally, if we fail to adequately respond to regulatory inspection observations identifying a deficiency during an inspection, or fail to comply with applicable regulatory requirements at all or within the targeted timeline, we could be subject to enforcement, remedial and/or punitive actions by the FDA (such as a Warning Letter or cease and desist orders), the EMA or other regulatory authorities. In addition, in order to comply with our duty to report adverse events and safety signals to regulatory authorities, we must regularly train our employees and third parties (such as external sales forces and distributor employees) on regulatory matters. If we fail to train these people, or fail to train them appropriately, or if they do not comply with contractual requirements, we may be exposed to the risk that safety events are not reported or not reported in a timely manner in breach of our reporting obligations.

In addition, all aspects of our business, including research and development, manufacturing, marketing, reimbursement, pricing and sales, are subject to extensive legislation and governmental regulation. Changes in applicable laws and the costs of compliance with such laws and regulations could have an adverse effect on our business.

For example, the implementation date for the new European Union regulations for Medical Devices (EU MDR) has been postponed from May 2020 to May 2021. Additionally, the implementation date of the new regulations for In-Vitro Diagnostic Devices (IVDR) is May 2022. A Sanofi EU MDR task force has been commissioned to address the risk of potential delays in approvals (for new drug-device combination products, for substantial changes to the design or intended purpose of the device component of already approved drug-device combination products, and for Medical Devices) and of product discontinuation (for some legacy medical devices), as well as non-compliance risks for existing products due to increased requirements for post-marketing surveillance, clinical evaluations, traceability and transparency. A similar task force will be set up in the first quarter of 2021 to examine risks related to the IDVR.

For information regarding risks related to changes in proprietary rights rules and regulations, see "– We rely on our patents and other proprietary rights to provide exclusive rights to market certain of our products. If such patents and other rights were limited, invalidated or circumvented, our financial results could be adversely affected" below.

For information regarding risks related to changes in environmental rules and regulations, see "– Management of the historical contamination related to our past industrial activities may have a significant adverse effect on our results of operations" below.

We rely on our patents and other proprietary rights to provide exclusive rights to market certain of our products. If such patents and other rights were limited, invalidated or circumvented, our financial results could be adversely affected.

Through patent and other proprietary rights, such as data exclusivity or supplementary protection certificates in Europe, we hold exclusivity rights for a number of our research-based products. However, the protection that we are able to obtain varies in its duration and scope. Furthermore, patents and other proprietary rights do not always provide effective protection for our products.

For example, governmental authorities are increasingly looking to facilitate generic and biosimilar competition for existing products through new regulatory proposals intended to achieve, or resulting in, changes to the scope of patent or data exclusivity rights and through the use of accelerated regulatory pathways for generic and biosimilar drug approvals. Such regulatory proposals could make patent prosecution for new products more difficult and time consuming or could adversely affect the exclusivity period for our products.

Moreover, manufacturers of generic products or biosimilars are increasingly seeking to challenge patent validity or coverage before the patents expire, and manufacturers of biosimilars or interchangeable versions of the products are seeking to have their version of the product approved before the exclusivity period ends. Furthermore, in an infringement suit against a third party, we may not prevail and the decision rendered may not conclude that our patent or other proprietary rights are valid, enforceable or infringed. Our competitors may also successfully avoid our patents. Even in cases where we ultimately prevail in an infringement claim, legal remedies available for harm caused to us by infringing products may be inadequate to make us whole. Moreover, a successful result against a competing product for a given patent or in a specific country is not necessarily predictive of our future success against another competing product or in another country because of local variations in the patents and patent laws.

In addition, if we lose patent protection as a result of an adverse court decision or a settlement, we face the risk that government and private third-party payers and purchasers of pharmaceutical products may claim damages alleging they have over-reimbursed or overpaid for a drug. For example, in Australia, our patent on clopidogrel was ultimately held invalid. Following this decision, the Australian Government sought damages for its alleged over-reimbursement of clopidogrel drugs due to the preliminary injunction we had secured against the sale of generic clopidogrel during the course of the litigation. The Australian Government's claim was dismissed following a decision of the Federal Court of Australia on April 28, 2020. Subsequently, the Australian Government appealed the decision of the Federal Court of Australia.

In certain cases, to terminate or avoid patent litigation we or our collaboration partners may be required to obtain licenses from the holders of third-party intellectual property rights. Any payments under these licenses may reduce our profits from such products and we may not be able to obtain these licenses on favorable terms or at all.

Third parties may also request a preliminary orpermanent injunction in a country from a court of law to prevent us from marketing a product if they consider that we infringe their patent rights in that country. For example, Sanofi is or was party to patent infringement proceedings in several countries initiated against us and Regeneron by Amgen relating to Praluent® in which Amgen requested injunctive relief (see Note D.22.b) to the consolidated financial statements included at Item 18. of this annual report for more information). If third parties obtain a preliminary or permanent injunction or if we fail to obtain a required license for a country where valid third-party intellectual property rights as confirmed by a court of law exist, or if we are unable to alter the design of our technology to fall outside the scope of third-party intellectual property rights, we may be unable to market some of our products in certain countries, which may limit our profitability.

Furthermore, some countries may consider granting a compulsory license to a third party to use patents protecting an innovator's product, which limits the value of the patent protection granted to such products.

We have increased the proportion of biological therapeutics in our pipeline relative to traditional small molecule pharmaceutical products. Typically, the development, manufacture, sale and distribution of biological therapeutics is complicated by third-party intellectual property rights (otherwise known as freedom to operate (FTO) issues), to a greater extent than for the development, manufacture, sale and distribution of small molecule therapeutics, because of the types of patents allowed by national patent offices. Further, our ability to successfully challenge third-party patent rights is dependent on the legal interpretation and case law of national courts. In addition, we expect to face increasing competition from biosimilars in the future. With the accelerated regulatory pathways provided in the United States and Europe for biosimilar drug approval, biosimilars can be a threat to the exclusivity of any biological therapeutics we sell or may market in the future and can pose the same issues as the small molecule generic threat described above. If a biosimilar version of one of our products were to be approved, it could reduce our sales and/or profitability of that product.

If our patents and/or proprietary rights to our products were limited or circumvented, our financial results could be adversely affected.

Risks relating to our business

The manufacture of our products is technically complex, and supply interruptions, product recalls or inventory losses caused by unforeseen events may reduce sales, adversely affect our operating results and financial condition, delay the launch of new products and negatively impact our image.

Many of our products are manufactured using technically complex processes requiring specialized facilities, trained and certified employees, highly specific raw materials and other production constraints; all of these elements as a whole are governed by extensive and complex regulations issued by governmental health authorities around the world. We must ensure that all manufacturing processes comply with current Good Manufacturing Practices (cGMP) and other applicable regulations, as well as with our own quality standards. For example, the ICH Q7 Guidelines from the EMA outline recommendations for the assessment and control of DNA reactive impurities in pharmaceuticals to limit potential carcinogenic risks. Third parties supply us with a portion of our raw materials, active ingredients and medical devices, which exposes us to the risk of a supply shortage or interruption in the event that these suppliers are unable to manufacture our products in line with quality standards or if they experience financial difficulties. Epidemics and other public health crises, such as the ongoing coronavirus expose us to risks of a slowdown or temporary suspension in the production of our active pharmaceutical ingredients (API), raw materials and some of our products. Any prolonged restrictive measures put in place in order to control an outbreak of contagious disease or other adverse public health development, in any of our principal production sites, may have a material and adverse effect on our manufacturing operations. Any of these factors could adversely affect our business, operating results or financial condition (see "Item 4. Information on the Company — B. Business Overview — B.8. Production and Raw Materials" for a description of these outsourcing arrangements and "The extent to which the COVID-19 pandemic and related developments, including measures implemented in response thereto, may impact our business, operations and financial performance is highly uncertain and difficult to predict" below).

We must also be able to produce sufficient quantities of our products to satisfy demand. We may have difficulties transforming and adapting our existing plants to manufacture new products (including biologics) and scaling up production of our products currently under development once they are approved. Some specific regulatory situations may also require transformation of our facilities: for example, the fact that insulin is no longer regulated by the FDA as a drug but rather as a biologic requires the complete transformation and adaptation of our insulin manufacturing plant in Frankfurt. There is no guarantee that we will manage to complete that plan within the expected time. Furthermore, our biological products, in particular, are subject to the risk of manufacturing stoppages or the risk of loss of inventory because of the difficulties inherent in the processing of biological materials and the potential difficulties in accessing adequate amounts of raw materials meeting required standards. In addition, specific storage and distribution conditions are required for many biological products (for example, cold storage is required for certain vaccines, insulin-based products and some hemophilia products). These production difficulties may also be encountered during testing, which is a mandatory requirement prior to drug products being released. For example, in 2018 in China, we encountered supply constraints of Pentaxim® vaccine due to problems with the supplier of a raw material used in the formulation of Pentaxim® for China. As a result we had to find an alternative raw material to meet Chinese requirements.

Some of our own production sites, and some of our suppliers' and/or contractors' sites are located in areas exposed to natural disasters such as floods, earthquakes and hurricanes. Such disasters could be exacerbated by global warming. In the event of a major disaster we could experience severe destruction or interruption of our operations and production capacity at these sites. The complexity of these processes, as well as standards required for the manufacture of our products, subject us to risks because the investigation and remediation of any identified or suspected problems can cause production delays, substantial expense, product recalls or lost sales and inventories, and delay the launch of new products; this could adversely affect our operating results and financial condition, and cause reputational damage and the risk of product liability (see "– Product liability claims could adversely affect our business, results of operations and financial condition" above).

When manufacturing disruptions occur, we may not have alternate manufacturing capacity, particularly for certain biologics. In the event of manufacturing disruptions, our ability to use backup facilities or set up new facilities is more limited because biologics are more complex to manufacture and generally require dedicated facilities. Even though we aim to have backup sources of supply whenever possible, including by manufacturing backup supplies of our principal active ingredients at additional facilities when practicable, we cannot be certain they will be sufficient if our principal sources become unavailable. Switching sources and manufacturing facilities requires significant time and prior approval by health authorities.

Supply shortages generate even greater negative reactions when they occur with respect to life saving medicines with limited or no viable therapeutic alternatives. Shortages of specific products can have a negative impact on the confidence of patients, customers and professional healthcare providers and the image of Sanofi and may lead to lower product revenues.

The pricing and reimbursement of our products is increasingly affected by cost reduction initiatives and decisions of governments and other third parties.

The commercial success of our existing products and our product candidates depends in part on their pricing and the conditions under which they are reimbursed. At a time of intense scrutiny over drug prices, the pricing for our products continues to be negatively affected by downward pressure due, inter alia, to:

- tighter price and access controls imposed by governments and other payers in most countries:
  - requirements for increased disclosure of drug pricing and drug development costs,
  - widespread use of international reference pricing and therapeutic reference pricing,
  - generic/biosimilar competition and incentives (e.g. prescribing quotas/targets),
  - mandatory price cuts, renegotiations, industry paybacks and rebates,
  - shifting of the payment burden to patients through higher co-payments and co-pay accumulator programs,
  - delisting from reimbursement and restrictions on the label population,
  - access restrictions for high-priced innovative medicines,
  - tighter formulary management (including stepped therapy, strict prior authorization criteria, and formulary exclusions) mainly by insurers and pharmacy benefit managers ("PBMs") in the United States,
  - prescribing guidelines and binding medicine utilization controls,
  - trend toward centralized procurement and tendering (national/regional/class-wide level),
  - cross-country cooperation in price negotiations, contracting or procurement, which are already occurring to some extent (for example the BeNeLuxA agreement in Europe and the South America/PAHO arrangements), and
  - discriminatory and non-transparent pricing and procurement policies (e.g. government procurement restrictions, import bans) in favor of domestic pharmaceutical companies;
- increasing use of health technology assessment ("HTA") to inform coverage and pricing decisions:
  - stringent evidence and value requirements (e.g., comparative effectiveness, patient preferences, real-world evidence, health economic modelling) by payers and HTA authorities, raising the bar for market entry,
  - unreasonable thresholds for cost-effectiveness, and
  - increasingly restrictive HTA decisions with significant variation across markets.

In the United States, which accounted for 37.4% of our net sales in 2020, the COVID-19 pandemic continues to impact lives and livelihoods across the country and there is a high level of uncertainty on what will dominate the US healthcare policy in 2021 and beyond, particularly with respect to likely policy changes related to the Affordable Care Act ("ACA") provisions and drug pricing reforms. With a new Administration focused on addressing COVID-19 and supporting and expanding the ACA, there is a window of opportunity to shape policy reforms in a balanced manner, materially lower out-of-pocket costs, improve access for patients, and maintain incentives for innovation and scientific advancement in the US system. Given the new Administration's inclusion of drug pricing reform in its campaign platform, previously proposed legislation introducing price controls in the commercial insurance and Medicare systems may continue to be part of the Democratic agenda. Many of the previous Administration's pricing proposals (announced in a series of executive orders on lowering drug prices on July 24, 2020 and through November 2020 regulatory actions) may be rolled-back or abrogated, but the concept of drug pricing reform remains. These or other pricing proposals and regulatory actions could have the potential to change how our business operates in the US, including policies related to rebates, importation, "Buy American" preferences for procurement, and Most Favored Nation price controls. But many implementation challenges and questions remain.

We also encounter cost containment issues in countries outside the United States. In certain countries, including countries in the European Union, China and Canada, the coverage of prescription drugs and pricing and levels of reimbursement are subject to governmental control. For example, in Europe, various authorities are developing the use of tenders for expensive products and are considering joint procurement mechanisms to negotiate lower prices.

In China, a high degree of uncertainty results from the complexity of market access, from increasing price pressure, and from intensifying competition among both multinational and local companies. The continuous downward pressure on prices from National Reimbursement Drug List (NRDL) negotiation for innovative products and from the expansion of volume-based procurement (VBP) for established products, may accelerate the erosion of our sales and profit margins. The consolidation of the local industry, actively encouraged by the government, may also pose a downside risk. We believe it will become increasingly difficult to compete with local players with the emergence of volume-based tendering. In addition, greater emphasis on import substitution and localization, partly catalyzed by COVID-19, is expected to favor local companies.

Furthermore, while we attempt to predict the level of reimbursement and related restrictions for our product candidates, external events and unexpected decisions can occur which could materially and adversely affect our sales, profits and financial results more generally.

The concentration of the US market exposes us to greater pricing pressure.

The consolidation of the US market may expose us to greater pricing pressure. With the largest three PBMs (OptumRx, CVS/Caremark, and Express Scripts) now covering over 75% of the market, consolidation has led to strong bargaining power enabling them to negotiate deeper discounts and rebates with manufacturers in return for the inclusion of drugs on their formularies. Inclusion on formularies for PBMs and managed care organizations (MCOs) remains an important aspect of Sanofi's negotiation strategy, as a drug's exclusion from such formularies may result in a significant reduction in sales.

Due to these pressures on our prices, our revenues and margins are, and could continue to be, negatively affected.

Breaches of data security, disruptions of information technology systems and cyber threats could result in financial, legal, business or reputational harm.

Our business depends heavily on the use of interdependent information technology systems, including internet-based systems and digital tools. Certain key areas such as research and development, production and sales are to a large extent dependent on our information systems (including cloud-based computing) or those of third-party providers (including for the storage and transfer of critical, confidential, sensitive or personal information regarding our patients, clinical trials, vendors, customers, employees, collaborators and others).

We and our third-party service providers, suppliers, contract manufacturers, distributors or other contracting third parties use secure information technology systems for the protection of data and threat detection. Like many companies, we may experience certain of the following events: breakdown, service disruption or impairment, data loss or deterioration in the event of a system malfunction, or increasing threat of data theft or corruption in the event of a cyber-attack, security breach, industrial espionage attacks or insider threat attacks. The pandemic has exacerbated attacks related to competitive intelligence by criminal organizations targeting information related to COVID-19 research, development and production.

Each of these events could negatively impact important processes, such as scientific research and clinical trials, the submission of outcomes to health authorities for marketing authorizations, the functioning of production processes and the supply chain, compliance with legal requirements and other key activities, including Sanofi's employees' ability to communicate between themselves as well as with third parties (see also "– Product liability claims could adversely affect our business, results of operations and financial condition" above). This could result in material financial, legal, business or reputational harm.

Although we maintain insurance coverage, this insurance may not be sufficiently available in the future to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems. For example, certain types of cyber-attacks could be considered as an Act of War subject to insurance exclusion.

Our research and development efforts may not succeed in adequately renewing our product portfolio.

Discovering and developing a new product is a costly, lengthy and uncertain process. To be successful in the highly competitive pharmaceutical industry, we must commit substantial resources each year to research and development in order to develop new products to compensate for decreasing sales of products facing patent expiration and termination of regulatory data exclusivity, introduction of lower-priced generics, or competition from new products of competitors that are perceived as being superior or equivalent to our products. We must pursue both early stage research and early and late development stages in order to propose a sustainable and well-balanced portfolio of products. In 2020, we spent €5,529 million on research and development, amounting to 15.3% of our net sales.

In December 2019, as part of our strategic roadmap we announced our intent to prioritize six potentially transformative therapies in areas of high unmet patient need: fitusiran and BIVV001 (hemophilia); SERD (breast cancer); venglustat (rare diseases); nirsevimab (respiratory syncytial virus); and BTKi (multiple sclerosis). We also announced our intent to discontinue our research in diabetes and cardiovascular (DCV). However, we may choose the wrong areas of research or products of our portfolio, and may not be able to improve our research productivity sufficiently to sustain our pipeline. In addition, numerous companies are working on the same targets and a product considered as promising at the beginning of its development may become less attractive if a competitor addressing the same unmet need reaches the market earlier. There can be no assurance that any of our product candidates will be proven safe or effective (see "Item 4. Information on the Company — B. Business Overview — B.5. Global Research & Development"). Over these research and development cycles, usually spanning several years, there is a substantial risk at each stage of development – including clinical trials – that we will not achieve our goals of safety and/or efficacy and that we will have to abandon a product in which we have invested substantial amounts of money and human resources. More and more trials are designed with clinical endpoints of superiority; failure to achieve those endpoints could damage the product's reputation and our overall development program.

Decisions concerning the studies to be carried out can have a significant impact on the marketing strategy for a given product. Multiple in-depth studies can demonstrate that a product has additional benefits, facilitating the product's marketing, but such studies are expensive and time consuming and may delay the product's submission to regulatory authorities for approval.

In addition, following (or in some cases contemporaneously with) the marketing authorization, the dossier is also submitted to governmental agencies and/or national or regional third-party payers (HTA bodies) for review. These HTA bodies evaluate evidence on the value of the new product, assess the medical need it serves, and provide recommendations on the corresponding reimbursement. Such analyses may require additional studies, including comparative studies, which may effectively delay marketing, change the population which the new product treats, and add costs to its development. Our continuous investments in research and development for future products and for the launches of newly registered molecules could therefore result in increased costs without a proportionate increase in revenues, which would negatively affect our operating results and profitability.

Lastly, there can be no assurance that all the products approved or launched will achieve commercial success.

A substantial share of the revenue and income of Sanofi depends on the performance of certain flagship products.

As part of the presentation of our strategy in December 2019 we announced our intent to prioritize our activities on growth drivers including Dupixent® and our Vaccines operations, which we have identified as key growth drivers. Nevertheless market expansion and new launches of medicines and vaccines may not deliver the expected benefits. We may also encounter failures or delays in our launch strategy (in terms of timing, pricing, market access, marketing efforts and dedicated sales forces), such that our products that may not deliver the expected benefits. The competitive environment for a given product may also have changed by the time of the actual launch, modifying our initial expectations. The need to prioritize the allocation of resources may also cause delays in or hamper the launch or expansion of some of our products.

Also, we currently generate a substantial share of our net sales from certain key products (see "Item 5. Operating and Financial Review and Prospects — Results of Operations — Year ended December 31, 2020 compared with year ended December 31, 2019 — Net Sales — Pharmaceuticals segment"). For example, Dupixent® generated net sales of €3,534 million in 2020.

Among our flagship products, Lantus®, Lovenox® and Plavix® already face generic competition on the market. Lantus® is particularly important; it was one of Sanofi's leading products in 2020 with net sales of €2,661 million, representing 7.4% of our net sales for the year.

Aubagio®, another leading product, is expected to face generic competition in the US starting from March 2023, following a settlement agreement entered into in 2017. Jevtana® is expected to face generic competition from September 2021 in the US and the end of March 2021 in Europe.

More generally, an expiration of effective intellectual property protections for our products typically results in the market entry of one or more lower-priced generic competitors, often leading to a rapid and significant decline in revenues on those products (for information regarding ongoing patent litigation see Note D.22.b.) to the consolidated financial statements included at Item 18. of this annual report).

The introduction of a generic product results in adverse price and volume effects for our branded or genericized products. For example, although we do not believe it is possible to state with certainty what level of net sales would have been achieved in the absence of generic competition, a comparison of our consolidated net sales for 2020 and 2019 for the main products affected by generic and biosimilar competition shows a loss of €525 million of net sales on a reported basis (see “Item 5. Operating and Financial Review and Prospects — A.1.2. Impacts of Competition from Generics and Biosimilars”). However, other parameters may have contributed to the loss of sales, such as a fall in the average price of certain products (e.g. Lantus®).

Furthermore, in general, if one or more of our flagship products were to encounter problems (such as material product liability litigation, unexpected side effects, product recalls, non-approval by the health authorities of a new indication for a marketed product, and manufacturing or supply issues), the adverse impact on our business, results of operations and financial condition could be significant.

We rely on third parties for the discovery, manufacture and marketing of some of our products.

Our industry is both highly collaborative and competitive, whether in the discovery and development of new products, in-licensing, the marketing and distribution of approved products, or manufacturing activities. We expect that we will continue to rely on third parties for key aspects of our business and we need to ensure our attractiveness as a potential partner.

We conduct a number of significant research and development programs and market some of our products in collaboration with other biotechnology and pharmaceutical companies. For example, we currently have a global strategic collaboration with Regeneron on monoclonal antibodies. Dupixent®, Kevzara® (sarilumab) and SAR440340 (REGN3500- itepekimab) are also part of a development and commercialization collaboration with Regeneron. Further, in April 2020, Sanofi and Regeneron restructured their antibody collaboration related to Praluent® (alirocumab) (see "Item 5. Financial Presentation of Alliances — A.1.7.1/ Alliance Arrangements with Regeneron"). We rely upon Regeneron to successfully carry out their responsibilities with regard to the manufacture and supply of these collaboration antibodies. In immuno-oncology, we have a global collaboration with Regeneron for the joint development and commercialization of cemiplimab, a programmed cell death protein 1 (PD-1) inhibitor antibody (Libtayo®). (see “Item 4. Information on the Company — B. Business Overview”). Finally, we may also rely on partners to design and manufacture medical devices, notably for the administration of our products.

As regards products recently launched or under development for which we have a collaboration agreement with partners, the terms of the applicable alliance agreement may require us to share profits and losses arising from commercialization of such products with our partners. This differs from the treatment of revenue and costs generated by other products for which we have no alliance agreement, and such profit sharing may deliver a lower contribution to our financial results.

We could also be subject to the risk that we may not properly manage the decision-making process with our partners. Decisions may also be under the control of or subject to the approval of our collaboration partners, who may have views that differ from ours. We are also subject to the risk that our partners may not perform effectively, which could have a detrimental effect when our collaboration partners are responsible for the performance of certain key tasks or functions. We are also subject to the risk that contract research organizations or other vendors retained by us or our collaboration partners may not perform effectively. Any such failures in the development process or differing priorities may adversely affect the activities conducted through the collaboration arrangements.

We could face conflicts or difficulties with these partners during the course of these agreements or at the time of their renewal or renegotiation. All of these events may affect the development, manufacturing, launch and/or marketing of certain of our products or product candidates and may cause a decline in our revenues or otherwise negatively affect our results of operations.

The extent to which the COVID-19 pandemic and related developments, including measures implemented in response thereto, may impact our business, operations and financial performance is highly uncertain and difficult to predict.

We are unable to predict the extent to which the pandemic and related developments, including the duration and long-term magnitude of the disruption, may impact our business, operations and financial performance. The degree to which COVID-19 impacts our results will depend on future developments, including, but not limited to, the duration and spread of the outbreak, its severity, the actions taken to contain the virus or treat its impact, and how quickly and to what extent normal economic and operating conditions can resume.

In an increasingly budget-constrained healthcare environment as economic disruption continues due to the pandemic, we expect to see a higher pressure on drug prices worldwide and, in the longer term, a reallocation of funding across therapeutic areas, driven in particular by evolving public health priorities, which could negatively impact our business operations (see “– The pricing and reimbursement of our products is increasingly affected by cost reduction initiatives and decisions of governments and other third parties” above). For example, the pandemic may reduce our sales in targeted markets due to lower healthcare spending on other diseases and fewer promotional activities.

If the pandemic is further prolonged, we may face delays in our clinical trials due to restrictions imposed on clinical trial sites and/or delays or disruptions related to regulatory approvals and/or delays in label expansions for existing products, any of which may have a negative impact on our product development and launches and hence, on future product sales, business and results of operations.

The global COVID-19 pandemic also exposes us to a slowdown or temporary suspension in production of our active pharmaceutical ingredients (API), raw materials and some of our other products. Extension of the restrictive measures put in place in order to control the pandemic may lead to manufacturing delays or disruptions and supply chain interruptions (including to the extent those measures apply to our third-party suppliers) and may have an adverse effect on our business (see “– The manufacture of our products is technically complex,

and supply interruptions, product recalls or inventory losses caused by unforeseen events may reduce sales, adversely affect our operating results and financial condition, delay the launch of new products and negatively impact our image" above).

In addition, it is not certain that we will successfully develop a treatment or vaccine for COVID-19, nor that a product or vaccine candidate, if approved, would be commercially successful, nor that demand for such a vaccine or product would still exist, despite significant research and development costs already generated for its development. Post marketing clinical data and analysis of existing clinical data could also give rise to unexpected safety, quality or manufacturing issues.

In response to the COVID-19 pandemic, we have implemented proactive measures in order to protect our employees, including restricting employee travel and adopting a work-from-home policy. However, the pandemic could continue to pose risks to the health and safety of our employees, especially when employees may elect to return to the office in jurisdictions where both local requirements and our own health and safety standards have been met.

Finally, the COVID-19 pandemic, and the volatile global economic conditions stemming from the pandemic, could precipitate or amplify the other risk factors that we identify in this "Risk Factors" section, which could adversely affect our business, operations and financial conditions and results. If the pandemic is further prolonged, our operations could also be adversely impacted by the work-from-home, lockdown and other restrictions that have been adopted in response to the pandemic. Any of these risks could cause actual results to differ materially from those described elsewhere in this report (see "Item 3.D. Risk Factors" and "– Global economic conditions and an unfavorable financial environment could have negative consequences for our business" below).

We are subject to the risk of non-payment by our customers[(1)].

We run the risk of delayed payments or even non-payment by our customers, which consist principally of wholesalers, distributors, pharmacies, hospitals, clinics and government agencies. This risk is accentuated by recent concentrations among distributors, as well as by uncertainties around global credit and economic conditions, in particular in emerging markets. The United States poses particular customer credit risk issues because of the concentrated distribution system: our three main customers represented respectively 10%, 6% and 5% of our consolidated net sales in 2020. We are also exposed to large wholesalers in other markets, particularly in Europe. Although we assign some of our receivables to factoring companies or banks, an inability of one or more of these wholesalers to honor their debts to us could adversely affect our financial condition (see Note D.34. to our consolidated financial statements included at Item 18. of this annual report).

In some countries, some customers are public or subsidized health systems. The economic and credit conditions in these countries may lead to an increase in the average length of time needed to collect on accounts receivable or the ability to collect 100% of receivables outstanding. Because of this context, we may need to reassess the recoverable amount of our debts in these countries during future financial years (see also "Item 5. Operating and Financial Review and Prospects — Liquidity and Capital Resources — Liquidity.").

Global economic conditions and an unfavorable financial environment could have negative consequences for our business[(2)].

Over the past several years, growth of the global pharmaceutical market has become increasingly tied to global economic growth. In this context, a substantial and lasting slowdown of the global economy, major national economies or emerging markets could negatively affect growth in the global pharmaceutical market and, as a result, adversely affect our business.

Unfavorable economic conditions have reduced the sources of funding for national social security systems, leading to austerity measures including heightened pressure on drug prices, increased substitution of generic drugs, and the exclusion of certain products from formularies (see "– The pricing and reimbursement of our products is increasingly affected by cost reduction initiatives and decisions of governments and other third parties" above).

Further, our net sales may be negatively impacted by the continuing challenging global economic environment, as high unemployment, increases in cost-sharing, and lack of developed third-party payer systems in certain regions may lead some patients to switch to generic products, delay treatments, skip doses or use other treatments to reduce their costs. In the United States there has been a significant increase in the number of beneficiaries in the Medicaid program, under which sales of pharmaceuticals are subject to substantial rebates and, in many US states, to formulary restrictions limiting access to brand-name drugs, including ours. Also, employers may seek to transfer a greater portion of healthcare costs to their employees due to rising costs, which could lead to further downward price pressure and/or lower demand.

Our Consumer Healthcare business could also be adversely impacted by difficult economic conditions that limit the financial resources of our customers.

If economic conditions worsen, or in the event of default or failure of major players including wholesalers or public sector buyers financed by insolvent states, our financial situation, the results of our operations and the distribution channels of our products may be adversely affected. See also "– We are subject to the risk of non-payment by our customers" above.

The United Kingdom left the European Union effective January 31, 2020 ("Brexit"). Given the lack of comparable precedent, it is unclear what financial, trade, regulatory and legal implications the withdrawal of the United Kingdom from the European Union will have. Brexit creates global economic and financial uncertainty, which may cause, among other consequences, volatility in exchange rates and interest rates and changes in regulations. In addition, the relocation of the headquarters of the European Union's health authority, the EMA, from the United Kingdom to the Netherlands has impaired the work of the EMA and could also delay new drug approvals in the European Union. However, our internal Brexit Task Force has developed and deployed, and is continuing to develop and deploy, contingency measures aiming at avoiding interruption of supply to patients. As a result, we currently do not believe that these effects will have a material impact on our financial situation or the results of our operations. As of December 31, 2020, the United Kingdom represented 1.6% of our consolidated net sales in the 2020 fiscal year and less than 1% of our total assets.

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(1) The information in this section supplements the disclosures required under IFRS 7 as presented in Notes B.8.7., D.10. and D.34. to our consolidated financial statements, provided at Item 18. of this annual report.

(2) The information in this section supplements the disclosures required under IFRS 7 as presented in Note B.8.7. to our consolidated financial statements, provided at Item 18. of this annual report.

The increasing use of social media platforms and new technologies present risks and challenges for our business and reputation.

We increasingly rely on social media, new technologies and digital tools to communicate about our products and diseases or to provide health services. The use of these media requires specific attention, monitoring programs and moderation of comments. Political and market pressures may be generated by social media because of rapid news cycles. This may result in commercial harm, overly restrictive regulatory actions and erratic share price performance. In addition, unauthorized communications, such as press releases or posts on social media, purported to be issued by Sanofi, may contain information that is false or otherwise damaging and could have an adverse impact on our image and reputation and on our stock price. Negative or inaccurate posts or comments about Sanofi, our business, directors or officers on any social networking website could seriously damage our reputation. In addition, our employees and partners may use social media and mobile technologies inappropriately, which may give rise to liability for Sanofi, or which could lead to breaches of data security, loss of trade secrets or other intellectual property or public disclosure of sensitive information. Such uses of social media and mobile technologies could have an adverse effect on our reputation, business, financial condition and results of operations.

Risks relating to Sanofi's structure and strategy

We may fail to successfully identify external business opportunities or realize the anticipated benefits from our strategic investments or divestments.

We pursue a strategy of selective acquisitions, in-licensing and collaborations in order to reinforce our pipeline and portfolio. We are also proceeding to selective divestments to focus on key business areas. The implementation of this strategy depends on our ability to identify transaction opportunities, mobilize the appropriate resources in order to enter into agreements in a timely manner, and execute these transactions on acceptable economic terms. Moreover, entering into in-licensing or collaboration agreements generally requires the payment of significant "milestones" well before the relevant products reach the market, without any assurance that such investments will ultimately become profitable in the long term (see Note D.21.1. to the consolidated financial statements included at Item 18. of this annual report and also "– We rely on third parties for the discovery, manufacture and marketing of some of our products" above).

For newly acquired activities or businesses our growth objectives could be delayed or ultimately not realized, and expected synergies could be adversely impacted if:

- we are unable to quickly or efficiently integrate those activities or businesses;
- key employees leave; or
- we have higher than anticipated integration costs.

For instance, in 2019 we had to book a €2.8 billion impairment on Eloctate®, acquired through the Bioverativ acquisition completed in 2018, due to revisions of previous sales projections.

For divestments, their financial benefit could be impacted if we face significant financial claims or significant post-closing price adjustments. We may miscalculate the risks associated with business development transactions at the time they are made or not have the resources or ability to access all the relevant information to evaluate them properly, including with regard to the potential of research and development pipelines, manufacturing issues, compliance issues, or the outcome of ongoing legal and other proceedings. It may also take a considerable amount of time and be difficult to implement a risk analysis and risk mitigation plan after the acquisition of an activity or business is completed due to lack of historical data. As a result, risk management and coverage of such risks, particularly through insurance policies, may prove to be insufficient or ill-adapted.

Because of the active competition among pharmaceutical groups for such business development opportunities, there can be no assurance of our success in completing these transactions when such opportunities are identified.

The globalization of our business exposes us to increased risks in specific areas.

As part of the presentation of our strategy in December 2019, we identified our strong presence in China among our core drivers, with revenue amounting to 6.8% of our net sales in 2020.

Nevertheless, the difficulties in operating in emerging markets, a significant decline in the anticipated growth rate or an unfavorable movement of the exchange rates of currencies against the euro could impair our ability to take advantage of growth opportunities and could adversely affect our business, results of operations or financial condition. For instance, while it is not possible as of the date of this report to predict the economic impact and the magnitude of the ongoing coronavirus epidemic which started in China in December 2019, if a long-lasting epidemic and prolonged restrictive measures to control the outbreak were to result in an economic slowdown in any of our targeted markets, it would reduce our sales due to lower healthcare spending on other diseases and fewer promotional activities, and could significantly impact our business operations. Furthermore, it is not possible to predict if or how the current health crisis will impact any particular affected jurisdiction, or to what extent (see also "– Global economic conditions and an unfavorable financial environment could have negative consequences for our business" and "The extent to which the COVID-19 pandemic and related developments, including measures implemented in response thereto, may impact our business, operations and financial performance is highly uncertain and difficult to predict" above).

Emerging markets also expose us to more volatile economic conditions, political instability (including a backlash in certain areas against free trade), competition from multinational or locally based companies that are already well established in these markets, the inability to adequately respond to the unique characteristics of emerging markets (particularly with respect to their underdeveloped judicial systems and regulatory frameworks), difficulties in recruiting qualified personnel or maintaining the necessary internal control systems, potential exchange controls, weaker intellectual property protection, higher crime levels (particularly with respect to counterfeit products), and compliance issues including corruption and fraud (see particularly "– Claims and investigations relating to compliance, ethics, competition law, marketing practices, pricing, human rights of workers, data protection and other legal matters could adversely affect our business, results of operations and financial condition" above).

We may fail to develop or take advantage of digitalization.

We have undertaken a number of digital initiatives (such as the opening in October 2019 of our Framingham digitally enabled manufacturing facility in the US, and our Darwin real-world data platform). However there is no guarantee that our efforts toward a digital transformation will succeed. More generally, we may fail to capture the benefits of digitalization at an appropriate cost and/or in a timely manner, and/or enter into appropriate partnerships. Competitors, including new entrants such as tech companies, may outpace us in this fast-moving area. If we fail to adequately integrate digitalization into our organization and business model, we could lose patients and market share. This could have an adverse impact on our business, prospects and results of operations.

We may fail to accelerate our operational efficiency.

As part of our strategy we announced our intent to improve our operating efficiencies to fund growth and expand our business operating income margin. We have also announced savings initiatives that we expect will generate €2.5 billion of savings by 2022 to fund investment in our key growth drivers, to accelerate priority pipeline projects and to support the expansion of our BOI margin. Nevertheless there is no guarantee that we will be able to fully deliver these operating efficiencies within the targeted timeline or generate the expected benefits.

Our success depends in part on our senior management team and other key employees and our ability to attract, integrate and retain key personnel and qualified individuals in the face of intense competition.

We depend on the expertise of our senior management team and other key employees. In 2020, there were 2,219 “Senior Leaders” within Sanofi, including Executive Committee members and other executives. In addition, we rely heavily on recruiting and retaining talented people to help us meet our strategic objectives. We face intense competition for qualified individuals for senior management positions, or in specific geographic regions or in specialized fields such as clinical development, biosciences and devices, or digital and artificial intelligence. Our ability to hire qualified personnel also depends in part on our ability to reward performance, incentivize our employees and pay competitive compensation. Laws and regulations on executive compensation may restrict our ability to attract, motivate and retain the required level of talented people. The inability to attract, integrate and/or retain highly skilled personnel, in particular those in leadership positions, may weaken our succession plans, may materially adversely affect the implementation of our strategy and our ability to meet our strategic objectives, and could ultimately adversely impact our business or results of operations.

Environmental and safety risks of our industrial activities

Risks from manufacturing activities and the handling of hazardous materials could adversely affect our results of operations.

Manufacturing activities, such as the chemical manufacturing of the active ingredients in our products and the related storage and transportation of raw materials, products and waste, expose us to risks of industrial accidents that may lead to discharges or releases of toxic or pathogenic substances or other events that can cause personal injury, property damage and environmental contamination, and may result in additional operational constraints, including the shutdown of affected facilities and/or the imposition of civil, administrative, criminal penalties and/or civil damages.

The occurrence of an industrial accident may significantly reduce the productivity and profitability of a particular manufacturing facility and adversely affect our operating results and reputation. Although we maintain property damage, business interruption and casualty insurance that we believe is in accordance with customary industry practices, this insurance may not be adequate to fully cover all potential hazards incidental to our business.

Management of the historical contamination related to our past industrial activities may have a significant adverse effect on our results of operations.

The environmental laws of various jurisdictions impose actual and potential obligations on our Company to manage and/or remediate contaminated sites. These obligations may relate to sites:

- that we currently own or operate;
- that we formerly owned or operated; or
- where waste from our operations was disposed.

These environmental remediation obligations could reduce our operating results. Sanofi accrues provisions for remediation when our management believes the need is probable and that it is reasonably possible to estimate the cost. See “Item 4. Information on the Company — B. Business Overview — B.10. Health, Safety and Environment (HSE)” for additional information regarding our environmental policies. In particular, our provisions for these obligations may be insufficient if the assumptions underlying these provisions prove incorrect or if we are held responsible for additional, currently undiscovered contamination. These judgments and estimates may later prove inaccurate, and any shortfalls could have an adverse effect on our results of operations and financial condition. For more detailed information on environmental issues, see “Item 4. Information on the Company — B. Business Overview — B.10. Health, Safety and Environment (HSE) and Notes B.12. and D.19.3. to the consolidated financial statements”.

We are or may become involved in claims, lawsuits and administrative proceedings relating to environmental matters. Some current and former Sanofi subsidiaries have been named as “potentially responsible parties” or the equivalent under the US Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended (also known as “Superfund”), and similar statutes or obligations in France, Germany, Italy, Brazil and elsewhere. As a matter of statutory or contractual obligations, we and/or our subsidiaries may retain responsibility for environmental liabilities at some of the sites of our predecessor companies, or of subsidiaries that we demerged, divested or may divest. We have disputes outstanding regarding certain sites no longer owned or operated by the Company. An adverse outcome in such disputes might have an adverse effect on our operating results. See Note D.22.d) to the consolidated financial statements included at Item 18. of this annual report and “Item 8. Financial Information — A. Consolidated Financial Statements and Other Financial Information — Information on Legal or Arbitration Proceedings”.

Environmental regulations are evolving. For example, in Europe, new or evolving regulatory regimes include REACH, CLP/GHS, SEVESO, IPPC/IED, the Waste Framework Directive, the Emission Trading Scheme Directive, the Water Framework Directive, the Directive on Taxation of Energy Products and Electricity and several other regulations aimed at preventing global warming. Stricter environmental, safety and health laws and enforcement policies could result in substantial costs and liabilities to our Company and could subject our handling, manufacture, use, reuse or disposal of substances or pollutants, site restoration and compliance to more rigorous scrutiny than is currently the case. Consequently, compliance with these laws could result in capital expenditures as well as other costs and liabilities, thereby adversely affecting our business, results of operations or financial condition.

Risks related to financial markets[3]

Fluctuations in currency exchange rates could adversely affect our results of operations and financial condition.

Because we sell our products in numerous countries, our results of operations and financial condition could be adversely affected by fluctuations in currency exchange rates. We are particularly sensitive to movements in exchange rates between the euro and the US dollar, the Japanese yen, the Chinese yuan, and currencies in emerging markets. In 2020, 37.4% of our net sales were generated in the United States, 25.4% in Europe, and 37.2% in the Rest of the World region (see the definition in “Item 5. Operating and Financial Review and Prospects — A/ Operating results”), including countries that are, or may in future become, subject to exchange controls (including 6.8% in China and 4.8% in Japan). While we incur expenses in those currencies, the impact of currency exchange rates on these expenses does not fully offset the impact of currency exchange rates on our revenues. As a result, currency exchange rate movements can have a considerable impact on our earnings. When deemed appropriate and when technically feasible, we enter into transactions to hedge our exposure to foreign exchange risks. These efforts, when undertaken, may fail to offset the effect of adverse currency exchange rate fluctuations on our results of operations or financial condition. For more information concerning our exchange rate exposure, see “Item 11. Quantitative and Qualitative Disclosures about Market Risk.”

Risks relating to an investment in our shares or ADSs

Foreign exchange fluctuations may adversely affect the US dollar value of our ADSs and dividends (if any).

Holders of ADSs face exchange rate risk. Our ADSs trade in US dollars and our shares trade in euros. The value of the ADSs and our shares could fluctuate as the exchange rates between these currencies fluctuate. If and when we pay dividends, they would be denominated in euros. Fluctuations in the exchange rate between the euro and the US dollar will affect the US dollar amounts received by owners of ADSs upon conversion by the depositary of cash dividends, if any. Moreover, these fluctuations may affect the US dollar price of the ADSs on the NASDAQ Global Select Market (NASDAQ) whether or not we pay dividends, in addition to any amounts that a holder would receive upon our liquidation or in the event of a sale of assets, merger, tender offer or similar transaction denominated in euros or any foreign currency other than US dollars.

Persons holding ADSs rather than shares may have difficulty exercising certain rights as a shareholder.

Holders of ADSs may have more difficulty exercising their rights as a shareholder than if they directly held shares. For example, if we issue new shares and existing shareholders have the right to subscribe for a pro rata portion of the new issuance, the depositary is allowed, at its own discretion, to sell this right to subscribe for new shares for the benefit of the ADS holders instead of making that right available to such holders. In that case, ADS holders could be substantially diluted. Holders of ADSs must also instruct the depositary how to vote their shares. Because of this additional procedural step involving the depositary, the process for exercising voting rights will take longer for holders of ADSs than for holders of shares. ADSs for which the depositary does not receive timely voting instructions will not be voted at any meeting.

Sales of our shares may cause the market price of our shares or ADSs to decline.

Sales of large numbers of our shares, or a perception that such sales may occur, could adversely affect the market price for our shares and ADSs. To our knowledge, L’Oréal, our largest shareholder, is not subject to any contractual restrictions on the sale of the shares it holds in our Company. L’Oréal does not consider its stake in our Company as strategic.

Our largest shareholder owns a significant percentage of the share capital and voting rights of Sanofi.

As of December 31, 2020, L’Oréal held approximately 9.39% of our issued share capital, accounting for approximately 16.82% of the voting rights (excluding treasury shares) of Sanofi. See “Item 7. Major Shareholders and Related Party Transactions — A. Major Shareholders.” Affiliates of L’Oréal currently serve on our Board of Directors. To the extent L’Oréal continues to hold a large percentage of our share capital and voting rights, it will remain in a position to exert greater influence in the appointment of the directors and officers of Sanofi and in other corporate actions that require shareholders’ approval.

The Public Company Accounting Oversight Board, or PCAOB, is currently unable to inspect the audit work and practices of auditors operating in France, including our auditors

Our auditors, Ernst & Young et Autres and PricewaterhouseCoopers Audit, are registered with the Public Company Accounting Oversight Board, or PCAOB, in the United States. The PCAOB’s cooperative arrangement with the French audit authority expired in December 2019. The expiration of this cooperation arrangement prevents inspections of registered firms in France until a new arrangement is concluded. Such inspections assess a registered firm’s compliance with U.S. law and professional standards in connection with the performance of audits of financial statements filed with the SEC. As a result, our investors may not realize the potential benefits of such inspections until a new cooperative arrangement, which is currently under negotiation, is entered into and inspections in France resume. The current inability of the PCAOB to conduct inspections of auditors in France also makes it more difficult to evaluate the effectiveness of our auditor’s audit procedures or quality control procedures as compared to auditors outside France that are subject to PCAOB inspections.

[3] *The information in this section supplements the disclosures required under IFRS 7 as presented in Notes B.8.8. to our consolidated financial statements, provided at Item 18. of this annual report.*

Item 4. Information on the Company

Introduction

Sanofi is a leading global healthcare company, focused on patient needs and engaged in the research, development, manufacture and marketing of therapeutic solutions.

In the remainder of this section, a product is referred to either by its international non-proprietary name (INN) or its brand name, which is generally exclusive to the company that markets it. In most cases, the brand names of our products, which may vary from country to country, are protected by specific registrations. In this document, products are identified by their brand names used in France and/or in the US.

Sanofi has three principal activities: Pharmaceuticals, Consumer Healthcare, and Vaccines. These activities are operating segments within the meaning of the IFRS 8 accounting standard (see Note D.35. to our consolidated financial statements, included at Item 18. of this annual report). Our activities comprise: Dupixent®; Multiple Sclerosis, Neurology, Other Inflammatory Diseases and Immunology; Rare Diseases; Oncology; Rare Blood Disorders; Diabetes; Cardiovascular and Established Prescription Products; Consumer Healthcare; and Vaccines. Unlike our Vaccines and Consumer Healthcare activities, which are also operating segments within the meaning of IFRS 8, our Pharmaceutical activities are franchises whose performance is monitored primarily on the basis of net sales; the products sold by each of those franchises are included in our Pharmaceuticals operating segment. For a presentation of the net sales of our activities for the year ended December 31, 2020, refer to “Item 5. — Results of Operations — Year Ended December 31, 2020 Compared with Year Ended December 31, 2019”.

In 2020, we obtained marketing authorizations for a number of our products. In the United States, the Food and Drug Administration (FDA) approved **Sarclisa**® (isatuximab-irfc) in combination with pomalidomide and dexamethasone (pom-dex) for the treatment of adults with relapsed refractory multiple myeloma (RRMM). The European Commission and the Japanese healthcare authorities (PMDA) also approved Sarclisa® for the treatment of adults with RRMM. The FDA and the European Commission approved **Dupixent**® (dupilumab) for children aged 6 to 11 years with moderate-to-severe atopic dermatitis. The Chinese National Medical Products Administration (NMPA) approved Dupixent® for the treatment of adults with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies, or when those therapies are not advisable. This came after the NMPA identified Dupixent® as an overseas medicine urgently needed in clinical practice, leading to an expedited review and approval process. Dupixent® was also approved by the PDMA in Japan for chronic rhinosinusitis with nasal polyposis. The NMPA approved **Aldurazyme**® in China for mucopolysaccharidosis type 1. **Soliqua**® was approved in Japan for the treatment of type 2 diabetes. The European Commission granted marketing approval for insulin aspart, a biosimilar used to improve blood sugar control in people with diabetes. In China, the NMPA approved **Toujeo**® for the treatment of type 1 and 2 diabetes. **MenQuadfi™**, a conjugate meningococcal vaccine to prevent invasive meningococcal infections (serogroups A, C, W and Y), was approved by the FDA for ages 2 and older, and by the European Commission for ages 12 months and older. Also approved by the European Commission were **Efluelda**®, an inactivated high-dose quadrivalent influenza vaccine; and **Supemtek**®, a quadrivalent (four-strain) recombinant influenza vaccine for the prevention of influenza in adults aged 18 years and older.

Collaborations are essential to our business and a certain number of our products, whether on the market or under development, are in-licensed products relying on third-party rights or technologies.

A. History and development of the Company

The current Sanofi corporation was incorporated under the laws of France in 1994 as a *société anonyme*, a form of limited liability company, for a term of 99 years. Since May 2011, we have operated under the commercial name “Sanofi” (formerly known as Sanofi-Aventis). Our registered office is located at 54, rue La Boétie, 75008 Paris, France, our main telephone number is +33 1 53 77 40 00 and our website is www.sanofi.com. Our principal US subsidiary’s office is located at 55 Corporate Drive, Bridgewater, NJ 08807; telephone: +1 (908) 981 5000.

The SEC maintains an internet site at http://www.sec.gov that contains reports, information statements, and other information regarding issuers that file electronically with the SEC.

Main changes over the last five years

At the end of December 2016, Sanofi Pasteur and MSD ended their vaccines joint venture in Europe and integrated their respective European vaccines businesses into their own operations.

On January 1, 2017, Sanofi and Boehringer Ingelheim (BI) successfully closed in most markets a transaction to swap Sanofi’s Animal Health business for BI’s CHC business.

On March 8, 2018, following a tender offer, we acquired control of Bioverativ Inc., a US biopharmaceutical company headquartered in Waltham, Massachusetts, engaged in the development of therapies for people with hemophilia and other rare blood disorders.

On June 19, 2018, Sanofi finalized the acquisition of Ablynx, a Belgian biopharmaceutical company engaged in the development of Nanobodies® – which combine the advantages of conventional antibody drugs with some of the features of small-molecule drugs – in various therapeutic areas.

On September 30, 2018, we completed the divestment of our European generics business Zentiva to Advent International, a US global private equity firm.

On January 23, 2020, following a tender offer, we acquired control of Synthorx, a US clinical-stage biotechnology company based in La Jolla, California, focused on prolonging and improving the lives of people suffering from cancer and autoimmune disorders.

On September 28, 2020, we completed the acquisition of Principia Biopharma Inc., a late-stage biopharmaceutical company focused on developing treatments for autoimmune diseases.

B. Business overview

B.1. Strategy

The market context for Sanofi

A number of fundamental trends continue to point to a positive outlook for the pharmaceutical industry. The global population is growing, and aging, and unmet medical needs remain high. With the COVID-19 pandemic, health needs have further increased, strengthening the key roles of innovation in R&D activities and cutting-edge manufacturing. The industry has taken steps to increase R&D productivity, with the objective of launching a higher number of innovative medicines and vaccines. Patients around the world – including a rising middle class in emerging markets – are demanding better healthcare, empowered by access to more and more information. It is a particularly exciting time scientifically and technologically: the promise of genomics is being realized, immuno-oncology is transforming cancer treatments, and big data is generating new insights into how to diagnose and treat diseases. Digital technologies and advanced data analytics are having a transformative effect across sales and marketing activities, R&D and manufacturing, and are acting as enablers for new businesses.

At the same time, increased geopolitical uncertainties, the economic crisis linked to the COVID-19 pandemic, and issues around budget tightening will continue to put pressure on healthcare costs, and on the entire healthcare value chain. Although we believe that pharmaceuticals and vaccines will remain a fundamentally attractive business within that value chain, the bar for innovation will most likely continue to rise. Payers will continue to put scrutiny on prices and reimbursement criteria, and demand demonstration of real-life outcomes to confirm the efficacy of medicines and vaccines. This will be coupled with more innovative pricing and contracting practices, and more transparent policies. In view of growing concerns over increasing healthcare costs across global markets, the pharmaceutical industry will be increasingly judged by its contribution to improved access for patients and to the development of innovative, highly cost-effective medicines.

Strategic framework

The Sanofi “Play to Win” strategy is organized around four key priorities: (1) focus on growth; (2) lead with innovation; (3) accelerate efficiency; and (4) reinvent how we work to drive innovation and growth.

1) Focus on growth

- **Dupixent® (dupilumab)**[(1)] – By leveraging the product's unique mechanism of action targeting the type 2 inflammation pathway and its favorable safety profile, Sanofi is maximizing the value of Dupixent® in multiple indications, with the ambition for the product to deliver strong growth to over €10bn in net sales.
- **Vaccines** – Our Vaccines business is expected to deliver mid-to-high single digit net sales growth[(2)] through differentiated products, market expansions and launches. Contributors to growth are expected to be pediatric combinations, boosters, influenza vaccines, meningitis and the launch of nirsevimab, a monoclonal antibody addressing Respiratory Syncytial Virus (RSV)[(3)].
- **Pipeline** – We are focusing our investments on priority projects, including six potentially transformative therapies in oncology, hematology, rare diseases, neurology and vaccines.

2) Lead with innovation

Sanofi has prioritized six potentially practice-changing assets in areas of high unmet patient need. These investigational therapies are listed below:

- **Amcenestrant** is an oral selective estrogen receptor degrader, which aims to be the new standard of care in hormone-receptor-positive breast cancer.
- **Fitusiran** is a small interference RNA therapeutic in development for the treatment of hemophilia A and B with or without inhibitors, with the potential to be a first-in-class therapeutic option.
- **Efanesoctocog alfa**[(4)] is a new class of factor therapy engineered to achieve higher factor levels with the potential to deliver unprecedented protection for people with hemophilia A, allowing them to achieve near-normal factor activity with a once-weekly dose.
- **Venglustat** is an oral therapy in development for several rare diseases in the category of lysosomal storage disorders (Gaucher type 3 disease, Fabry disease, GM2 gangliosidoses, etc.). Venglustat also shows promise for rare but more common disorders, including autosomal dominant polycystic kidney disease.
- **Nirsevimab**[(3)], a monoclonal antibody, is a potentially cost-effective prevention against respiratory syncytial virus (RSV), for all infants. Its high affinity to RSV could potentially allow a single injection to cover the patient for the entire RSV season.
- **Tolebrutinib** is an oral selective, brain penetrant BTK inhibitor with the potential to be the first disease-modifier to address sources of multiple sclerosis damage in the brain.

To continue fueling our promising pipeline and enhance our position as an emerging leader in the area of oncology and immunology, we have (i) entered into a multiple-program strategic collaboration with Kymera Therapeutics Inc.[(5)] (a US biotechnology company) to develop and commercialize a first-in-class protein degrader in immuno-inflammatory disease; (ii) made a public offer to acquire the entire share capital of Kiadis (an EU biotechnology company focused on cell-based immunotherapy products for oncology), with an anticipated closing date in the first half of 2021 (subject to completion of the public offer); (iii) completed the acquisition of Synthorx, Inc.; and (iv) acquired

(1) In partnership with Regeneron.
(2) CAGR based from 2018-2025.
(3) In partnered with AstraZeneca.
(4) In partnership with Swedish Orphan Biovitrum (Sobi).
(5) Subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and other customary closing conditions

Principia Biopharma Inc. (a biopharma company focused on immune-mediated diseases), giving us complete control and ownership of two late-stage assets: tolebrutinib and rilzabrutinib. In January 2021, Sanofi and Kymab entered into an agreement under which we will acquire this US clinical-stage biopharmaceutical company developing fully human monoclonal antibodies with a focus on immune-mediated diseases and immuno-oncology therapeutics.

To fight COVID-19, we signed a collaboration with GlaxoSmithKline (GSK) to combine innovative technologies to develop an adjuvanted recombinant COVID-19 vaccine. In parallel, we reinforced our existing 2018 collaboration and license agreement with Translate Bio (a clinical-stage mRNA company) to develop vaccines for infectious diseases, including a novel mRNA vaccine candidate against COVID-19 and influenza.

3) Accelerate efficiency

We aim to increase our business operating income (BOI) margin through efficiency initiatives, and we expect to generate €2.5 billion of savings by 2022. These savings will fund investments in growth drivers, as well as supporting an increase of our BOI margin.

In 2020, we have achieved around €1.7 billion of savings from (i) limiting spend on de-prioritized businesses; (ii) smart spending initiatives in procurement; and (iii) operational excellence in manufacturing and organizational productivity – almost 85% of our 2022 target. We are increasing our cost savings target by €500m to €2.5bn by 2022. These savings will be derived from continued operational excellence, and we plan to reinvest 100% of this extra €500 million of savings into supporting the sales growth and funding the pipeline.

In order to better adapt our industrial capability to our evolving manufacturing needs, we announced in February 2020 a plan to create a leading European company named EUROAPI dedicated to the production and marketing of active pharmaceutical ingredients (API) to third parties. The project involves creating a standalone company which combines Sanofi's API commercial and development activities from six of our European API production sites. The new company is expected to rank as the world's second largest API company with approximately €1 billion in sales expected by 2022. A planned IPO on Euronext Paris is being evaluated with a decision expected by 2022, subject to market conditions.

To embrace the transformative effect offered by digital technologies and advanced data analytics, we are investing to become the leading digital healthcare platform for employees, patients and providers. This will help us discover, test and deliver medicines faster, run our business more efficiently, and create engaging digital experiences. The digital transformation required to meet our ambition is under way. Our Framingham facility received the Overall Facility of the Year Award from the International Society for Pharmaceutical Engineering for its digital innovation. We are using advanced algorithms to harvest real world data to support our R&D efforts. We are also developing new go-to-market models by closer physician engagement through a variety of channels, building precision marketing, and providing better e-commerce capabilities. And in parallel, we are investigating the possibility of integrating drugs, devices, data and services, to bring innovative solutions to patients across many different disease areas such as diabetes and atopic dermatitis.

4) Reinvent how we work

Transformation and simplification have started, with the aim of increasing empowerment and accountability. To drive implementation of our new culture built on stronger focus, diversity and teamwork, we have streamlined our executive leadership team from fifteen to ten members. Four new members to the executive leadership team were appointed in 2020: Natalie Bickford as Chief People Officer, Arnaud Robert as Chief Digital Officer, Julie Van Ongevalle as Head of Consumer Healthcare, and Thomas Triomphe as Head of Sanofi Pasteur (Vaccines). The complete Sanofi Executive Committee now includes the four managers who head up our global business units (Sanofi Genzyme, Sanofi Pasteur, General Medicines, and Consumer Healthcare) as well as the head of each of the following support functions: Research and Development, Industrial Affairs, Finance, Human Resources, Legal and Digital.

The creation of our standalone Consumer Healthcare business unit, with integrated R&D, manufacturing and information technology capabilities, has started. The objective is to enhance the speed and agility of the business unit, and to accelerate its digital transformation, which is critical if it is to remain competitive.

To embed ESG (Environmental, Social and Governance) into our strategy, we have designed a new policy "Our new contract to society" around four key priorities:

- Affordable access – to ensure affordable global access to health, while helping healthcare systems to remain sustainable.
- R&D for unmet medical needs – to be at the cutting edge of R&D innovation, to help people live fully and drive growth.
- Efficiency & sustainability – to reconnect health with the planet.
- Beyond the workplace – to give all Sanofi colleagues the chance to become a leader of change, unlocking the potential of our diverse teams.

With this new policy, Sanofi aims to extend its "Play to Win" commitment to society. More details on Sanofi's contribution to sustainable development goals and Corporate Social Responsibility initiatives are available in Chapter 4 of our *Document d'Enregistrement Universel*.

Capital allocation policy

We will continue to pursue our focused and disciplined capital allocation policy. Our priorities in deploying the cash generated from our three core GBUs and the future standalone CHC business are, in the following order: (i) organic investment; (ii) business development and merger & acquisition activities, focusing on bolt-on, value-enhancing opportunities to drive scientific and commercial leadership in core therapeutic areas; (iii) growing the annual dividend; and (iv) anti-dilutive share buybacks. We also have the potential to raise capital through asset disposals, including streamlining "tail" brands in our Established Products business.

In May 2020 we announced the closing of the sale of 13.0 million shares of Regeneron common stock through a registered offering at a public offering price of $515.00 per share. In addition, Regeneron completed a repurchase of 9.8 million shares or approximately $5 billion in common stock directly from Sanofi. The registered offering and share repurchase have no impact on the ongoing collaboration between Sanofi and Regeneron.

Sanofi originally purchased a shareholding in Regeneron in 2004 representing an equity interest of approximately 20%. The decision to sell the Regeneron common shares was made in consultation with Regeneron and the contemplated structure will allow both companies to

achieve their mutual objectives. As a result of the offering, Sanofi has sold its entire equity investment in Regeneron, (excluding 400,000 Regeneron shares, which we retained) for total gross proceeds amounting to $11.7 billion.

B.2. Main pharmaceutical products

The sections below provide additional information on our main products. Our intellectual property rights over our pharmaceutical products are material to our operations and are described at "B.7. Patents, Intellectual Property and Other Rights" below. As disclosed in "8. Financial Information — A. Consolidated Financial Statements and Other Financial Information — Patents" of this annual report, we are involved in significant litigation concerning the patent protection of a number of these products. For more information on sales performance, see "Item 5. Operating and Financial Review and Prospects — Results of Operations".

Specialty Care

Dupixent®

Dupixent® (dupilumab), a human monoclonal antibody, binds to the interleukin-4 receptor alpha (IL-4Ra) and has been shown to specifically inhibit overactive signaling of two key proteins (IL-4 and IL-13), which are believed to be major drivers of multiple diseases with underlying type 2 signatures, such as atopic and inflammatory disorders like atopic dermatitis (AD) and asthma. Dupixent® comes in either a pre-filled syringe for use in a clinic or at home by self-administration as a subcutaneous injection; or in a pre-filled pen for at-home administration, providing patients with a more convenient option. Dupixent® is available in more than 47 countries including the US (since April 2017), several European Union countries (the first launch was in Germany in December 2017), and Japan (since April 2018).

Atopic Dermatitis (AD)

Moderate-to-severe atopic dermatitis, a form of eczema and a chronic inflammatory disease, is characterized by rashes that sometimes cover much of the body and can include intense, persistent itching and skin dryness, cracking, redness, crusting and oozing.

Dupixent® was granted marketing authorization by the FDA in March 2017 for the treatment of adults with moderate-to-severe AD whose disease is not adequately controlled with topical prescription therapies, or when those therapies are not advisable. In March 2019, the FDA extended the marketing authorization for adolescent patients aged 12 to 17 years. The FDA previously granted Breakthrough Therapy designation to Dupixent® for the treatment of severe atopic dermatitis in children 6 months to 11 years of age not well controlled on topical prescription medications. In January 2020, the FDA accepted for Priority Review a supplemental Biologics License Application (sBLA) for children aged 6 to 11 years. On March 26, 2020, the FDA approved Dupixent® as the first biologic medicine for children aged 6 to 11 years with moderate-to-severe AD.

The European Commission approved Dupixent® in September 2017 for use in adults with moderate-to-severe AD who are candidates for systemic therapy and extended the marketing authorization in August 2019 to include adolescents aged 12 to 17 years. On November 30, 2020, the European Commission extended the marketing authorization to children aged 6 to 11 years with severe AD.

On June 19, 2020, the National Medical Products Administration (NMPA) in China approved Dupixent® for the treatment of moderate-to-severe AD after identifying dupilumab as an overseas medicine regarded as urgently needed in clinical practice, leading to an expedited review and approval process. On December 28, 2020, the National Healthcare Security Administration (NHSA) officially announced the results of the 2020 National Reimbursement Drug List (NRDL) negotiations, with Dupixent® included in the updated NRDL effective March 1, 2021.

On October 29, 2020, new analyses of Phase III Dupixent® data in adults, adolescents, and children with atopic dermatitis were presented. The Phase III trial in adults includes efficacy and safety follow-up data over a three-year period. This is the longest data period for any approved systemic therapy in atopic dermatitis. The new data built on the existing wealth of evidence supporting the unique way Dupixent® specifically targets the underlying type 2 inflammation that contributes to diseases like atopic dermatitis, thus significantly improving itch and skin lesions and other important measures that impact a patient's quality of life.

Asthma

Dupixent® was granted marketing authorization by the FDA in October 2018 as an add-on maintenance therapy in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid-dependent asthma. In May 2019, the European Commission approved Dupixent® for use as an add-on maintenance treatment in severe asthma patients aged 12 years and older with type 2 inflammation who are inadequately controlled with high dose inhaled corticosteroid plus another medicinal product for maintenance treatment.

In September 2020, new long-term data from a Phase III open-label extension trial showed sustained improvement in lung function and reduction in severe exacerbations in adults and adolescents with moderate-to-severe asthma. In October 2020, a pivotal Phase III trial of Dupixent® met its primary and all key secondary endpoints in children aged 6 to 11 years with uncontrolled moderate-to-severe asthma, significantly reducing severe asthma attacks in children and consolidating Dupixent® as the only biologic to demonstrate improvement in children's lung function in a randomized Phase III trial.

Chronic rhinosinusitis with nasal polyposis (CRSwNP)

CRSwNP is a chronic disease of the upper airway that obstructs the sinuses and nasal passages. It can lead to breathing difficulties, nasal congestion and discharge, reduced or loss of sense of smell and taste, and facial pressure.

In June 2019, the FDA approved Dupixent® for use with other medicines to treat CRSwNP in adults whose disease is not controlled. In October 2019, the European Commission approved Dupixent® for use as an add-on therapy with intranasal corticosteroids in adults with severe CRSwNP for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control.

Eosinophilic esophagitis (EoE)

EoE is a chronic and progressive type 2 inflammatory disease that damages the esophagus and prevents it from working properly, leading to difficulties swallowing. There are currently no FDA-approved medicines for EoE. In May 2020, we announced positive results from

Part A of the pivotal Phase III trial evaluating Dupixent® in patients aged 12 years and older with EoE. The trial met both of its co-primary endpoints, as well as all key secondary endpoints. Dupixent® is the first and only biologic to show positive and clinically-meaningful results in this population as part of a Phase III trial. In September 2020, the FDA granted Breakthrough Therapy designation to Dupixent® (dupilumab) for the treatment of patients aged 12 years and older with EoE. On October 26, 2020, additional positive results were announced from Part A of a pivotal Phase III trial showing significant improvement in disease severity and extent, as well as normalized gene expression associated with type 2 inflammation. Data from this trial further support the well-established safety profile of Dupixent®.

Dupilumab is currently being evaluated in younger populations (pediatric atopic dermatitis for patients aged 6 months to 5 years, and pediatric asthma for patients aged 6 to 11 years), and in a broad range of clinical development programs for diseases that are driven by type 2 inflammation. These include chronic obstructive pulmonary disease, prurigo nodularis, chronic spontaneous urticaria and bullous pemphigoid. See "- B.5. Global Research & Development".

During our 2020 third-quarter earnings announcement, we communicated our intent to target three new indications within the type 2 inflammation space. One is a dermatological condition, chronic inducible urticaria (CINDU). The other two are in the respiratory field: chronic rhinosinusitis without nasal polyposis (CRSsNP), and allergic fungal rhinosinusitis (AFRS).

Dupixent® is developed and commercialized in collaboration with Regeneron Pharmaceuticals, Inc. For additional information on the collaboration, see "Item 5. Financial Presentation of Alliances — Alliance Arrangements with Regeneron".

There are ongoing patent infringement proceedings in several countries initiated by Sanofi and Regeneron against Amgen and Immunex relating to Dupixent®. See Note D.22.b.) to the consolidated financial statements included at Item 18. of this annual report.

Multiple sclerosis, neurology, other inflammatory diseases and immunology

Multiple Sclerosis

Multiple sclerosis (MS) is an autoimmune neurological disease in which a person's immune system attacks the central nervous system, damaging myelin, the protective sheath that covers nerve fibers. This causes a break in communication between the brain and the rest of the body, ultimately destroying the nerves themselves, and causing irreversible damage. More than 2.5 million people suffer from MS worldwide.

Our MS franchise consists of Aubagio® (teriflunomide), a once-daily, oral immunomodulator, and Lemtrada® (alemtuzumab), a monoclonal antibody. Both products treat patients with relapsing forms of MS.

Aubagio®

Aubagio® (teriflunomide), a small molecule immunomodulatory agent with anti-inflammatory properties, is a once-daily oral therapy.

Aubagio® is approved in more than 80 countries around the world including the US (since September 2012) for the treatment of patients with relapsing forms of MS, the EU (since August 2013) for the treatment of adult patients with relapsing remitting MS, and China (since July 2018). Ongoing development efforts include the TeriKIDS study to assess the safety and efficacy of teriflunomide in children (see "B.5. Global research & development") and global post-marketing registries for pregnancy.

In 2017, Sanofi reached settlement with all 20 generic Aubagio® ANDA first filers, granting each a royalty-free license to enter the US market on March 12, 2023.

Lemtrada®

Lemtrada® (alemtuzumab) is a humanized monoclonal antibody targeting the CD52 antigen. Lemtrada® is administered by intravenous infusion as two short courses 12 months apart; for the majority of patients no further treatment is necessary, making Lemtrada® the only disease-modifying therapy (DMT) that can provide long term durable efficacy in the absence of continuous dosing.

Lemtrada® is approved in more than 70 countries including the EU (since September 2013) and the US (since November 2014). Because of its safety profile, the FDA approved the use of Lemtrada® in patients with relapsing forms of MS who have had an inadequate response to two or more drugs indicated for the treatment of MS, and included a black-box warning on potential side effects. In the US, Lemtrada® is only available through a restricted distribution program called the Lemtrada® Risk Evaluation and Mitigation Strategy (REMS) Program. In January 2020, the EMA updated the indication for Lemtrada® to include treatment of relapsing-remitting multiple sclerosis if the disease is highly active despite treatment with at least one disease-modifying therapy, or if the disease is worsening rapidly. The EMA also added new contra-indications for patients with certain heart, circulation or bleeding disorders, and those who have autoimmune disorders other than MS. Alemtuzumab is being evaluated in pediatric patients (see "B.5. Global research & development").

Bayer Healthcare receives contingent payments based on alemtuzumab global sales revenue. For additional information, see Note D.18. to our consolidated financial statements, included at Item 18. of this annual report.

Rheumatoid Arthritis

Rheumatoid arthritis (RA) is a chronic inflammatory autoimmune disease causing inflammation, pain, and eventually joint damage and disability.

Kevzara®

Kevzara® (sarilumab) is a human monoclonal antibody that binds to the interleukin-6 receptor (IL-6R) and has been shown to inhibit IL-6R mediated signaling. IL-6 is a cytokine in the body that, in excess and over time, can contribute to the inflammation associated with rheumatoid arthritis. Kevzara® is available in 20 countries, including the US.

In May 2017, the FDA approved Kevzara® for the treatment of adult patients with moderately to severely active RA who have had an inadequate response or intolerance to one or more disease modifying anti-rheumatic drugs (DMARDs), such as methotrexate. In June 2017, the European Commission granted marketing authorization for Kevzara® in combination with methotrexate for the treatment of moderately to severely active RA in adult patients who have responded inadequately to – or who are intolerant to – one or more DMARDs, such as methotrexate. The product is also in development in pediatric populations . See "- B.5. Global Research & Development".

Kevzara® is developed and commercialized in collaboration with Regeneron. For additional information, see “Item 5. Financial Presentation of Alliances — Alliance Arrangements with Regeneron”.

Rare Diseases

Our Rare Diseases business is focused on products for the treatment of rare genetic diseases and other rare chronic debilitating diseases of high unmet medical need, including lysosomal storage disorders (LSDs), a group of metabolic disorders caused by enzyme deficiencies.

Cerezyme®

Cerezyme® (imiglucerase) is an enzyme replacement therapy used to treat Gaucher disease, a chronic, inherited, progressive and potentially life-threatening LSD. Gaucher disease is caused by deficiency of the enzyme glucocerebrosidase; this causes a fatty substance called glucosylceramide (also called GL-1) to build up in certain areas of the body including the spleen, liver, and bone. Gaucher disease exhibits diverse manifestations, a broad range of age of onset of symptoms, and a wide clinical spectrum of disease severity. It is estimated that Gaucher disease occurs in approximately one in 120,000 newborns in the general population and one in 850 in the Ashkenazi Jewish population worldwide, but the incidence and patient severity vary among regions. Cerezyme® has been marketed in the US since 1994, in the EU since 1997, in Japan since 1998 and in China since 2008, and is approved to treat Type 1 Gaucher disease in more than 85 countries. It has also been approved to treat the systemic symptoms of Type 3 Gaucher disease in most non-US markets, including the EU and Japan.

Cerezyme® is typically given by intravenous infusions for 1-2 hours every two weeks at an infusion center, a doctor’s office, or at home as medically appropriate. The dose of Cerezyme® is individualized based on the weight of the patient and disease severity. The most common dosing schedule for Cerezyme® is 60 units per kilogram of body weight, every two weeks.

Cerdelga®

Cerdelga® (eliglustat) is the first and only first-line oral therapy for Gaucher disease Type 1 adult patients. A potent, highly specific ceramide analog inhibitor of GL-1 synthesis with broad tissue distribution, Cerdelga® has demonstrated efficacy in the treatment of naive Gaucher disease patients and in patients who switch from enzyme replacement therapy. Cerdelga® has been approved to treat Type 1 Gaucher disease in the US (2014), and in the EU and Japan (2015). It is also in development for the treatment of type I Gaucher disease in pediatric patients. See “- B.5. Global Research & Development”.

There are ongoing patent infringement proceedings in the US. For further information, see “Item 8. Information on Legal or Arbitration Proceedings — Cerdelga® Patent Litigation”.

Cerdelga® comes in a capsule, with a recommended dosage of 84 mg once or twice daily depending on the patient's CYP2D6-metabolizer status.

Myozyme® and Lumizyme®

Myozyme® (alglucosidase alfa) is an enzyme replacement therapy used to treat both Infantile Onset and Late Onset Pompe disease (IOPD and LOPD). Pompe disease is an inherited, progressive and often fatal neuromuscular disease, caused by a genetic deficiency or dysfunction of the lysosomal enzyme acid alpha-glucosidase (GAA) that results in the build-up of glycogen in the muscles’ cells. For infantile-onset Pompe disease, symptoms begin within a few months of birth and there is impact to the heart in addition to skeletal muscle weakness. Other symptoms include difficulties breathing, frequent chest infections, problems feeding that result in failure to gain weight as expected, and failure to meet certain developmental milestones. Patients with late-onset Pompe disease typically present symptoms any time after the first year of life to late adulthood and rarely manifest cardiac problems. The hallmark symptom of late-onset Pompe disease is skeletal muscle weakness, which often leads to walking disability and reduced respiratory function. Patients often require wheelchairs to assist with mobility and may require mechanical ventilation to help with breathing. Pompe disease occurs in approximately one in 40,000 newborns worldwide, but incidence and patient severity vary among regions.

Myozyme® was first approved in 2006 in the EU and has since been approved in more than 70 countries. In the US, alglucosidase alfa has been marketed as Lumizyme® since 2010.

The recommended dosage regimen of Myozyme® and Lumizyme® is 20 mg per kilogram of body weight administered every two weeks as an intravenous infusion. Myozyme® should be reconstituted, diluted and administered by a healthcare professional.

Fabrazyme®

Fabrazyme® (agalsidase beta) is an enzyme replacement therapy used to treat Fabry disease. Fabry disease (FD) is a multisystemic, progressive, X-linked inherited disorder of glycosphingolipid metabolism due to deficient or absent lysosomal α-galactosidase A activity resulting in progressive globotriaosylceramide (GL-3) accumulation in the lysosomes of various tissues. Fabry Disease affects both genders. With age, progressive organ damage develops, leading to potentially life-threatening renal, cardiac and/or cerebrovascular complications. Fabry disease is characterized by different symptom severities and rates of progression, ranging from classic disease with early symptom onset to late onset disease with cardiac and/or renal complications later in life. Fabry disease occurs in approximately one in 35,000 newborns worldwide, but incidence and patient severity vary among regions. Fabrazyme® has been marketed in the EU since 2001 and in the US since 2003, and is approved in more than 70 countries.

The recommended dosage of Fabrazyme® is 1 mg per kilogram of body weight, infused intravenously every two weeks at an infusion center, a doctor’s office, or at home as medically appropriate.

Aldurazyme®

Aldurazyme® (laronidase) is the only approved enzyme replacement therapy for mucopolysaccharidosis type 1 (MPS I), an inherited lysosomal storage disorder caused by a deficiency of alpha-L-iduronidase, a lysosomal enzyme normally required for the breakdown of certain complex carbohydrates known as glycosaminoglycans (GAGs). MPS I is multi-systemic, and children with MPS I are described as having either a severe or attenuated form of the disorder based on age of onset, severity of symptoms, rate of disease progression and whether there is early and direct involvement of the brain. MPS I occurs in approximately one per 100,000 live births worldwide, but incidence and patient severity vary among regions. Aldurazyme® has been marketed in the EU and the US since 2003, and is approved in more than 75 countries.

The recommended dosage regimen of Aldurazyme® is 0.58 mg per kilogram of body weight, administered once weekly as an intravenous infusion.

Oncology

Sarclisa®

Sarclisa® is a monoclonal antibody that binds a specific epitope on the human CD38 receptor and has antitumor activity via multiple mechanisms of action. It was approved in combination with pomalidomide and dexamethasone in March 2020 in the US for the treatment of adults with relapsed refractory multiple myeloma (RRMM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor, and by the European Commission in June 2020. Sarclisa® has now been launched in the US, Austria, Japan, Switzerland, Canada and the UK. Additional commercial launches are ongoing.

Libtayo®

Libtayo® (cemiplimab-rwlc), an immune therapy drug, is a fully human monoclonal antibody targeting the immune checkpoint receptor PD-1 (programmed cell death protein-1). This may restore immune function through the activation of cytotoxic T cells, thereby avoiding tumor evasion from host immunity.

In September 2018, the FDA approved Libtayo® for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation. The European Commission granted conditional marketing authorization in July 2019. Libtayo® is the only treatment specifically approved and available for advanced CSCC in the EU. CSCC is the second most common form of skin cancer. The Libtayo® launch rollout is ongoing.

Cemiplimab has been filed for label extensions with the FDA and the EMA in basal cell carcinoma (BCC) and non small cell lung cancer (NSCLC), and the FDA has granted a priority review for both indications (See recent updates in Item 8. — B. Significant Changes). Cemiplimab is also being investigated in several other clinical development programs. See "– B.5. Global Research & Development".

Libtayo® is developed and commercialized in collaboration with Regeneron. For additional information on the commercialization of this product, see "Item 5. Financial Presentation of Alliances — Alliance Arrangements with Regeneron".

Jevtana®

Jevtana® (cabazitaxel), a chemotherapy drug and cytotoxic agent, is a semi-synthetic second-generation taxane that prevents many cancer cells from dividing, which ultimately results in destroying many such cells. It is approved in combination with prednisone for the treatment of patients with metastatic castration resistant prostate cancer previously treated with a docetaxel-containing treatment regimen. Jevtana® was granted marketing authorization by the FDA in June 2010, by the European Commission in March 2011, and in Japan in July 2014. The product is marketed in over 75 countries. In Europe, we expect generic competition for Jevtana® from the end of March 2021. In the United States, generic manufacturers of cabazitaxel are currently prevented from obtaining final approval from the FDA until September 26, 2021. In addition, Sanofi has filed patent infringement suits against all generic manufacturers of cabazitaxel, asserting patents with an expiration date of October 2030. Sanofi has entered into settlement agreements with some of the defendants and the suit against the remaining defendants is still ongoing.

Fasturtec®/Elitek®

Fasturtec®/Elitek® is used for the management of plasma uric levels in patients with leukemia, lymphoma, and solid tumor malignancies receiving anticancer therapies.

Rare Blood Disorders

The Rare Blood Disorders franchise was created in 2018 following Sanofi's acquisition of Bioverativ and Ablynx (see "– A. History and Development of the Company").

Eloctate®

Eloctate® (antihemophilic factor (recombinant), Fc fusion protein), is an extended half-life clotting-factor therapy to control and prevent bleeding episodes in adults and children with hemophilia A. In the US, it is indicated for use in adults and children with hemophilia A for on-demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine prophylaxis to reduce the frequency of bleeding episodes.

Hemophilia A is a rare, x-linked genetic bleeding disorder characterized by a deficiency of functional coagulation Factor VIII, resulting in a prolonged patient plasma-clotting time. As a consequence, people with hemophilia A bleed for a longer time than normal. Eloctate® temporarily replaces the missing coagulation Factor VIII by intravenous injection.

We market Eloctate® primarily in the US (since 2014), Japan, Canada, Australia, South Korea, Taiwan, and Colombia.

Eloctate® is developed and commercialized in collaboration with Swedish Orphan Biovitrum AB (Sobi), whose territories include Europe, Russia, the Middle East, and some countries in North Africa.

Alprolix®

Alprolix® (coagulation Factor IX (recombinant), Fc fusion protein) is an extended half-life clotting-factor therapy to control and prevent bleeding episodes in adults and children with hemophilia B. In the US, it is indicated for use in adults and children with hemophilia B for on-demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine prophylaxis to reduce the frequency of bleeding episodes.

Hemophilia B is a rare, x-linked genetic bleeding disorder characterized by a deficiency of functional coagulation Factor IX, resulting in a prolonged patient plasma-clotting time. As a consequence, people with hemophilia B bleed for a longer time than normal. Alprolix® temporarily replaces the missing coagulation Factor IX by intravenous injection.

We market Alprolix® primarily in the US (since 2014), Japan, Canada, Australia, New Zealand, South Korea, Taiwan, and Colombia.

Alprolix® is developed and commercialized in collaboration with Swedish Orphan Biovitrum AB (Sobi), whose territories include Europe, Russia, the Middle East, and some countries in North Africa.

Cablivi®

Cablivi® (caplacizumab) is a bivalent anti-von Willebrand Factor (vWF) Nanobody® for the treatment of adults experiencing an episode of acquired thrombotic thrombocytopenic purpura (aTTP). Cablivi® is the first therapeutic specifically indicated for the treatment of aTTP.

Acquired thrombotic thrombocytopenic purpura is an ultra-rare (3.5-4.5 episodes per million of population), life-threatening, autoimmune-based blood clotting disorder characterized by extensive clot formation in small blood vessels throughout the body, leading to severe thrombocytopenia (very low platelet count); microangiopathic hemolytic anemia (loss of red blood cells through destruction); ischemia (restricted blood supply to parts of the body); and widespread organ damage, especially in the brain and heart. Cablivi® has an immediate effect on platelet adhesion and the ensuing formation and accumulation of the micro-clots.

Cablivi® was granted marketing authorization by the European Commission in September 2018 and by the FDA in February 2019. Cablivi® is marketed in the US, Germany, Denmark, Austria, Belgium, Luxembourg, the Netherlands, Italy, Finland, Romania, the Czech Republic and the Gulf states. It is also available under a temporary user license in France (*autorisation temporaire d´utilisation)* and in Switzerland.

Cablivi® was developed by Ablynx, a Sanofi company since mid-2018. See “- A. History and Development of the Company”.

General Medicines

Sanofi has prioritized core medicines with differentiated and/or established profiles that have significant opportunity for growth in key markets. Some of these well-established medicines are the standard-of-care for patients living with diabetes or cardiovascular disease. These core medicines include Toujeo®, Soliqua®, Praluent®, Multaq®, Lovenox®, and Plavix®.

Diabetes

Lantus®

Lantus® (insulin glargine 100 units/mL) is a long-acting analog of human insulin, indicated for once-daily administration for the treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above. Lantus® relies on more than 15 years of clinical evidence in diabetes treatment and a well established safety profile. Approved in the US and the EU in 2000 and in Japan in 2008, Lantus® is available in over 130 countries worldwide. Two insulin glargine biosimilars are available in the US, two in European markets, and two in Japan.

There are ongoing patent infringement proceedings in the US against Mylan. See “Item 8. Financial information — Information on Legal or Arbitration Proceedings”.

Toujeo®

Toujeo® (insulin glargine 300 units/mL) is a long-acting analog of human insulin, indicated for the treatment of diabetes mellitus in adults. Toujeo® has been granted marketing authorization by the FDA (February 2015); the European Commission (April 2015); and the Ministry of Health, Labor and Welfare (J-MHLW) in Japan, where its approved brand name is Lantus® XR (June 2015). Toujeo® has now been launched in more than 60 countries, including China since the end of 2020. In January 2020, the European Commission approved an expansion of the indication to include the treatment of diabetes in adolescents and children (aged 6 years and above).

Toujeo® is available in Toujeo® SoloSTAR®, a disposable prefilled pen which contains 450 units of insulin glargine and requires one-third of the injection volume to deliver the same number of insulin units as Lantus® SoloSTAR®. In the US (since 2018) and the EU (since 2019), Toujeo® is also available in a disposable prefilled pen which contains 900 units of insulin glargine.

Apidra®

Apidra® (insulin glulisine) is a rapid-acting analog of human insulin, indicated to improve glycemic control in adults and children with diabetes mellitus. It is administered around meal time, and is used in a regimen with an intermediate or long-acting insulin (Apidra® has a more rapid onset and shorter duration of action than fast-acting human insulin). Apidra® is available in over 100 countries worldwide.

Soliqua® 100/33 – Suliqua®

Soliqua® 100/33 or Suliqua® is a once-daily fixed-ratio combination of insulin glargine 100 Units/mL, a long-acting analog of human insulin, and lixisenatide, a GLP-1 receptor agonist. The FDA approved Soliqua® 100/33 in November 2016 for the treatment of adults with type 2 diabetes inadequately controlled on basal insulin (less than 60 units daily) or lixisenatide; and in February 2019 for patients uncontrolled on oral antidiabetic medicines. In January 2017, Suliqua® (the product’s brand name in Europe) was approved for use in combination with metformin for the treatment of adults with type 2 diabetes to improve glycemic control, when this has not been provided either by metformin alone or by metformin combined with another oral glucose-lowering medicinal product or with basal insulin. In Japan, Soliqua® was approved in May 2020 for type 2 diabetes mellitus, where treatment with insulin is required. Suliqua® is available in over 40 countries.

Admelog®/Insulin lispro Sanofi®

Admelog® (or Insulin lispro Sanofi®) is a rapid-acting insulin similar to Humalog®, another insulin lispro 100 Units/mL. Admelog® was approved by the FDA in December 2017, and was also granted marketing authorization as a biosimilar (under the proprietary name Insulin lispro Sanofi®) by the European Commission in July 2017. It is used to improve blood sugar control in adults with type 2 diabetes and adults and children (aged 3 years and above) with type 1 diabetes. Admelog® was launched in the US and several European countries during 2018.

Amaryl®/Amarel®/Solosa®

Amaryl® (glimepiride) is an orally administered once-daily sulfonylurea available in single form or in combination with metformin, indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes. A number of glimepiride generics are available in most markets.

Truvelog™/TruRapi™/Insulin aspart Sanofi®

Truvelog™ (also known as TruRapi™ or Insulin aspart Sanofi®) is a rapid-acting insulin similar to Novorapid®/Novolog®, another insulin aspart 100 Units/mL. It was granted marketing authorization as a biosimilar (under the proprietary name Insulin aspart Sanofi®) by the European Commission in June 2020. It is used to improve blood sugar control in adults with type 2 diabetes, and in adults and children (aged 1 year and above) with type 1 diabetes. Insulin aspart Sanofi® was launched in several European countries during 2020.

Integrated Care Solutions

Sanofi, in collaboration with Abbott and Biocorp, is building a connected set of tools to support people living with diabetes and taking insulin. Sanofi intends to use de-identified data to generate insights to inform patients and providers, and to evaluate additional clinical or quality-of-life outcomes. Successful pilot launches of the MyDoseCoach® tool in several countries demonstrate the value of digital features such as basal titration for integration into a fully connected system.

Cardiovascular Diseases and Established Prescription Products

Praluent®

Praluent® (alirocumab) is a human monoclonal antibody (mAb) for self-administered injection every two weeks or once-monthly. It blocks the interaction of proprotein convertase subtilisin/kexin type 9 (PCSK9) with low-density lipoprotein (LDL) receptors, increasing the recycling of LDL receptors and reducing LDL cholesterol levels.

Praluent® is indicated as an adjunct to diet and maximally tolerated statin therapy in certain adult patients with uncontrolled LDL cholesterol. Praluent® has been approved in more than 60 countries worldwide, including the US (in 2015), Canada and Switzerland, as well as in the European Union (in 2015). In 2018, the FDA approved a Praluent® label update for some patients currently requiring LDL apheresis therapy. In March 2019 in the EU and in April 2019 in the US, Praluent® was approved for use in patients with established cardiovascular disease to reduce the risk of cardiovascular events. In December 2019, Praluent® was approved in China, where it started to be commercialized in May 2020.

Since April 2020, Praluent® has no longer been commercialized in collaboration with Regeneron. Regeneron is responsible for commercialization in the US, and Sanofi for all other markets outside the US. For additional information on the commercialization of this product, see “Item 5. Financial Presentation of Alliances — Alliance Arrangements with Regeneron”.

In October 2020, the European Patent Office Technical Boards of Appeal ruled in Sanofi/Regeneron’s favor, invalidating claims of Amgen’s European Patent No. 2215124 relevant to Praluent® for lack of inventive step. This means that Praluent® will continue to be marketed and sold in the EU.

Multaq®

Multaq® (dronedarone) is an oral multichannel blocker with anti-arrhythmic properties for prevention of atrial fibrillation recurrences in certain patients with a history of paroxysmal or persistent atrial fibrillation. Multaq® was approved in the US and in the EU in 2009. Multaq® is available in about 35 countries.

Plavix®/Iscover®

Plavix® or Iscover® (clopidogrel bisulfate) is a platelet adenosine diphosphate (ADP) receptor antagonist. It is indicated for the prevention of atherothrombotic events in patients with a history of recent myocardial infarction (MI), recent ischemic stroke or established peripheral arterial disease (PAD), and for patients with acute coronary syndrome (ACS). Plavix® is also indicated in combination with acetylsalicylic acid (ASA) for the prevention of atherothrombotic and thromboembolic events in atrial fibrillation, including stroke.

CoPlavix®/DuoPlavin®, a fixed-dose combination of clopidogrel bisulfate and ASA, is indicated for the prevention of atherothrombotic events in adult patients with acute coronary syndrome who are already taking both clopidogrel and ASA.

A number of clopidogrel bisulfate generics have been launched in most markets. Plavix® or Iscover® are available in more than 80 countries. For additional information on the commercialization of these products, see “Item 5. Financial Presentation of Alliances — Alliance Arrangements with Bristol-Myers Squibb”.

Sanofi is involved in two Plavix® product lawsuits. See Note D.22.c) to our consolidated financial statements, included at Item 18 of this annual report.

Lovenox®/Clexane®

Lovenox® or Clexane® (enoxaparin sodium) is a low molecular weight heparin (LMWH) indicated for use in the prophylaxis and treatment of venous thromboembolism and in the treatment of acute coronary syndrome. Enoxaparin generics are available in the US, and biosimilar enoxaparin products have gradually become available across various European countries and in a growing number of international markets. Lovenox® or Clexane® is marketed in more than 100 countries.

Aprovel®/Avapro®/Karvea®

Aprovel®, also known as Avapro® or Karvea® (irbesartan), is an angiotensin II receptor antagonist indicated as a first-line treatment for hypertension and for the treatment of nephropathy in hypertensive patients with type 2 diabetes. We also market CoAprovel®/Avalide®/Karvezide®, a combination of irbesartan and the diuretic hydrochlorothiazide. A combination with amlodipine (Aprovasc®) has been launched in several emerging market countries.

A number of irbesartan generics have been launched in most markets. Aprovel® and CoAprovel® are marketed in more than 80 countries. For additional information on the commercialization of this product, see “Item 5. Financial Presentation of Alliances — Alliance Arrangements with Bristol-Myers Squibb”. In Japan, the product is licensed to Shionogi Co. Ltd and BMS KK. BMS KK has sublicensed the agreement to Dainippon Pharma Co. Ltd.

Renagel® and Renvela®

Renagel® (sevelamer hydrochloride) and Renvela® (sevelamer carbonate) are oral phosphate binders used by chronic kidney disease (CKD) patients on dialysis as well as late stage CKD patients in Europe to treat hyperphosphatemia, or elevated phosphorus levels, which is associated with heart and bone disease. Renvela® is a second-generation buffered phosphate binder.

Generics of sevelamer carbonate are available in the US and in various European countries. A generic of sevelamer hydrochloride was approved in the US in February 2019, and was subsequently launched. Renagel® and Renvela® are marketed in more than 85 countries. In Japan and several Pacific Rim countries, Renagel® is marketed by Chugai Pharmaceutical Co., Ltd and its sublicensee, Kyowa Hakko Kirin Co., Ltd.

Synvisc®/Synvisc-One®

Synvisc® and Synvisc-One® (hylan G-F 20) are viscosupplements used to treat pain associated with osteoarthritis. Synvisc® and Synvisc-One® are marketed in over 60 countries.

Depakine®

Depakine® (sodium valproate) is a broad-spectrum anti-epileptic that has been prescribed for more than 50 years and remains a reference treatment for epilepsy worldwide. Depakine® is also a mood stabilizer, registered in the treatment of manic episodes associated with bipolar disorder (in some countries this indication is branded differently, for example as Depakote® in France). We hold no rights to Depakine® in the US, and sodium valproate generics are available in most markets.

Sanofi is involved in product litigation related to Depakine®. See Note D.22.a) to the consolidated financial statements included at Item 18. of this annual report.

Legacy Oncology and Transplant

Thymoglobulin®

Thymoglobulin® (anti-thymocyte Globulin) is a polyclonal anti-human thymocyte antibody preparation that acts as a broad immunosuppressive and immunomodulating agent. In the US, Thymoglobulin® is indicated for the prophylaxis and treatment of acute rejection in patients receiving a kidney transplant, used in conjunction with concomitant immunosuppression. Outside the US, depending on the country, Thymoglobulin® is indicated for the treatment and/or prevention of acute rejection in organ transplantation; immunosuppressive therapy in aplastic anemia; and the treatment and/or prevention of Graft-versus-Host Disease (GvHD) after allogeneic hematopoietic stem cell transplantation. Thymoglobulin® is currently marketed in over 65 countries.

Taxotere®

Taxotere® (docetaxel), a chemotherapy drug and cytotoxic agent, is a semi-synthetic taxane. It has been approved for use in 11 indications in five different tumor types (breast, prostate, gastric, lung, and head and neck). Generics of docetaxel have been launched globally.

Sanofi is involved in Taxotere® product litigation in the US. See Note D.22.a) to our consolidated financial statements, included at Item 18. of this annual report.

Eloxatin®

Eloxatin® (oxaliplatin), a chemotherapy drug, is a platinum-based cytotoxic agent. In combination with the infusional administration of two other chemotherapy drugs (5-fluorouracil/leucovorin, in the FOLFOX regimen), Eloxatin® is approved by the FDA for adjuvant treatment of people with stage III colon cancer who have had their primary tumors surgically removed. It is also approved for the treatment of advanced colorectal cancer and in some countries for the treatment of early-stage gastric cancer. Generics of oxaliplatin have been launched globally. Eloxatin® is in-licensed from Debiopharm.

Mozobil®

Mozobil® (plerixafor injection) is a hematopoietic stem cell mobilizer. It is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM). Mozobil® is marketed in over 65 countries.

Zaltrap®

Zaltrap® (aflibercept/ziv-aflibercept) is a recombinant fusion protein. The FDA approved Zaltrap® in August 2012 for use in combination with FOLFIRI (a chemotherapy regimen made up of 5-fluorouracil/leucovorin/irinotecan), in patients with metastatic colorectal cancer (mCRC) that is resistant to or has progressed following an oxaliplatin-containing regimen. To avoid confusion with Eylea®, the FDA assigned a new name, ziv-aflibercept, to the active ingredient. The European Commission approved Zaltrap® (aflibercept) in February 2013 to treat mCRC that is resistant to or has progressed after an oxaliplatin-containing regimen.

Zaltrap® is marketed in 50 countries. For additional information on the commercialization of Zaltrap®, see "Item 5. Financial Presentation of Alliances — Alliance Arrangements with Regeneron".

Generics

On September 30, 2018, we completed the divestment of our European generics business Zentiva to Advent International, a US global private equity firm. We have retained our presence in Generics in Emerging Markets, especially in Latin America with two top-of-mind brands – Medley (Brazil) and Genfar (Colombia, Peru, Ecuador and Central America) – and also in Russia, South Africa and Turkey.

B.3. Consumer Healthcare

In December 2019, we announced that Consumer Healthcare would become a standalone business unit with integrated R&D and manufacturing functions plus dedicated support functions and information technology. Implementation progressed as planned in 2020. In addition, we divested some non-core brands in Europe, the US and Latin America. Going forward we will continue to reduce the complexity of the portfolio and reduce the number of brands by roughly 60% in two years, from more than 250 to about 100. We will also optimize the Go-To-Market model by tailoring it more closely to the actual needs of our markets.

Our CHC sales are supported by a range of products, including the following brands:

Allergy, Cough & Cold

- Allegra® comprises a range of fexofenadine HCl–based products. Fexofenadine is an anti-histamine for relief from allergy symptoms including sneezing, runny nose, itchy nose or throat, and itchy, watery eyes. The Allegra® OTC brand family is sold in more than 80 countries across the world.
- Mucosolvan® is a cough brand with many different formulations. It contains the mucoactive agent ambroxol; this stimulates synthesis and release of surfactant. It is sold in various countries in Europe, Latin America and Asia, and in Russia.

Pain

- Doliprane® offers a range of paracetamol/acetaminophen-based products for pain and fever with a wide range of dosage options and pharmaceutical forms, and is sold mainly in France and various African countries.
- The Buscopan® range (hyoscine butylbromide) has an antispasmodic action that specifically targets the source of abdominal pain and discomfort. It is sold across the globe.
- We also have local pain brands such as Eve® in Japan; Dorflex® and Novalgina® in Brazil; and IcyHot® and Aspercreme® in the US.

Digestive

- Dulcolax® products offer a range of constipation solutions from predictable overnight relief to comfortable natural-feeling relief. The products are sold in over 80 countries. Dulcolax® tablets contain the active ingredient bisacodyl or sodium picosulfate, which works directly on the colon to produce a bowel movement.
- Enterogermina® is a probiotic indicated for the maintenance and restoration of intestinal flora in the treatment of acute or chronic intestinal disorders. Enterogermina® is sold primarily in Europe, and in Latin America and parts of Asia.
- Essentiale® is a natural soybean remedy to improve liver health. It is composed of essential phospholipids extracted from highly purified soya and contains a high percentage of phosphatidylcholine, a major component of the cell membrane. Essentiale® is used in fatty liver disease and is sold mainly in Russia, Eastern Europe, various countries in Southeast Asia, and China.
- Zantac® products are for the prevention and relief of heartburn. In October 2019, Sanofi initiated a voluntary recall of all Zantac® OTC in the US and in Canada as a precautionary measure, following inconsistencies in preliminary test results on the active ingredient used in the US product.

Nutritionals

- Nutritionals include a range of products to maintain general health, provide immune system support, or supplement vitamin deficiencies. These products help manage energy, stress, sleep and anxiety, and include a number of brands across the globe including Nature's Own® in Australia to improve and maintain health; Pharmaton® (mainly in Europe and Latin America); Magne B6® in Europe; and a range of sleep brands, including Novanuit® in Europe, Unisom® in USA and Drewell® in Japan.

Other

- Gold Bond® offers a broad range of products including daily body lotions, anti-itch products, moisturizing and soothing lotions, body and foot creams and powders for eczema. Gold Bond® is only sold in the US.

Going forward we will be taking a more granular approach and focus on attractive sub-categories in key geographies, based on consumer trends, portfolio strengths and opportunities. These sub-categories include Allergy, Pain, Liver Care, Physical and Mental Wellness, and Probiotics. These sub-categories in our key geographies account for about one-third of our total CHC business today.

B.4. Vaccine products

Sanofi Pasteur, the Vaccines division of Sanofi, is a world leader in the vaccine industry and a key supplier of life-saving vaccines all over the world and in publicly funded international markets such as UNICEF, the Pan American Health Organization (PAHO) and the Global Alliance for Vaccines and Immunization (GAVI).

The Sanofi Pasteur portfolio includes the following vaccines:

a) Poliomyelitis, Pertussis and Hib pediatric vaccines

Sanofi Pasteur is one of the key players in pediatric vaccines in both developed and emerging markets, with a broad portfolio of standalone and combination vaccines protecting against up to six diseases in a single injection. Due to the diversity of immunization schedules throughout the world, vaccines vary in composition according to regional specificities.

Tetraxim®, a pediatric combination vaccine protecting against diphtheria, tetanus, pertussis and poliomyelitis (polio), was first marketed in 1998. To date, the vaccine has been launched in close to 90 countries outside the US.

Pentaxim®, a pediatric combination vaccine protecting against diphtheria, tetanus, pertussis, polio and Hemophilus influenzae type b (Hib), was first marketed in 1997. To date, the vaccine has been launched in more than 100 countries outside the US. In most European, Latin American, Asian and Middle Eastern markets, Pentaxim® is being gradually replaced by Hexaxim®.

Hexaxim®/Hexyon®/Hexacima® is a fully liquid, ready-to-use 6-in-1 (hexavalent) pediatric combination vaccine that provides protection against diphtheria, tetanus, pertussis, polio, Hib and hepatitis B. Hexaxim® is the only combination vaccine including acellular pertussis (acP) and inactivated polio vaccines (IPV) currently prequalified by the WHO. Hexaxim® is now available in 100 countries outside the US.

Pentacel®, a pediatric combination vaccine protecting against diphtheria, tetanus, pertussis, polio and Hib, was launched in the US in 2008.

Shan5® is a 5-in-1 (whole-cell pertussis based) combination vaccine protecting against five diseases (diphtheria, tetanus, pertussis, Hib and hepatitis B). Shan5® is WHO pre-qualified and procured through Unicef to the GAVI countries.

Act'Hib® is a standalone vaccine protecting against Hib, and is mainly distributed in the US, Japan and China in conjunction with pertussis combination vaccines that do not contain the Hib valence.

Sanofi Pasteur is a leading provider of polio vaccines and has been a partner of the Global Polio Eradication Initiative (GPEI) for over 30 years, with more than 13 billion doses of oral polio vaccines (OPV) delivered during that time.

Since 2014, when the WHO recommended that every child should receive at least one dose of IPV, Sanofi Pasteur has provided 287 million doses to support the WHO "Polio End Game" strategy for the world's 73 poorest countries, representing 80% of the total IPV volumes used in those countries.

Vaxelis® is a PR5i hexavalent combination vaccine protecting against diphtheria, tetanus, pertussis, polio, Hib and hepatitis B. This vaccine (developed and distributed in partnership with Merck) was approved in 2016 by the EMA and is distributed in various EU countries. Vaxelis® was approved by the FDA in December 2018, becoming the first hexavalent vaccine to be approved in the US. Launch is scheduled from 2021.

b) Influenza vaccines

Sanofi Pasteur is a world leader in the production and marketing of influenza vaccines, offering several distinct influenza vaccines that are sold globally to meet growing demand.

Fluzone® Quadrivalent is a quadrivalent inactivated influenza vaccine, produced in the US, containing two type A antigens and two type B antigens in order to provide increased protection against more circulating strains of influenza viruses. Fluzone® Quadrivalent/FluQuadri® is available in 27 countries (including the US) for children aged over six months, adolescents and adults. Fluzone® 0.5ml QIV is the currently-licensed standard dose (15 µg/strain) quadrivalent influenza vaccine for ages 6 months and older.

Fluzone® High-Dose trivalent vaccine, launched in the US in 2010, was specifically designed to provide greater protection against influenza in people aged 65 and older. It includes two influenza A strains and one influenza B strain and contains 60µg/strain (four times the amount of antigen included in the standard dose vaccine). Fluzone® High-Dose has to date been sold in the US, Canada, Australia and the UK. It is now being replaced by Fluzone® High-Dose Quadrivalent for adults aged 65 years of age and older, which was approved by the FDA in November 2019 and is available for the 2020/2021 influenza season and contains an additional influenza B strain compared to the Fluzone® High-Dose trivalent vaccine. Fluzone® High-Dose Quadrivalent was first approved in the EU in the second quarter of 2020, under the name Efluelda®.

Flublok® is a quadrivalent influenza vaccine for adults aged 18 and older. It is the only recombinant protein-based influenza vaccine approved by the FDA. Flublok® is currently sold in the US, with global expansion planned over the next several years. Flublok® was approved in the EU under the name Supemtek® in November 2020.

Vaxigrip® is licensed in over 150 countries outside the US for people aged six months and older. It is a trivalent influenza vaccine, containing two antigens against type A influenza viruses and one antigen against type B influenza viruses. It has now been replaced by VaxigripTetra® in most countries.

VaxigripTetra® is the quadrivalent (QIV) version of Vaxigrip®, including two antigens against A strains of influenza viruses and two antigens against B strains. Compared to the trivalent influenza vaccine, it contains an additional influenza B strain; it was licensed in 2016 and has been launched in more than 40 countries since 2017. VaxigripTetra® is not licensed in the US where Fluzone® Quadrivalent, which is produced in the US, is distributed.

c) Adult booster vaccines

Adacel® is the first trivalent booster vaccine offering protection against diphtheria, tetanus and pertussis. The vaccine can be used from 4 years of age following primary immunization and is the first and only Tdap vaccine indicated for use during pregnancy for protection against pertussis in newborns. It is available in 55 countries including the US, and otherwise mostly in Europe, Asia and Latin America.

Repevax®/Adacel®-Polio is a combination vaccine that provides protection against diphtheria, tetanus, pertussis and polio. It is the first and only Tdap-IPV vaccine indicated for use during pregnancy for protection against pertussis in newborns. It is currently marketed in 23 countries outside the US, with a strong focus on European markets (France, Germany).

d) Meningitis vaccines

Menactra® is the first quadrivalent conjugate vaccine against meningococcal meningitis (serogroups: A, C, Y, and W-135), one of the deadliest forms of meningitis. Menactra® is indicated for people aged 9 months through 55 years in the US, Canada, several Middle Eastern countries including Saudi Arabia, and numerous other countries (outside Europe). It is a strong leader in the meningitis quadrivalent market in the US and globally. More than 100 million doses of Menactra® have been distributed since launch. It is the only fully liquid (no reconstitution needed) meningitis quadrivalent conjugated vaccine available in the market.

MenQuadfi™ is a novel fully-liquid formulation. It is expected to have a broad age indication from infants (6 weeks) to the elderly, with flexible dosing schedules and to be available worldwide, allowing Sanofi Pasteur to enter the European meningococcal market, where it is not currently present. MenQuadfi™ was approved in the US in April 2020 for people aged 2 years and older; and in Australia, Canada, and the EU in October/November 2020 for people aged 12 months and older.

e) Travel and endemic vaccines

Sanofi Pasteur provides a wide range of travel and endemic vaccines including hepatitis A, typhoid, cholera, yellow fever, Japanese encephalitis and dengue, as well as rabies vaccines and immunoglobulins. These products are used in endemic settings in the developing world and are the foundation for important partnerships with governments and organizations such as UNICEF. They are also used by travelers and military personnel in industrialized countries and in endemic areas.

Dengvaxia®: The European Medicines Agency, the FDA and more than 20 countries worldwide have authorized the use of Dengvaxia® in high endemic areas.

In most countries where Dengvaxia® is approved, the indication is for individuals aged 9 to 45 years or older living in a dengue-endemic area. Based on new results from a supplemental analysis of the long-term clinical data on the vaccine reported in November 2017, Sanofi Pasteur has recommended a label update for Dengvaxia® to target its use at people with prior dengue infection.

- The WHO has recognized the public health value of introducing Dengvaxia® in targeted immunization programs, recommending that the vaccine be offered to individuals who have tested positive for prior dengue infection – a condition that can be fulfilled through a 'screen and vaccinate' approach. This will allow health authorities to make the best use of their resources by targeting the population which will benefit most from vaccination.
- Sanofi Pasteur has collaborated with CTK Biotech to develop and register a new rapid diagnostic test (RDT) that accurately identifies individuals who have experienced a past dengue infection. Our goal is to ensure higher sensitivity than currently available tests (thereby improving the ability to detect those with a past infection), while maintaining high specificity (to avoid vaccinating truly seronegative people). This collaboration led to the first licensure of the new CTK OnSite Dengue IgG RDT in Thailand on September 1, 2020; CE marking was granted in September 2020. Regulatory submissions are currently ongoing in other countries, and a pilot program will be put in place to test the ‘screen and vaccinate’ approach.

B.5. Global research & development

Since 2018, Sanofi has been engaged in a strong reshaping of its R&D strategy, strengthening the development of innovative products that aim to substantially elevate the standard of care for patients, and prioritizing therapeutic areas where patient need is most urgent: oncology, immunology, rare diseases and multiple sclerosis/neurology. The objective is to develop transformative medicines with the potential to change patients' lives. However, discovering and developing a new product is a costly, lengthy and uncertain process and our continuous investments in research and development for future products and for the launches of newly registered molecules could result in increased costs without a proportionate increase in revenues. See “Item 3.D risk Factors” for further information.

In development, sustained efforts are being made to accelerate the pace of delivery for patients, adopting a quick win, fast-fail approach that is underpinned by streamlined governance and pushing decision-making downward with strong team empowerment.

Our aspiration is to build a pipeline of first-in-class or truly differentiated best-in-class medicines, with two-thirds of biologic compounds and two-thirds of the pipeline directly derived from Sanofi internal research.

In December 2019, as part of our strategic framework we announced our intent to prioritize six potentially transformative therapies in areas of high unmet patient need: fitusiran and efanesoctocog alfa (hemophilia); amcenestrant (breast cancer); venglustat (rare diseases); nirsevimab (respiratory syncytial virus); and tolebrutinib(multiple sclerosis).

In 2020, Sanofi acquired a clinical-stage biotechnology company specialized in oncology and auto-immune diseases, as well as a late-stage biopharmaceutical company focused on developing treatments for immune-mediated diseases.

B.5.1. Pharmaceuticals

B.5.1.1. Products in Development

For 2020, the main pipeline events related to the pharmaceuticals portfolio were:

Project	Potential Indication	Change	Reason
SAR444727 – BTK inhibitor (PRN473)	Immune-mediated diseases	Added	Acquired from Principia
SAR444671 – BTK Inhibitor - rilzabrutinib	Pemphigus Vulgaris	Added	Acquired from Principia
SAR444245 – Not-alpha IL-2	Solid tumors	Added	Acquired from Synthorx
SAR442257 – Tri specific mAb	Multiple Myeloma	Added	Entered confirmatory development
SAR443820 – RIPK1 Inhibitor	Amyotrophic Lateral Sclerosis	Added	Entered confirmatory development
SAR442501 - Anti-FGFR3 mAb	Achondroplasia	Added	Entered confirmatory development
SAR341402 – Insulin aspart	Type 1 &2 Diabetes – Solution		Commercialized
SAR650984 – Sarclisa®	Relapsed or Refractory Multiple Myeloma		Commercialized
SAR439977 – efpeglenatide	Type 2 Diabetes	Removed	Development discontinued
SAR439483 – GUCY2D Modulation	Leber's Congenital Amaurosis	Removed	Development discontinued
SAR443060 – RIPK1 inhibitor	Amyotrophic Lateral Sclerosis	Removed	Development discontinued
SAR156597 – romilkimab	Systemic Scleroderma	Removed	Development discontinued

The clinical portfolio of new products as of December 31, 2020 is summarized in the table below; where several indications are being developed for one product, each indication is regarded as a separate project and specified individually.

For more information on Dupixent®, Kevzara®, Aubagio®, Cerdelga®, and Libtayo®, see also "– Item 4. Information on the Company — B. Business Overview — B.2. Main Pharmaceutical Products".

	Phase I	Phase II	Phase III/registration
Oncology	**SAR439459** mono & with cemiplimab (advanced solid tumors) **SAR442720** + pembrolizumab (solid tumors) **SAR440234** (leukemia) **SAR442085** (multiple myeloma) **SAR444245** mono & combo (solid tumors) **SAR442720** mono & with cobimetinib (relapsed refractory solid tumors) **SAR44720** + osimertinib (solid tumors) **SAR441000** mono & with PD1 (solid tumors) **SAR442257** (multiple myeloma/non Hodgkins lymphoma) ***REGN5458** (relapsed refractory multiple Myeloma) ***REGN4018** mono & with cemiplimab (ovarian cancer) ***REGN5459** (relapsed refractory Multiple Myeloma)	**amcenestrant** (metastatic breast cancer 2nd/3rd line) **amcenestrant** (breast cancer adjuvant) **Sarclisa®** (Acute Myelogenous Leukemia/ Acute Lymphoblastic Leukemia 1st/2nd line pediatric) **Sarclisa®** +atezolizumab (solid tumors) **SAR408701**+ ramucirumab (Non-Small Cell Lung Cancer 2nd/3rd Line) **Sarclisa®** (patients awaiting kidney transplantation)	**Sarclisa®**(1st-3rd Line Relapsed Refractory Multiple Myeloma – IKEMA) **Sarclisa®** (1st Line Newly Diagnosed Multiple Myeloma Ti - IMROZ) **Sarclisa®** (1st Line Newly Diagnosed Multiple Myeloma Te - GMMG) **SAR408701** (2nd-3rd line Non-Small Cell Lung Cancer) **Sarclisa®** (Smoldering Multiple Myeloma) **amcenestrant + palbociclib** (metastatic breast cancer)
Rare Blood Disorders	**BIVV003** (Sickle Cell disease) **ST400** (ß thalassemia) **BIVV020** **sutimlimab** (Immune Thrombocytopenia)		**fitusiran** (Hemophilia A&B) **fitusiran** (Hemophilia A&B pediatric) **sutimlimab** (Cold Agglutinin Disease) **BIVV001** (Hemophilia A)
Immunology & Inflammation	**SAR443122** (inflammatory diseases) **SAR441236** (HIV) **SAR444727** (Immune mediated diseases)	**rilzabrutinib** (IgG4 related disease)	**rilzabrutinib** (Pemphigus) **itepekimab** (Chronic Obstructive Pulmonary Disease) **rilzabrutinib** (Immune Thrombocytopenia Purpura)
Multiple Sclerosis Neurology	**SAR441344** (Multiple Sclerosis) **SAR443820** RIPK1 inh (central DNL788) (Amyotrophic Lateral Sclerosis)	** **venglustat** (GBA-related Parkinson's Disease)	**tolebrutinib** (Primary Progressive Multiple Sclerosis) **tolebrutinib** (Non Relapsing Secondary Progressive Multiple Sclerosis) **tolebrutinib** (Multiple Sclerosis)
Rare Diseases	**SAR442501** (Achondroplasia)	**venglustat** (Gaucher type 3) **venglustat** (Fabry) **SAR339375** (Alport syndrome) **olipudase alfa** (Niemann Pick)	**Avalglucosidase alfa** (Pompe) **venglustat** (Autosomal Dominant Polycystic Kidney Disease) **venglustat** (GM2 gangliosidosis)

* *Opt-in from Regeneron.*
** *The development of venglustat in this indication was halted in January 2021. See item 8.B - Significant changes.*

Phase I studies are the first studies performed in humans, who are mainly healthy volunteers, except for studies in oncology, where Phase I studies are performed in patients. Their main objective is to assess the tolerability, the pharmacokinetic profile (the way the product is distributed and metabolized in the body and the manner by which it is eliminated) and where possible the pharmacodynamic profiles of the new drug (i.e. how the product may react on some receptors).

Phase II studies are early controlled studies in a limited number of patients under closely monitored conditions to show efficacy and short-term safety, and to determine the dose and regimen for Phase III studies.

Phase III studies have the primary objective of demonstrating or confirming the therapeutic benefit and the safety of the new drug in the intended indication and population. They are designed to provide an adequate basis for registration.

a) Oncology

Products in development

Isatuximab (Sarclisa®) is a monoclonal antibody which selectively binds to CD38, a cell surface antigen expressed in multiple myeloma cancer cells, and other hematological malignancies. Isatuximab kills tumor cells via multiple biological mechanisms including:

- antibody-dependent cellular-mediated cytotoxicity (ADCC);
- complement-dependent cytotoxicity (CDC);
- antibody-dependent cellular phagocytosis (ADCP); and
- direct induction of apoptosis (pro-apoptosis) without cross-linking.

Isatuximab also inhibits CD38 ectoenzymatic activity and the expansion of immune-suppressive regulatory T cells and myeloid derived suppressor cells.

Based on the results of the Phase III ICARIA trial, it was approved in the United States in March 2020, and by the European Commission in June 2020, in combination with pomalidomide and dexamethasone for the treatment of adults with relapsed refractory multiple myeloma (RRMM) who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.

A type II variation, supporting a new indication for Sarclisa® in combination with carfilzomib and dexamethasone (Kd) in patients with multiple myeloma (MM) who have received at least one previous treatment, is currently in the registration phase. This submission is based on the phase III IKEMA trial.

In addition, multiple studies in multiple myeloma are under way, and include:

- three pivotal Phase III trials:
  - the Phase III IMROZ trial is a randomized, open-label, multicenter study assessing the clinical benefit of isatuximab in combination with bortezomib (Velcade®), lenalidomide (Revlimid®) and dexamethasone versus bortezomib, lenalidomide and dexamethasone in patients with newly diagnosed multiple myeloma not eligible for transplant,
  - the Phase III GMMG HD7 trial is a randomized, open-label, multicenter study assessing the clinical benefit of isatuximab in combination with lenalidomide, bortezomib, and dexamethasone (RVd) for induction and with lenalidomide for maintenance in patients with newly diagnosed multiple myeloma. This study is conducted in collaboration with the German-speaking Myeloma Multicenter Group (GMMG),
  - the Phase III ITHACA trial is a randomized, open-label, multicenter study assessing isatuximab in combination with lenalidomide and dexamethasone versus lenalidomide and dexamethasone in patients with high-risk smoldering multiple myeloma;
- several early phase studies:
  - a Phase Ib study evaluating the pharmacokinetics, safety and efficacy of isatuximab (SC and IV) in combination with pomalidomide and dexamethasone in patients with RRMM,
  - a Phase II study assessing the antitumor activity, safety, and pharmacokinetics of isatuximab in combination with chemotherapy in pediatric patients with relapsed/refractory B or T acute lymphoblastic leukemia or acute myeloid leukemia in first or second relapse,
  - a Phase Ib/II study to evaluate the safety, pharmacokinetics, and preliminary efficacy of isatuximab in patients awaiting kidney transplantation,
  - a Phase II study in combination with atezolizumab in the treatment of solid tumors.

SAR439859 (amcenestrant), a selective estrogen receptor degrader (SERD), is being assessed in a pivotal Phase II study in second and third line metastatic breast cancer as monotherapy versus physician's choice of single-agent endocrine therapy. A Phase II 14-day window of opportunity study (AMEERA-4) is ongoing in the prior to surgery/neoadjuvant-like setting to inform further development in the adjuvant setting. Amcenestrant is also ongoing in a Phase III efficacy study in combination with Palbociclib (AMEERA-5).

SAR408701 (tusamitamab ravtansine) is an antibody drug conjugate (ADC) that binds to CEACAM-5, a membrane glycoprotein originally identified as a surface marker on adenocarcinomas of the human gastrointestinal tract. The compound is in Phase III (CARMEN-LC03) in the treatment of metastatic non-squamous non-small cell lung cancer (NSQ NSCLC) with CEACAM-5 positive tumors. In addition, two Phase II studies are ongoing to evaluate the activity of the drug in combination with ramucirumab (CARMEN-LC04) or with pembrolizumab (CARMEN-LC05) in patients with metastatic NSQ NSCLC.

SAR439459 is a monoclonal antibody which inhibits the activity of transforming growth factor beta (TGFß). TGFß regulates several biological processes (including wound healing, embryonic development, and malignant transformation) by controlling many key cellular functions including proliferation, differentiation, survival, migration, and epithelial mesenchyme transition. The antibody anti-TGFß is expected to alleviate the tumor microenvironment and allow checkpoint modulators, such as anti-programmed cell death 1 (PD-1), to better induce immune responses and thus increase the proportion of patients benefiting from anti-PD-1 treatment. The compound is in Phase I in the treatment of advanced solid tumors in monotherapy and in combination with cemiplimab.

SAR440234 is a novel bispecific T-cell engager (TCE) that has been engineered incorporating the proprietary Cross-Over-Dual-Variable-Domain (CODV) format, a fully humanized Fc-silenced IgG1 backbone, and variable domains from two antibodies, targeting CD3 (T-cell co-receptor) and CD123 respectively, with the goal of developing a therapeutic molecule active against leukemic stem cells and blasts. A First in Human study testing dose-escalation of SAR440234 in patients with acute myeloid leukemia, acute lymphoid leukemia and myelodysplastic syndrome is ongoing.

SAR441000 is an immunostimulatory mRNA mixture designed to stimulate both innate and adaptive arms of the immune system to maximize anti-tumor activity. It is developed in collaboration with BioNTech. A First In Human study in patients with advanced melanoma, assessing the safety, PK/PD and anti-tumor activity of SAR441000 as monotherapy and in combination with a PD1 inhibitor, is ongoing.

SAR442720 is an inhibitor of SHP2 designed to reduce cell growth signaling that is overactive in patients with non-small cell lung cancer and other types of cancers having specific types of genetic mutations. This compound is developed jointly by Sanofi and Revolution Medicines. The First in Human study in advanced non-small cell lung cancer with mutations (KRAS or in NF1) is ongoing. A Phase I/II study is ongoing to assess the activity of the compound in combination with cobimetinib in solid tumors with specific genomic aberrations and in combination with osimertinib in EGFR-positive locally advanced/metastatic NSCLC.

SAR442085 is an Fc-engineered anti-CD38 mAb mutated on the Fc fragment of IgG1 to enhance its affinity for the activated Fcg receptor (in particular FcgRIIIa) and to improve antibody-dependent cell-mediation cytotoxicity (ADCC) and clinical activity, while keeping a manageable toxicity profile. A Phase I study in the treatment of multiple myeloma is ongoing.

SAR444245 (THOR707) is a non-alpha IL-2 candidate currently being evaluated in Phase I trials for the treatment of solid tumors.

SAR442257, an Anti-CD3/CD28/CD38 Trispecific mAb, is currently in Phase I in the treatment of multiple myeloma/non-Hodgkin lymphoma.

b) Immunology & Inflammation

SAR440340 (itepekimab), a human anti-IL33 monoclonal antibody derived from our alliance with Regeneron, is in Phase III for the treatment of chronic obstructive pulmonary disease in former smokers.

SAR443122 (topical DNL758), a small molecule against the receptor-interacting serine/threonine-protein kinase 1 (RIPK1), developed in collaboration with Denali, completed its Phase I in 2020.

SAR441236, a tri-specific neutralizing anti-HIV antibody, is in Phase I for the treatment of HIV.

SAR 444727 (PRN473 topical), an inhibitor of Bruton's tyrosine kinase that joined the Sanofi portfolio following the acquisition of Principia, is currently in Phase I for the treatment of immune mediated diseases.

SAR444671 (rilzabrutinib), an inhibitor of Bruton's tyrosine kinase that joined the Sanofi portfolio following the acquisition of Principia, is currently in Phase III for the treatment of Pemphigus Vulgaris and immune thrombocytopenia (ITP), and in Phase II for the treatment of IgG4-related diseases. In November 2020, rilzabrutinib was granted FDA Fast Track Designation for the treatment of ITP.

c) Multiple Sclerosis and Neurology

SAR442168 (tolebrutinib) is an orally administered Bruton's tyrosine kinase (BTK) inhibitor which was designed to access the brain and spinal cord by crossing the blood-brain barrier and impacting immune cell and brain cell signaling. Positive results of the Phase IIb Proof of Concept/dose-ranging study in relapsing multiple sclerosis patients were published early February 2020. Three Phase III studies in relapsing multiple sclerosis, primary progressive multiple sclerosis and non relapsing secondary progressive multiple sclerosis were initiated in 2020.

SAR443820 (DNL788), a RIPK1 inhibitor developed in collaboration with Denali, entered Phase I in 2020.

Venglustat (GZ402671), an orally administered brain penetrant glucosylceramide synthase (GCS) inhibitor, is currently in Phase IIa for the treatment of Parkinson's disease with an associated GBA mutation (the development of venglustat in this indication was halted in January 2021. See item 8.B. — Significant changes). The product is also being developed in other rare diseases indications (Gaucher disease type 3, Fabry disease, and autosomal dominant polycystic kidney disease: see Rare Diseases section).

SAR441344, an anti-CD40L mAb developed in collaboration with Immunext, is in Phase I for the treatment of multiple sclerosis.

d) Rare Diseases

Avalglucosidase alfa (GZ402666 Neo GAA) is a second generation enzyme replacement therapy targeting the treatment of Pompe disease. The Phase III program was launched in November 2016, with the COMET study targeting treatment naive late onset Pompe disease patients. The Phase IIb/III mini-COMET study started in 2017, targeting treatment experienced infantile onset Pompe disease patients. In October 2020, the EMA accepted the submission of avalglucosidase alfa; and in November 2020 the FDA granted it priority review status.

GZ402665 (rhASM) olipudase alfa is an enzyme replacement therapy targeting the treatment of non-neurological manifestations of acid sphingomyelinase deficiency (ASMD), also known as Niemann-Pick B disease. Both the open label pivotal Phase I/II trial in the pediatric population and the Phase II/III trial in the adult population have successfully completed enrollment for the target number of patients. Positive results were published at the end of January 2020.

Venglustat (GZ402671 – GCS inhibitor) is in development in Autosomal Dominant Polycystic Kidney Disease (ADPKD), late-onset GM2 gangliosidosis, Fabry disease, and Gaucher disease type 3. The extension study of the Phase II trial for the treatment of Fabry disease to understand the long term effects of venglustat therapy in Fabry patients has been completed. A Phase II study in Gaucher disease type 3 (LEAP) is ongoing; the first enrolled patient is about to reach two-year treatment, and preliminary results have shown pharmacokinetic evidence that venglustat crosses the blood–CSF barrier. A Phase III pivotal study (STAGED-PKD) in rapidly progressive autosomal ADPKD patients started in 2019. A Phase III study in late-onset GM2 gangliosidosis (Tay-Sachs disease and Sandhoff disease) was initiated in 2020.

SAR339375 is an anti-miR21 RNA in Phase II for the treatment of Alport syndrome.

SAR442501, an anti FGFR3 mAb entered Phase I in 2020.

e) Rare Blood Disorders

Sutimlimab (formerly BIVV009/TNT009) is a monoclonal antibody targeting C1. It is a product candidate intended to selectively inhibit the classical complement pathway of the immune system. The Phase III program includes two parallel trials evaluating the efficacy and safety of sutimlimab in adult patients with primary cold agglutinin disease (CAD). Sutimlimab was awarded Breakthrough Therapy Designation by the US Food and Drug Administration in 2018. In November 2020, Sanofi received a Complete Response Letter (CRL) regarding the Biologics License Application (BLA) for sutimlimab, an investigational monoclonal antibody for the treatment of hemolysis in adults with CAD. The CRL refers to certain deficiencies identified by the agency during a pre-license inspection of a third-party facility responsible for manufacturing. There were no clinical or safety deficiencies noted in the CRL with respect to the application. Satisfactory resolution of the observations by the third-party manufacturer is required before the BLA can be approved and Sanofi remains in close contact with the FDA and the third-party manufacturer to reach a resolution in a timely manner.

Fitusiran (SAR439774 ALN-AT3) is a program in collaboration with Alnylam for the development of a siRNA therapeutic agent to treat hemophilia A and B (adults & adolescents as well as pediatric programs). It uses a novel approach targeting antithrombin (AT), with AT knockdown leading to increase in thrombin generation. The Phase III program (ATLAS) started in 2018. Sanofi voluntarily paused dosing in all ongoing fitusiran clinical studies on October 30, 2020 to assess reports of non-fatal thrombotic events in patients participating in the Phase III program. Dosing resumed again in January 2021 following protocol amendments with an adjusted dose and dosing regimen aimed at further strengthening the benefit-risk profile. To allow for the appropriate collection and assessment of safety and efficacy data under the amended protocols, Sanofi expects that global regulatory submission timelines for the adult and adolescent studies will be delayed by up to approximately 18 months, to 2022, subject to alignment with health authorities.

BIVV001 (efanesoctocog alfa), developed in collaboration with Sobi, is an investigational von Willebrand factor (VWF)-independent factor VIII therapy for people with hemophilia A, designed to potentially extend protection from bleeds with prophylactic dosing of once weekly or longer. The product entered Phase III in 2019. Efanesoctogog alfa has received a Fast Track designation from the FDA.

Sanofi and Sangamo Therapeutics are working in collaboration to research, develop and commercialize treatments for sickle cell disease and beta thalassemia **(BIVV003, ST-400)**, two inherited blood disorders that result from the abnormal structure or underproduction of hemoglobin. The collaboration combines the extensive expertise of Sangamo in developing their genome editing technology with Sanofi's deep understanding of hematology, and is focused on the goal of providing a single, lasting treatment for both sickle cell disease and beta thalassemia. Currently, Sanofi is responsible for execution of the sickle cell disease Phase I/II program (BIVV003), while Sangamo is responsible for the beta thalassemia Phase I/II program (ST-400). Both programs are in Phase I.

BIVV020, a humanized IgG4 mAb that binds to and inhibits the classical pathway (CP) specific serine protease (C1s), thereby inhibiting CP activity. Activation of the CP of complement is associated with a variety of immune disorders involving the presence of autoantibodies. Inhibition of autoantibody mediated CP activation on the surface of erythrocytes via C1s binding prevents complement opsonin deposition on red blood cells and protects them from phagocytosis and extravascular hemolysis in autoimmune hemolytic anemia such as cold agglutinin disease (CAD). Inhibition of CP activation via C1s prevents both immune mediated platelet destruction and inhibition of platelet production caused by anti-platelet autoantibodies (ITP). The product entered Phase I in 2019.

f) Line extensions

Libtayo® – cemiplimab (SAR439684)

Two programs have been submitted to the regulatory authorities: one in the treatment of basal cell carcinoma, and the other in the first-line treatment of patients with advanced or metastatic non-small cell lung cancer (NSCLC) whose tumors express PD-L1, as monotherapy and in combination with Platinum-based Doublet Chemotherapy.

Additional Phase III studies are also running in different indications:

- chemotherapy combination in first line non-small cell lung cancer;
- adjuvant in cutaneous squamous cell carcinoma; and
- second line cervical cancer.

Dupixent® – dupilumab (SAR231893), an interleukin-4 receptor alpha antagonist, is a human monoclonal antibody of the IgG4 subclass that binds to the IL-4Ra subunit and inhibits IL-4 and IL-13 signalling. Dupilumab is being jointly developed with Regeneron in several indications:

- **atopic dermatitis**: the product was approved for its first pediatric population (aged 6 to 11 years) in the US in May 2020 and in Europe in November 2020, and was also approved in China for adults in June 2020;
- **asthma**: a Phase III study in children aged 6 to 11 years is ongoing. FDA Filing acceptance is likely to be on March 2, 2021;
- **nasal polyposis**: this indication was approved by the Japanese PMDA in March 2020;
- **eosinophilic esophagitis**: a Phase III study is ongoing;
- **adjunct to immunotherapy**: proof-of-concept studies to evaluate dupilumab as an adjunct to immunotherapy (peanut and grass allergies) are ongoing;
- **chronic obstructive pulmonary disease**: a Phase III study is ongoing, and
- **six new Phase III studies in the following indications were initiated in 2020:**
  - chronic spontaneous urticaria,
  - prurigo nodularis,
  - chronic rhinosinusitis without nasal polyps,
  - bullous pemphigoid,
  - chronic inducible urticaria – cold, and
  - allergic fungal rhinosinusitis.

Kevzara® (sarilumab) is a monoclonal antibody against the Interleukin-6 Receptor derived from our alliance with Regeneron, and is already marketed in the treatment of moderate to severe rheumatoid arthritis. The product is in Phase IIb in pediatric populations for two indications: polyarticular juvenile idiopathic arthritis, and systemic juvenile idiopathic arthritis.

Aubagio® (teriflunomide) is currently marketed for the treatment of relapsing forms of multiple sclerosis and relapsing remitting multiple sclerosis. The dossier in the pediatric population (aged 10 to 17 years) was submitted in the EU in April 2020 and in the US in November 2020.

Cerdelga® (eliglustat) is currently in Phase III for the treatment of Gaucher disease type I in pediatric patients.

B.5.2. Vaccines

The Vaccines R&D portfolio includes 10 projects in advanced development (including one antibody), as shown in the table below. The portfolio includes five projects for novel targets and five enhancements of existing vaccines.

In 2020, we obtained regulatory approval in Europe for Efluelda®, a higher dose vaccine to prevent influenza in individuals aged 65 years and older. In April, we obtained regulatory approval in the US for MenQuadfi™, a vaccine to help prevent meningococcal meningitis caused by serogroups A, C, Y and W in people aged 2 and older. In November, MenQuadfi™ was licensed in the European Union for the prevention of invasive meningococcal disease in people aged 12 months and older. In the same month, Flublok®/Supemtek®, a recombinant hemagglutinin (rHA), was registered in the EU for the prevention of influenza infections in people aged 18 years and older. In June, Shan6™, a pediatric hexavalent DTwP-HepB-Polio-Hib(b) vaccine, was submitted in India for the prevention of diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B and invasive infections caused by Hemophilus type b in infants aged 6 weeks and older. In June, our local partner in Japan decided to terminate development of a pediatric pentavalent DTaP-Polio-Hib vaccine that was in Phase III. In May, our pneumococcal conjugate vaccine (PCV) candidate to prevent pneumococcal disease entered Phase II in toddlers. In September, our vaccine candidate to prevent respiratory syncytial virus (RSV) infections in infants aged 4 months and older entered Phase I/II. Also in September, Phase I/II started for our recombinant adjuvanted COVID-19 vaccine, a new entrant to our portfolio that we are developing in partnership with GlaxoSmithKline (GSK).

For strategic reasons, Sanofi Pasteur has decided to terminate the development of SP0173 Tdap booster vaccine for prevention of Tetanus, Diphtheria and Pertussis infections, which was in Phase II and intended for people aged 10 years and older.

Phase I	Phase II	Phase III	Registration
Herpes Simplex Virus (HSV) vaccine HSV-2 therapeutic vaccine	Fluzone® QIV HD Quadrivalent inactivated influenza vaccine – High dose for pediatric use	Nirsevimab, mAb[(a)] Passive prevention of respiratory syncytial virus infections in all infants	Shan6 DTwP-HepB-Polio-Hib[(b)] Pediatric hexavalent vaccine
Vero Yellow Fever vaccine	Pneumo Conjugate Vaccine (PCV)[(a)] Prevention of pneumococcal disease	MenQuadfi™ Advanced generation meningococcal ACYW conjugate vaccine US / EU infants aged 6 weeks & older	
	Respiratory Syncytial Virus (RSV) vaccine (PhI/II) Prevention of RSV infections in infants aged 4 months & older	VerorabVax® (VRVg) Purified vero rabies vaccine	
	COVID-19 recombinant adjuvanted[(a)] vaccine (Phase I/II) Prevention of novel Coronavirus		

(a) Partnered and/or in collaboration: Sanofi may have limited or shared rights to some of these products.
(b) D = Diphtheria, T = Tetanus, wP = whole cell Pertussis, Hib = Hemophilus influenzae type b, HepB = Hepatitis B.

Enhancements of existing vaccines

Fluzone® QIV HD is a higher dose quadrivalent influenza vaccine for the elderly (aged 65 years and older), who do not respond as well to standard-dose influenza vaccines due to aging of the immune system (immuno-senescence). A Phase III study has demonstrated non-inferior immunogenicity and comparable safety to the licensed trivalent Fluzone® High-Dose vaccine, which has shown greater protection versus standard dose. In November 2019, the product was approved by the FDA for use in people aged 65 and older, and it has been made available in the US for the 2020-2021 influenza season. In April 2020, Sanofi Pasteur obtained regulatory approval in Europe. Phase II trials are ongoing to evaluate safety in the pediatric population.

Shan6™ is a cost-effective, all-in-one liquid hexavalent combination vaccine being developed for low and middle income countries (WHO pre-qualification). It comprises detoxified whole-cell pertussis as well as diphtheria toxoid, tetanus toxoid, Hemophilus influenza type b PRP-T, inactivated poliovirus types 1, 2, and 3 and hepatitis B virus components.

MenQuadfi™: Sanofi Pasteur's Men ACYW-TT vaccine is our latest advance in meningococcal quadrivalent conjugate vaccination, designed to help protect an expanded patient group including infants and adolescents through older adults. Phase II and initial Phase III trials have been performed in the US and the EU. Additional Phase III trials are ongoing in the EU, Asia and Latin America. The safety and immunogenicity profiles of the vaccine candidate are encouraging. In April 2020, we obtained regulatory approval in the US for MenQuadfi™, to help prevent meningococcal meningitis in people aged 2 years and older. In November 2020, MenQuadfi™ was licensed in the European Union for the prevention of invasive meningococcal disease in people aged 12 months and older. Phase III trials are ongoing to evaluate immunogenicity and safety in infants aged 6 weeks and older.

VerorabVax® (VRVg) is a next-generation purified human rabies vaccine under development, aimed at replacing both of Sanofi Pasteur's currently commercialized rabies vaccines (Imovax® Rabies and Verorab®). It will be cultured on Vero cells and will be free of animal or human material.

New vaccine targets

Nirsevimab is a monoclonal antibody engineered to have a long half-life, so that only one dose would be needed for the entire respiratory syncytial virus (RSV) season to provide passive immunity and prevent RSV infection in all infants for their first RSV season (and in high-risk infants, for their first and second RSV seasons). Sanofi Pasteur has an agreement with AstraZeneca to develop and commercialize nirsevimab. Positive primary analysis of the Phase IIb trial, published in the New England Journal of Medicine in July 2020, demonstrated the safety and efficacy of nirsevimab. The Phase III program started in 2019, and submission is expected in 2023. Nirsevimab received fast-track designation from the FDA in 2015, and FDA Breakthrough Therapy designation in February 2019. The EMA granted PRIME eligibility to nirsevimab in February 2019. Nirsevimab has been selected by the Japan Agency for Medical Research and Development as a priority medicine, and received breakthrough therapy designation in China in January 2021.

RSV infant vaccine: Sanofi Pasteur has a Cooperative Research and Development Agreement (CRADA) with the US National Institute of Health (NIH) to develop a live attenuated RSV vaccine for immunization of infants aged 4 months and older. We initiated the Phase I/II study in the US on September 10, 2020. This trial is evaluating the safety and effectiveness of two doses of an intranasal delivery device in infants, the goal being to extend the immunity offered by nirsevimab to additional RSV seasons.

Pneumo Conjugate Vaccine (PCV): Sanofi Pasteur is collaborating with SK Chemicals (South Korea) to develop a pneumococcal conjugate vaccine with broader coverage. This vaccine entered Phase II in May 2020 in toddlers.

Herpes Simplex Virus (HSV) type 2 is a member of the herpes virus family and as such establishes life-long infections – mainly genital herpes – with latent virus established in neural ganglia. Although antivirals currently exist to treat these infections, no vaccine exists. Our vaccine candidate is a live attenuated virus and is being assessed as a therapeutic vaccine to reduce recurrence and transmission. It is currently in Phase I. In 2014, Sanofi Pasteur signed a contract with Immune Design Corp. (acquired by Merck in 2019) to collaborate on the development of this therapeutic herpes simplex virus vaccine candidate by exploring the potential of various combinations of agents.

The Vero Yellow Fever (vYF) vaccine candidate is a next generation freeze-dried live attenuated yellow fever vaccine produced on a Vero cell line, for subcutaneous and intra-muscular administration in people aged 9 months and older. This vaccine aims to replace Stamaril® and YF-VAX® with a single product, securing a sustainable and consistent supply worldwide. In January 2020, the first Phase I/II trial was initiated in the US.

Recombinant adjuvanted COVID-19 vaccine candidate: this vaccine candidate is produced in the baculovirus expression system in SF9 cells, and is intended for use in active immunization for the prevention of COVID-19 (SARS-CoV-2) in a pandemic setting. This candidate is being developed in partnership with GlaxoSmithKline (GSK), as it uses GSK's adjuvant. The Coronavirus (COVID-19) vaccine program entered the Sanofi Pasteur portfolio in March 2020, and entered Phase I/II in September 2020. Interim Phase I/II results showed an immune response comparable to patients who had recovered from COVID-19 in adults aged 18 to 49 years. However, an insufficient response in older adults demonstrated the need to refine the concentration of antigen in order to provide a high-level immune response across all age groups. Therefore, we initiated a new Phase II study with an improved antigen formulation in February 2021, with support from the US Biomedical Advanced Research and Development Authority (BARDA). A Phase III trial will follow, to start in the second quarter of 2021. The vaccine is now expected to be available in the fourth quarter of 2021, subject to successful completion of the development plan.

COVID-19 mRNA vaccine candidate: this vaccine candidate is being developed in collaboration with Translate Bio. Our agreement with Translate Bio was expanded in June 2020 and gives Sanofi exclusive worldwide rights to develop, manufacture and commercialize vaccines to address current and future infectious diseases using Translate Bio's technology. We expect to enter Phase I/II clinical studies with our mRNA COVID-19 vaccine in the first quarter of 2021.

B.5.3. R&D expenditures for late stage development

Expenditures on research and development amounted to €5,529 million in 2020, comprising €4,331 million in the Pharmaceuticals segment; €136 million in the Consumer Healthcare segment; €692 million in the Vaccines segment; and €370 million allocated to "Other", representing the R&D support function. Research and development expenditures represented approximately 15.3% of our net sales in 2020, compared with approximately 16.7% in 2019.

The decrease in R&D expenditures in 2020 was mainly due to cost control, and to a reduction in R&D expenses in Diabetes and cardiovascular diseases. However, R&D expenditures in the Vaccines segment rose by 8.3% in 2020. Preclinical research expenditures in the Pharmaceuticals segment amounted to €775 million in 2020, compared with €825 million in 2019. Of the remaining €3,556 million relating to clinical development in the Pharmaceuticals segment in 2020, the largest portion covers Phase III or post-marketing studies, reflecting the cost of monitoring large scale clinical trials.

B.6. Markets

A breakdown of revenues by business segment and by geographical region for 2020, 2019, and 2018 can be found at Note D.35. to our consolidated financial statements, included at Item 18. of this annual report.

The following market shares and ranking information are based on consolidated national pharmaceutical sales data (excluding vaccines), in constant euros, on a September 2020 MAT (Moving Annual Total) basis. The data are mainly from IQVIA local sales audit supplemented by various other country-specific sources including Knobloch (Mexico), GERS (France) and HMR (Portugal).

B.6.1. Marketing and distribution

We have business operations in approximately 90 countries and our products are available in more than 170 countries. A breakdown of our aggregate net sales by geographical region is presented in "Item 5. Operating and Financial Review and Prospects — Results of Operations — Year Ended December 31, 2020 Compared with Year Ended December 31, 2019." Sanofi is the ninth largest pharmaceutical company globally by sales. Our main markets in terms of net sales are respectively:

- United States: we rank tenth with a market share of 4%;
- Europe: we are the second largest pharmaceutical company in France where our market share is 6.1%, and we rank seventh in Germany with a 3.8% market share; and
- Other countries: we are ranked seventeenth in Japan with a market share of 1.8%, and eleventh in China.

Although specific distribution patterns vary by country, we sell prescription drugs primarily to wholesale drug distributors, independent and chain retail drug outlets, hospitals, clinics, managed-care organizations and government institutions. Rare diseases products are also sold directly to physicians. With the exception of Consumer Healthcare products, our drugs are ordinarily dispensed to patients by pharmacies upon presentation of a doctor's prescription. Our Consumer Healthcare products are also sold and distributed through e-commerce, which is a growing trend in consumer behavior. Our vaccines are sold and distributed through multiple channels including physicians,

pharmacies, hospitals, private companies and distributors in the private sector, and governmental entities and non-governmental organizations in the public and international donor markets.

We use a range of channels from in-person to digital to disseminate information about and promote our products among healthcare professionals, ensuring that the channels not only cover our latest therapeutic advances but also our established prescription products, which satisfy patient needs in some therapy areas. We regularly exhibit at major medical congresses. In some countries, products are also marketed directly to patients by way of television, radio, newspapers and magazines, and digital channels (such as the internet). National education and prevention campaigns can be used to improve patients' knowledge of their conditions.

Our sales representatives, who work closely with healthcare professionals, use their expertise to promote and provide information on our drugs. They represent our values on a day-to-day basis and are required to adhere to a code of ethics and to internal policies in which they receive training.

Although we market most of our products through our own sales forces, we have entered into and continue to form partnerships to co-promote/co-market certain products in specific geographical areas. Our major alliances are detailed at "Item 5. Operating and Financial Review and Prospects — Financial Presentation of Alliances." See also "Item 3. Key Information — D. Risk Factors — We rely on third parties for the discovery, manufacture and marketing of some of our products."

B.6.2. Competition

The pharmaceutical industry continues to experience significant changes in its competitive environment.

There are four types of competition in the prescription pharmaceutical market:

- competition between pharmaceutical companies to research and develop new patented products or address unmet medical needs;
- competition between different patented pharmaceutical products marketed for the same therapeutic indication;
- competition between original and generic products or between original biological products and biosimilars, at the end of regulatory exclusivity or patent protection; and
- competition between generic or biosimilar products.

Generics manufacturers who have received all necessary regulatory approvals for a product may decide to launch a generic version before the patent expiry date, even in cases where the owner of the original product has already commenced patent infringement litigation against the generics manufacturer. Such launches are said to be "at risk" for the promoter of the generic product because it may be required to pay damages to the owner of the original product in the context of patent infringement litigation; however, such launches may also significantly impair the profitability of the pharmaceutical company whose product is challenged.

Drug manufacturers also face competition through parallel trading, also known as reimportation. This takes place when drugs sold abroad under the same brand name as in a domestic market are imported into that domestic market by parallel traders, who may repackage or resize the original product or sell it through alternative channels such as mail order or the internet. This situation is of particular relevance to the EU, where such practices have been encouraged by the current regulatory framework. Parallel traders take advantage of the price differentials between markets arising from factors including sales costs, market conditions (such as intermediate trading stages), tax rates, or national regulation of prices.

Finally, pharmaceutical companies face illegal competition from falsified drugs. The WHO estimates that falsified products account for 10% of the market worldwide, rising to 30% in some countries. All therapeutic areas are affected, also including vaccines. However, in markets where powerful regulatory controls are in place, falsified drugs are estimated to represent less than 1% of market value.

The same types of competition apply in Consumer Healthcare, except that in this business there are two types of generic products: private labels and store brands.

In Vaccines, there are two types of competition:

- competition between vaccine companies to research and develop new patented products or address unmet medical needs; and
- competition between different patented (or non-patented) vaccine products marketed for the same therapeutic indication.

Generics and biosimilars are not an issue in vaccines at present, since vaccines are still mostly produced from proprietary viral or bacterial strains. As with pharmaceutical drugs, vaccine manufacturers can face competition through parallel trading. However, the extent of such practices is limited by the need for cold chain distribution of vaccines, and by the fact that vaccines are sold and administered through pharmacies or dispensing physicians.

B.6.3. Regulatory framework

The pharmaceutical and health-related biotechnology sectors are highly regulated. National and supranational health authorities administer a vast array of legal and regulatory requirements that dictate pre-approval testing and quality standards to maximize the safety and efficacy of a new medical product. These authorities also regulate product labeling, manufacturing, importation/exportation and marketing, as well as mandatory post-approval requirements and commitments.

The submission of an application to a regulatory authority does not guarantee that a license to market will be granted or that a product will be approved. Furthermore, each regulatory authority may impose its own requirements during product development or during the application review. It may refuse to grant approval or require additional data before granting approval, even though the same product has already been approved in other countries. Regulatory authorities also have the authority to request product recalls and product withdrawals, and to impose penalties for violations of regulations.

Product review and approval can vary from six months or less to several years from the date of application submission depending upon the country. Factors such as the quality of data, the degree of control exercised by the regulatory authority, the review procedures, the nature of the product and the condition to be treated, play a major role in the length of time a product is under review.

In the EU, there are three main procedures for applying for marketing authorization:

- The centralized procedure is mandatory for drugs derived from biotechnologies; new active substances designed for human use to treat HIV, viral diseases, cancer, neurodegenerative diseases, diabetes and auto-immune diseases; orphan drugs; and innovative products for veterinary use. When an application is submitted to the EMA, the scientific evaluation of the application is carried out by the Committee for Medicinal Products for Human Use (CHMP) and a scientific opinion is prepared. This opinion is sent to the European Commission, which adopts the final decision and grants an EU marketing authorization. Such a marketing authorization is valid throughout the EU, and the drug may be marketed within all EU Member States.
- If a company is seeking a national marketing authorization in more than one Member State, two procedures are available to facilitate the granting of harmonized national authorizations across Member States: the mutual recognition procedure or the decentralized procedure. Both procedures are based on the recognition by national competent authorities of a first assessment performed by the regulatory authority of one Member State.
- National authorizations are still possible, but are only for products intended for commercialization in a single EU Member State or for line extensions to existing national product licenses.

In the EU, vaccines are treated as pharmaceutical products, and therefore have to obtain marketing authorization under the centralized procedures described above.

Generic products are subject to the same marketing authorization procedures. A generic product must contain the same active medicinal substance as a reference product approved in the EU. Generic applications are abridged: generic manufacturers only need to submit quality data and demonstrate that the generic drug is “bioequivalent” to the originator product (i.e. performs in the same manner in the patient’s body), but do not need to submit safety or efficacy data since regulatory authorities can refer to the reference product’s dossier.

Another relevant aspect in the EU regulatory framework is the “sunset clause” under which any marketing authorization ceases to be valid if it is not followed by marketing within three years, or if marketing is interrupted for a period of three consecutive years.

In the US, applications for pharmaceutical approval and biological product licensure are submitted for review to the FDA, which has broad regulatory powers over all pharmaceutical and biological products that are intended for sale and marketing in the US. To commercialize a product in the US, a new drug application (NDA) under the Food, Drug and Cosmetic (FD&C) Act, or a Biological License Application (BLA) under the Public Health Service (PHS) Act, must be submitted to the FDA for filing and pre-market review. Specifically, the FDA must decide whether the product is safe and effective for its proposed use; if the benefits of the drug’s use outweigh its risks; whether the drug’s labeling is adequate; and if the manufacturing of the drug and the controls used for maintaining quality are adequate to preserve the drug’s identity, strength, quality and purity. Based upon this review, the FDA can stipulate post-approval commitments and requirements. Approval for a new indication of a previously approved product requires submission of a supplemental NDA (sNDA) for a drug or a supplemental BLA (sBLA) for a biological product.

Sponsors wishing to market a generic drug can file an Abbreviated NDA (ANDA) under 505(j) of the FD&C Act. These applications are “abbreviated” because they are generally not required to include data to establish safety and effectiveness but need only demonstrate that their product is bioequivalent (i.e. performs in humans in the same manner as the originator’s product) to a reference product. Consequently, the length of time and cost required for development of generics can be considerably less than for the innovator’s drug. The ANDA pathway in the US can only be used for generics of drugs that can be referenced as having been approved under the FD&C Act.

The FD&C Act provides another abbreviated option for NDA approved products, which is a hybrid between an NDA and ANDA called the 505(b)(2) pathway. This 505(b)(2) pathway enables a sponsor to rely on the FDA’s findings that the reference product is safe and effective, based on the innovator’s preclinical and clinical data. Similarly, under the PHS Act, there exists an abbreviated licensure pathway for biological products shown to be biosimilar (highly similar with no clinically meaningful differences) or interchangeable with an FDA-licensed reference BLA product.

In Japan, the entire process of approval review from review-related inspections and clinical trial consultation to review for the drugs approved by the Ministry of Health, Labour and Welfare (MHLW) is undertaken by the Pharmaceuticals and Medical Devices Agency (PMDA). The PMDA conducts first scientific review of the NDA submitted, assessing particularly the safety, efficacy and quality of the product or medical device proposed. Results of this primary evaluation are then submitted to the PMDA’s external experts. After a second evaluation based on the external experts’ feedback, a report is provided; the Pharmaceutical Affairs and Foods Sanitation Council (PAFCS) – one of the councils organized under the J-MHLW as advisory commission – is consulted, and advises the MHLW on final approvability.

For Japanese registrations, clinical data for Japanese patients are necessary. The regulatory authorities can require local clinical studies, though they also accept multi-regional studies including Japan. In some cases, bridging studies have been conducted to verify extrapolability of foreign clinical data to Japanese patients and to obtain data to determine the appropriateness of the dosages for Japanese patients.

The MHLW may require additional post-approval studies (Phase IV) for some specific cases, to further evaluate safety and/or to gather information on the use of the product under specified conditions. In approval of new drugs, new indications, new dosages or new administrations, the re-examination period is determined by the MHLW. Post-marketing information on a drug for the predetermined period after approval is collected to reconfirm its efficacy, safety and quality at the end of the period. This collection process involves both post-marketing surveillance (PMS), which is a non-interventional study, and post-marketing clinical trials.

For generic products, the data necessary for filing are similar to EU and US requirements. Companies only need to submit quality data, and data demonstrating bioequivalence to the originator product, unless the drug is biopharmaceutical. Common Technical Document (CTD) submission for generics has been mandatory since March 2017.

The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) was created in 1990 and reformed in 2015.

The ICH currently includes 17 Members and 32 Observers. Harmonization is achieved through the development of ICH Guidelines via a process of scientific consensus with regulatory and industry experts working side-by-side.

In addition to the joint efforts, Free Trade Agreements (FTAs) have proven to be one of the best ways to open up foreign markets to exporters and to allow for discussions on harmonization topics for regulatory authorities. Some agreements, such as the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), are international in nature, while others are between specific countries. The requirements of many countries (including Japan and several EU Member States) to negotiate selling prices or reimbursement rates for pharmaceutical products with government regulators significantly extend the time to market entry beyond the initial marketing approval. While marketing authorizations for new pharmaceutical products in the EU have been largely centralized within the European Commission in collaboration with the EMA, pricing and reimbursement remain a matter of national competence.

B.6.4. Pricing & Reimbursement

As regards market access, we are operating in an increasingly uncertain and complex environment, with growing pressures on prices and the need to demonstrate that innovation adds value, which is exacerbated by the COVID-19 crisis.

At a time of intense public and political scrutiny of drug pricing, both nationally and at the European and global level, governments and payers are using increasingly restrictive price-control mechanisms. The mechanisms used vary from country to country, and include price referencing for imported drugs, increased patient co-payments, restrictive formularies, prescribing guidelines, tendering procedures, promoting generic and biosimilar substitution, and medico-economic evaluations of healthcare products.

In addition, pharmaceutical companies are expected to demonstrate value on an ongoing basis throughout the product life cycle (such as through comparative efficacy studies, real-world patient data, and budget modelling). This requires vast amounts of data and scientific evidence, raising the bar for bringing new medicines to market, and with significant variations from country to country.

Strong budgetary pressures at international level have stimulated growing payer interest in new drug funding models based on risk-sharing, aimed at promoting and rewarding innovation while ensuring that patients can access medicines and healthcare systems remain viable. Despite implementation challenges, new performance-linked, risk-sharing or outcome-based deals are gaining traction in a growing number of markets.

We expect these trends will continue and intensify in 2021 and beyond, potentially accelerated by COVID-19. How the environment in which we operate evolves will depend on the public health response to the virus and the speed of the post-Covid economic recovery, which will vary from country to country.

UNITED STATES

Overview of the US health insurance system:

Commercial insurance is offered widely as part of employee benefit packages and is the main source of access to subsidized healthcare provision. Some individuals purchase private health plans directly, while publicly subsidized programs provide cover for retirees, the poor, the disabled, uninsured children, and serving or retired military personnel. Double coverage can occur.

Commercial insurance includes:

- Managed Care Organizations (MCOs), combine the functions of health insurance, delivery of care, and administration. MCOs use specific provider networks and specific services and products. There are three types of managed care plans: Health Maintenance Organizations (HMOs), Preferred Provider Organizations (PPOs), and Point of Service (POS) plans.
- Pharmacy Benefit Managers (PBMs), serve as intermediaries between insurance companies, pharmacies and manufacturers to negotiate rebates and discounts on formulary placement for commercial health plans, self-insured employer plans, Medicare Part D plans, and federal and state government employee plans.

Government insurance includes:

- Medicare, which provides health insurance for retirees and for people with permanent disabilities. The basic Medicare scheme (Part A) provides hospital insurance only, and the vast majority of retirees purchase additional cover through some or all of three other plans named Part B, Part C and Part D. Part D enables Medicare beneficiaries to obtain outpatient drug coverage. Almost two-thirds of all Medicare beneficiaries have enrolled in Part D plans.
- Medicaid, which provides health insurance for low-income families, certain qualified pregnant women and children, individuals receiving supplemental security income, and other eligible persons determined on a state-by-state basis.

The US healthcare system is at an inflection point in the wake of the November 2020 presidential election, with uncertainty about the reform agenda for the years ahead.

The COVID-19 pandemic and subsequent mass unemployment have caused unprecedented disruption to the health insurance market, with a shift away from the private sector to the public sector (Medicaid).

In the near term, the priorities of the Biden administration are likely to focus on containing the pandemic, strengthening government health insurance under the Affordable Care Act (ACA), and lowering the cost of prescription medicines.

President Biden has pledged to build on the ACA for expanding coverage to millions of uninsured Americans, primarily by creating a new public insurance option, automatically enrolling low-income individuals in premium-free coverage, and lowering the Medicare age from 65 to 60.

With a Democratic majority in Congress, we may also see new measures at federal level to control prescription drug costs. Previously proposed legislation may continue to be part of the Democratic agenda, at least in some form. If implemented, these new rules could trigger a lasting, transformative change in market access in the United States, with a potential negative impact.

Another federal proposal that is likely to receive significant attention in 2021 is the 'Most Favored Nation' (MFN) interim final rule for Medicare Part B drug pricing (replacing the International Pricing Index). This new mandatory payment model, which aims to align US drug prices on the lowest price applied in a selection of OECD member countries (those whose per capita GDP at adjusted purchasing power parity is 60% or more above that of the United States), will likely apply to the 50 medicines and biological products with the highest level of Medicare B expenditures. However, the new MFN model is highly controversial and is encountering strong industry pushback, mainly due to the significant operational and legal issues it raises.

At state level, price transparency legislation is becoming increasingly widespread, which could affect our operations in an ever more competitive environment. To date, more than half of US states have passed or plan to pass laws to bring greater transparency and prevent price gouging – an issue that has led to an intense debate on insulin costs in recent years.

Consolidation in the commercial health insurance market is likely to continue, exerting greater price pressure. The three biggest players (OptumRx, CVS/Caremark and Express Scripts) now cover more than 75% of the market, giving them considerable bargaining power that enables them to negotiate deep discounts and rebates with manufacturers in return for including reimbursable drugs in their formularies.

Payers will continue to impose ever tighter controls over access to their formularies (such as pre-authorization requirements and exclusions), including for therapeutic classes that were traditionally protected such as oncology and rare diseases. It is possible that in the near future, medico-economic evaluation of innovative healthcare products will play a more important role in justifying or supporting payer decisions on whether to include or retain drugs in their reimbursement formularies.

CHINA

China is engaged on a vast program of reforms to its healthcare system, to promote better disease prevention and improve access to quality healthcare by 2030.

In recent years, China has accelerated its marketing approval processes, so that the entire population can access innovative medicines and vaccines to address unmet urgent medical needs. For example, the approval of Dupixent® in just six months (in June 2020) marked a major step forward in the treatment of adults with moderate-to-severe atopic dermatitis.

Since 2017, China has updated its National Reimbursement Drug List (NRDL) annually. In total, 206 innovative medicines have been added to the NRDL, many of them treating cancers and severe chronic diseases. National-level negotiations combined with sharp price cuts have become a requirement for NRDL listing. In December 2020, 119 new medicines, including Dupixent®, were added to the NRDL at the end of the negotiating process. It is notable that among the 17 oncology treatments added were three locally-developed PD-1 inhibitors (BeiGene's tislelizumab, Shanghai Junshi Biosciences' toripalimab, and Jiangsu Hengrui Medicine's camrelizumab), but no imported foreign PD-1 inhibitors. According to the National Healthcare Security Administration (NHSA), the three new locally-developed PD-1 inhibitors were listed with an average 80% price reduction following the negotiations, in line with the principle of lowest price wins.

Pricing pressure is also expected to intensify across the whole of our established products portfolio, including mature products like Plavix® and Aprovel®), in a highly competitive market dominated by generics (75% of the Chinese prescription drugs market). The Volume Based Procurement (VBP) program is bringing a growing number of foreign pharmaceutical products into head-to-head competition for public tenders with Chinese generics that have demonstrated bioequivalence. Since September 2019 there have been three rounds of tendering, generating average price cuts of 54% according to the NHSA, and guaranteeing substantial market share for the successful bidders. The next round of VBP tenders will likely accelerate the downward trend in prices of generics and of branded products that have lost exclusivity.

In addition, the reform of the public hospital sector will likely continue with the gradual implementation of a diagnosis-related groups (DRG) payment model beginning in 2021, which had been piloted in 30 cities (including Beijing and Tianjin, for example). DRG is expected to have a lasting, long-term impact on hospital cost-containment, although there remains uncertainty about the rollout timelines.

Other ongoing structural reforms and the digital transformation of the health care sector will likely be accelerated by the COVID-19 pandemic.

EUROPE

The economic and financial crisis triggered by the COVID-19 pandemic has had, and continues to have, a major (though varying) negative impact on many European healthcare systems. Governments have responded with a wide range of interventions to tackle increased budgetary pressures and other constraints.

At a time of great financial instability, the crisis has exacerbated the effect of existing cost-containment mechanisms, which are already widely established across Europe. These include price referencing, deeper discounting in tenders and renegotiating contracts, and further substitution of generics and biosimilars.

The pandemic might also engender more lasting disruptions to health technology assessment (HTA) over and above causing short-term delays. In particular, the crisis has highlighted the need to collect real-world patient data and to find new ways to pay for different types of innovation, for example through risk-sharing (managed entry agreements) and outcome-based models.

In the years ahead, the pandemic will likely reinforce the trend towards cooperation, especially through regional initiatives like BeNeLuxA that focus not only on data exchange but also on pricing transparency and bargaining power in dealings with the pharmaceutical industry.

At the same time, the European Commission's new Pharmaceutical Strategy for Europe, unveiled on November 25, proposes multiple levers for improving international cooperation and helping patients access innovative, affordable drugs. These will likely be embedded in a major overhaul of European pharmaceutical legislation, scheduled for 2022. The future implementation of that strategy – and in the nearer

term, changes to regulations on pediatric and orphan drugs – are a growing cause of concern, since they could be detrimental to existing incentive mechanisms that favor innovation.

Similar pressures are being felt in other regions and countries around the globe.

To address the multiple challenges mentioned above, we are continuously adapting our pricing and market access strategies to country-specific requirements, as well as piloting and developing new innovative contracting models with payers and new digital solutions.

B.7. Patents, intellectual property and other rights

B.7.1. Patents

• Patent protection

We own a broad portfolio of patents, patent applications and patent licenses worldwide. These patents are of various types and may cover: active ingredients; pharmaceutical formulations; product manufacturing processes; intermediate chemical compounds; therapeutic indications/methods of use; delivery systems; and enabling technologies, such as assays.

Patent protection for individual products typically extends for 20 years from the patent filing date in countries where we seek patent protection. A substantial part of the 20-year life span of a patent on a new molecule (small molecule or biologic) has generally already passed by the time the related product obtains marketing authorization. As a result, the effective period of patent protection for an approved product's active ingredient is significantly shorter than 20 years. In some cases, the period of effective protection may be extended by procedures established to compensate regulatory delay in Europe (via Supplementary Protection Certificate or SPC), in the US (via Patent Term Extension or PTE) and in Japan (also via PTE).

Additionally, the product may benefit from the protection of patents obtained during development or after the product's initial marketing authorization. The protection a patent provides to the related product depends upon the type of patent and its scope of coverage and may also vary from country to country. In Europe for instance, applications for new patents may be submitted to the European Patent Office (EPO), an intergovernmental organization which centralizes filing and prosecution. With effect from December 2017, an EPO patent application may cover the 38 European Patent Convention Member States, including all Member States of the EU. The granted "European Patent" establishes corresponding national patents with uniform patent claims among the Member States. However, some patents prosecuted through the EPO may pre-date the European Patent Convention accession of some current European Patent Convention Member States, resulting in different treatment in those countries.

In 2013, EU legislation was adopted to create a European Unitary Patent and a Unified Patent Court. However, it will only enter into force once the agreement on the Unified Patent Court is ratified by at least 13 Member States. As of the date of this document, 16 countries including France had ratified the agreement (but the UK has withdrawn its ratification, so there are now 15 ratifications). However, ratification by Germany is still outstanding, and the process is impacted by Brexit.

The Unitary Patent will provide unitary protection within the participating states of the EU (once ratified by the Member States other than Croatia, Spain, and Poland, which are not currently signatories to the agreement). The Unified Patent Court will be a specialized patent court with exclusive jurisdiction for litigation relating to European patents and Unitary Patents. The Court will be composed of a central division (headquartered in Paris) and several local and regional divisions in the signatory Member States to the agreement. The Court of Appeal will be located in Luxembourg.

We monitor our competitors and vigorously seek to challenge patent infringers when such infringement would negatively impact our business objectives. See "Item 8. — A. Consolidated Financial Statements and Other Financial Information — Information on Legal or Arbitration Proceedings — Patents" of this annual report.

The expiration or loss of a patent covering a new molecule, typically referred to as a compound patent, may result in significant competition from generic products and can result in a dramatic reduction in sales of the original branded product (see "Item 3. Key Information — D. Risk Factors"). In some cases, it is possible to continue to benefit from a commercial advantage through product manufacturing trade secrets or other types of patents, such as patents on processes, intermediates, compound structure, formulations, methods of treatment, indications or delivery systems. Certain categories of products, such as traditional vaccines and insulin, were historically relatively less reliant on patent protection and may in many cases have no patent coverage. It is nowadays increasingly frequent for novel vaccines and insulins also to be patent protected. Finally, patent protection is of comparatively lesser importance to our Consumer Healthcare and Generics businesses, which rely principally on trademark protection.

• Regulatory exclusivity

In some markets, including the EU and the US, many of our pharmaceutical products may also benefit from multi-year regulatory exclusivity periods, during which a generic or biosimilar competitor may not rely on our clinical trial and safety data in its drug application. Exclusivity is meant to encourage investment in research and development by providing innovators with exclusive use, for a limited time, of the innovation represented by a newly approved drug product. This exclusivity operates independently of patent protection and may protect the product from generic competition even if there is no patent covering the product.

In the US, the FDA will not grant final marketing authorization to a generic competitor for a New Chemical Entity (NCE) until the expiration of the regulatory exclusivity period (five years) that commences upon the first marketing authorization of the reference product. The FDA will accept the filing of an Abbreviated New Drug Application (ANDA) containing a patent challenge one year before the end of this regulatory exclusivity period. In addition to the regulatory exclusivity granted to NCEs, significant line extensions of existing NCEs may qualify for an additional three years of regulatory exclusivity if certain conditions are met. In the US, a different regulatory exclusivity period applies to biological drugs. The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") was enacted on March 23, 2010 as part of the Affordable Care Act. The BPCIA provides that an application for a biosimilar product that relies on a reference product may not be submitted to the FDA until four years after the date on which the reference product was first licensed, and that the FDA may not approve a biosimilar application until 12 years after the date on which the reference product was first licensed. US Federal and state officials are

continuing to focus on the cost of health coverage and health care although the future policy, including the nature and timing of any changes to the Affordable Care Act, remains unclear.

In the EU, regulatory exclusivity is available in two forms: data exclusivity and marketing exclusivity. Generic drug applications will not be accepted for review until eight years after the first marketing authorization (data exclusivity). This eight-year period is followed by a two-year period during which generics cannot be marketed (marketing exclusivity). The marketing exclusivity period can be extended to three years if, during the first eight-year period, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which are deemed to provide a significant clinical benefit over existing therapies. This is known as the "8+2+1" rule.

In Japan, the regulatory exclusivity period varies: four years for medicinal products with new indications, formulations, dosages, or compositions with related prescriptions; six years for new drugs containing a medicinal composition or requiring a new route of administration; eight years for drugs containing a new chemical entity; and ten years for orphan drugs or new drugs requiring pharmaco-epidemiological study.

• Emerging markets

One of the main limitations on our operations in emerging market countries is the lack of effective intellectual property protection or enforcement for our products. Additionally, these same countries frequently do not provide non-patent exclusivity for innovative products. While the situation has gradually improved, the lack of protection for intellectual property rights or the lack of robust enforcement poses difficulties in certain countries. Additionally, in recent years a number of countries facing health crises have waived or threatened to waive intellectual property protection for specific products, for example through compulsory licensing of generics. See "Item 3. Key Information — D. Risk Factors — Risks Relating to Sanofi's Structure and Strategy — The globalization of our business exposes us to increased risks in specific areas".

• Pediatric extension

In the US and the EU, under certain conditions, it is possible to extend a product's regulatory exclusivity for an additional period of time by providing data on pediatric studies.

In the US, the FDA has invited us by written request to provide additional pediatric data on several of our main products. Under the Hatch-Waxman Act, timely provision of data meeting the FDA's requirements may result in the FDA extending regulatory exclusivity and patent life by six months, to the extent these protections have not already expired (the so-called "pediatric exclusivity").

In Europe, a regulation on pediatric medicines provides for pediatric research obligations with potential associated rewards including extension of patent protection (for patented medicinal products) and six-month regulatory exclusivity for pediatric marketing authorization (for off-patent medicinal products).

In Japan, there is no pediatric research extension of patent protection for patented medicinal products. However, regulatory exclusivity may be extended from eight to ten years.

• Orphan drug exclusivity

Orphan drug exclusivity may be granted in the US to drugs intended to treat rare diseases or conditions (those affecting fewer than 200,000 patients in the US, or in some cases more than 200,000 with no expectation of recovering costs).

Obtaining orphan drug exclusivity is a two-step process. An applicant must first seek and obtain orphan drug designation from the FDA for its drug for one or more indications. If the FDA approves a drug for the designated indication, the drug will generally receive orphan drug exclusivity for such designated indication.

The FDA may approve applications for the "same" drug for indications not protected by orphan exclusivity.

Orphan drug exclusivities also exist in the EU and Japan.

• Product overview

We summarize below the intellectual property coverage (in some cases through licenses) of our most significant marketed products in terms of sales, in our major markets. In the discussion of patents below, we focus on active ingredient patents (compound patents) and, in the case of NCEs, on any later filed patents listed as applicable in the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") or in its foreign equivalents. For biologics, the Orange Book listing does not apply.

These patents or their foreign equivalents tend to be the most relevant in the event of an application by a competitor to produce a generic or a biosimilar version of one of our products (see "- Challenges to Patented Products" below). In some cases, products may also benefit from pending patent applications or from patents not eligible for Orange Book listing (in the case of NCEs for example, patents claiming industrial processes). In each case below, we specify whether the active ingredient is claimed by an unexpired patent. Where patent terms have been extended to compensate for US Patent and Trademark Office (USPTO) delays in patent prosecution (Patent Term Adjustment – PTA) or for other regulatory delays, the extended dates are indicated below. The US patent expirations presented below reflect USPTO dates, and also reflect six-month pediatric extensions when applicable. Where patent terms have expired we indicate such information and mention whether generics are on the market.

We do not provide later filed patent information relating to formulations already available as an unlicensed generic. References below to patent protection in Europe indicate the existence of relevant patents in most major markets in the EU. Specific situations may vary by country.

We additionally set out any regulatory exclusivity from which these products continue to benefit in the US, EU or Japan. Regulatory exclusivities presented below incorporate any pediatric extensions obtained. While EU regulatory exclusivity is intended to be applied throughout the EU, in some cases Member States have taken positions prejudicial to our exclusivity rights.

	United States	European Union	Japan
Aubagio® (teriflunomide)	Compound: expired	Compound: expired	Compound: expired
		Later filed patent: coverage ranging through September 2030	Later filed patent: coverage ranging through March 2024
		Regulatory exclusivity: August 2023	
Alprolix® (eftrenonacog alfa)	Use: March 2028 with PTA* and PTE*	Compound: May 2024 May 2029 with SPC* in most EU countries,	Compound: February 2026 with PTE*
	Later filed patents: coverage ranging through December 2037 (pending)	Later filed patents: coverage ranging through December 2037 (pending)	Later filed patents: coverage ranging through December 2037 (pending)
	Biologics regulatory exclusivity: March 2026	Regulatory exclusivity: May 2026	Regulatory exclusivity: July 2022
Cerezyme® (imiglucerase)	Patent: expired	Patent: expired	Patent: expired
Dupixent® (dupilumab)	Compound: October 2027 (March 2031 with PTE*)	Compound: October 2029 (September 2032 with SPC*)	Compound: October 2029 (May 2034 with PTE*)
	Later filed patents: coverage ranging through September 2037	Later filed patents: coverage ranging through September 2037 (pending)	Later filed patents: coverage ranging through September 2037 (pending)
	Regulatory exclusivity: March 2029	Regulatory exclusivity: September 2027	Regulatory exclusivity: January 2026
Eloctate® (efmoroctocog alfa)	Compound: June 2028 with PTA* and PTE*	Use: May 2024 May 2029 with SPC* in most EU countries	Compound : August 2026 with PTE*
	Later filed patents: coverage ranging through December 2037 (pending)	Later filed patents: coverage ranging through December 2037 (pending)	Later filed patents: coverage ranging through December 2037 (pending)
	Biologics regulatory exclusivity: June 2026	Regulatory exclusivity: November 2025	Regulatory exclusivity: December 2022
Fabrazyme® (agalsidase beta)	Patent: expired	Patent: expired	Patent: expired Generics/biosimilars on the market
Jevtana® (cabazitaxel)	Compound: September 26, 2021	Compound: expired	Compound: March 2021 with PTE*
	Later filed patents: coverage ranging through October 2030	Later filed patents: coverage ranging through May 2036 (pending)	Later filed patents: coverage ranging through November 2030
	NCE Regulatory exclusivity: expired	Regulatory exclusivity: March 2021	Regulatory exclusivity: July 2022
Lantus® (insulin glargine)	Compound: expired	Compound: expired	Compound: expired
	Later filed patents ranging through March 2033	Later filed patent: June 2023	Later filed patent: June 2023
	Generics/biosimilars on the market	Generics/biosimilars on the market	Generics/biosimilars on the market
Lovenox® (enoxaparin sodium)	Compound: expired	Compound: expired	Compound: expired
	Generics/biosimilars on the market	Generics/biosimilars on the market	
Lumizyme®/Myozyme® (alglucosidase alfa)	Compound: expired	Compound: expired	Compound: expired
Plavix® (clopidogrel bisulfate)	Compound: expired	Compound: expired	Compound: expired
	Generics on the market	Generics on the market	Generics on the market
Toujeo® (insulin glargine)	Compound: expired	Compound: expired	Compound: expired
	Later filed patents: coverage ranging through May 2031	Later filed patents: coverage ranging through May 2031	Later filed patents: coverage ranging through July 2033 with PTE*

** PTE: Patent Term Extension. – SPC: Supplementary Protection Certificate. – PTA: Patent Term Adjustment.*

Patents held or licensed by Sanofi do not in all cases provide effective protection against a competitor's generic version of our products. For example, notwithstanding the presence of unexpired patents, competitors launched generic versions of Allegra® in the US (prior to the product being switched to over-the-counter status) and Plavix® in the EU.

We caution the reader that there can be no assurance that we will prevail when we assert a patent in litigation and that there may be instances in which Sanofi determines that it does not have a sufficient basis to assert one or more of the patents mentioned in this report, for example in cases where a competitor proposes a formulation not appearing to fall within the claims of our formulation patent; a salt or crystalline form not claimed by our composition of matter patent; or an indication not covered by our method of use patent. See "Item 3. Key Information — D. Risk Factors — Risks Relating to Legal and Regulatory Matters — We rely on our patents and other proprietary rights to provide exclusive rights to market certain of our products, and if such patents and other rights were limited or circumvented, our financial results could be materially and adversely affected".

As disclosed in Item 8. of this annual report, we are involved in significant litigation concerning the patent protection of a number of our products.

Challenges to patented products

— Abbreviated New Drug Applications (ANDAs)

In the US, generic companies have filed Abbreviated New Drug Applications (ANDAs) containing challenges to patents related to a number of our small molecule products. An ANDA is an application by a drug manufacturer to receive authority to market a generic version of another company's approved product, by demonstrating that the purportedly generic version has the same properties (safety and other

technical data) as the original approved product. As a result of regulatory protection of our safety and other technical data, ANDA applications are generally four years after FDA approval, and include a challenge to a patent listed in the FDA's Orange Book. If the patent holder or licensee brings suit in response to the patent challenge within the statutory window, the FDA is barred from granting final approval to an ANDA during the 30 months following the expiry of the 5-year regulatory exclusivity (this bar is referred to in our industry as a "30-month stay") unless, before the end of the 30 months, the parties reach settlement or a court decision has determined either that the ANDA does not infringe the listed patent or that the listed patent is invalid and/or unenforceable.

FDA approval of an ANDA after this 30-month period does not resolve outstanding patent disputes, but it does remove the regulatory impediments to a product launch by a generic manufacturer willing to take the risk of later being ordered to pay damages to the patent holder.

Accelerated ANDA-type procedures are potentially applicable to many, but not all, of the products we manufacture. See "- B.6.3. Regulatory Framework — 6.3.2. Biosimilars" and "- Regulation" above. We seek to defend our patent rights vigorously in these cases. Success or failure in the assertion of a given patent against a competing product is not necessarily predictive of the future success or failure in the assertion of the same patent – or a fortiori the corresponding foreign patent – against another competing product due to factors such as possible differences in the formulations of the competing products; intervening developments in law or jurisprudence; local variations in the patents; and differences in national patent law and legal systems. See "Item 3. Key Information — D. Risk Factors — Risks Relating to Legal and Regulatory Matters — We rely on our patents and other proprietary rights to provide exclusive rights to market certain of our products, and if such patents and other rights were limited or circumvented, our financial results could be materially and adversely affected".

— Section 505(b)(2) New Drug Applications in the US

Our products and patents are also subject to challenge by competitors via another abbreviated approval pathway, under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. This provision expressly permits an applicant to rely, at least in part, on the FDA's prior findings of safety and effectiveness of a drug that has obtained FDA approval. The FDA may still require applicants to provide additional preclinical or clinical data to ensure that differences from the reference drug do not compromise safety and effectiveness. This pathway allows for approval for a wide range of products, especially for those products that represent only a limited change from an existing approved drug. The 505(b)(2) pathway is distinct from the ANDA pathway, which allows for approval of a generic product based on a showing that it is equivalent to a previously approved product.

A 505(b)(2) applicant is required to identify the reference drug on which it relies, as well as to certify to the FDA concerning any patents listed for the referenced product in the Orange Book. Specifically, the applicant must certify in the application that, for each patent that claims the drug or a use of the drug for which the applicant is seeking approval: (a) there is no patent information listed for the reference drug (paragraph I certification); (b) the listed patent has expired for the reference drug (paragraph II certification); (c) the listed patent for the reference drug has not expired, but will expire on a particular date and approval is sought after patent expiration (paragraph III certification); or (d) the listed patent for the reference drug is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of the product for which the 505(b)(2) NDA is submitted (paragraph IV certification).

A paragraph III certification may delay the approval of an application until the expiration of the patent. A paragraph IV certification generally requires notification of the patent owner and the holder of the NDA for the referenced product. If the patent owner or NDA holder brings patent litigation against the applicant within the statutory window, a 30-month stay is entered on the FDA's ability to grant final approval to the 505(b)(2) applicant unless, before the end of the stay, a court decision or settlement determines the listed patent is invalid, not enforceable, and/or not infringed. A 505(b)(2) application may also be subject to non-patent exclusivity, and the FDA may be prohibited from giving final approval to a 505(b)(2) application until the expiration of all applicable non-patent exclusivity periods.

Similarly, entities wishing to market a generic biologic can utilize an abbreviated approval pathway established in the PHS Act. This §351(k) pathway enables an applicant to rely on a reference product sponsor's data when seeking approval of a biological product shown to be biosimilar (highly similar with no clinically meaningful differences) or interchangeable with an FDA-licensed reference BLA product.

In the EU, a generic drug manufacturer may only reference the data of the regulatory file for the original approved product after data exclusivity has expired. However, there is no patent listing system in Europe comparable to the Orange Book, which would allow the patent holder to prevent the competent authorities from granting marketing authorization by bringing patent infringement litigation prior to approval. As a result, generic products may be approved for marketing following the expiration of marketing exclusivity without regard to the patent holder's rights. Nevertheless, in most of these jurisdictions once the competing product is launched, and in some jurisdictions even prior to launch (once launch is imminent), the patent holder may seek an injunction against such marketing if it believes its patents are infringed. See Item 8. of this annual report.

B.7.2. Trademarks

Our products are sold around the world under trademarks that we consider to be of material importance in the aggregate. Our trademarks help to identify our products and to protect the sustainability of our growth. Trademarks are particularly important to the commercial success of our Consumer Healthcare business.

It is our policy to protect our trademarks for products and/or services of interest, in the countries where they are commercialized. In certain cases, we may enter into a coexistence agreement with a third party that owns potentially conflicting rights in order to avoid any risk of confusion and better protect and defend our trademarks.

We monitor and defend our trademarks based on this policy in particular to prevent counterfeiting, infringement and/or unfair competition.

B.8. Production and raw materials

We have opted to manufacture the majority of our products in-house. There are three principal stages in our production process: the manufacture of active ingredients, the transformation of those ingredients into drug products or vaccines, and packaging those products.

Our general policy is to produce the majority of our active ingredients and principal drug products at our own plants in order to reduce our dependence on external suppliers. We also rely on third parties for the manufacture and supply of certain active ingredients, drug products

and medical devices. Active ingredients are manufactured using raw materials sourced from suppliers who have been subject to rigorous selection and approval procedures, in accordance with international standards and our own internal directives. We have outsourced some of our production under supply contracts associated with acquisitions of products or businesses or with plant divestitures, or to establish a local presence to capitalize on growth in emerging markets. Our pharmaceutical subcontractors follow our general quality and logistics policies, as well as meeting other criteria. See ''Item 3. Key Information — D. Risk Factors — Risks Relating to Our Business''.

We also obtain active ingredients from third parties under collaboration agreements. This applies in particular to the monoclonal antibodies developed with Regeneron.

Our pharmaceutical production sites are divided into three categories:

- global sites, which serve all markets: located mainly in Europe, these facilities are dedicated to the manufacture of our active ingredients, injectable products, and a number of our main solid-form products;
- regional sites, which serve markets at regional level, in Europe and particularly the BRIC-M countries (Brazil, Russia, India, China and Mexico), giving us a strong industrial presence in emerging markets; and
- local sites, which serve their domestic market only.

Sanofi Pasteur produces vaccines at various sites, with the main locations situated in France, the United States, Canada, India, Mexico and China. The pharmaceutical site at Le Trait (France) also contributes to Sanofi Pasteur's industrial operations by making available its sterile filling facilities.

All of our production facilities are good manufacturing practice (GMP) compliant, in line with international regulations.

Our principal sites approved by the FDA are:

- the Specialty Care facilities in the United States (Allston MA, Framingham MA and Northborough MA), France (Lyon Gerland, Vitry-sur-Seine, Le Trait), Germany (Frankfurt), Ireland (Waterford) and Belgium (Geel);
- the General Medicines facilities in Germany (Frankfurt), France (Aramon, Sisteron, Ambarès and Tours), Italy (Anagni), Singapore (Jurong) and the United States (Ridgefield NJ);
- the chemical facilities producing active ingredients for third parties, including those located in France (Vertolaye, Saint-Aubin-les-Elbeuf), Germany (Frankfurt) and Hungary (Ujpest);
- the Consumer Healthcare facilities in France (Compiègne) and the United States (Chattanooga TN); and
- the Vaccines facilities in France (Marcy l'Étoile, Le Trait, Val-de-Reuil and Neuville-sur-Saône), the United States (Swiftwater PA), and Canada (Toronto).

Wherever possible, we seek to have multiple plants approved for the production of key active ingredients and our strategic finished products (this is the case with Lovenox®, and Dupixent®, for example).

In May 2010, Genzyme's Allston facility in the United States entered into a consent decree with the US government following FDA inspections at the facility that resulted in observations and a warning letter raising Current Good Manufacturing Practices (CGMP) deficiencies.

The workplan was completed on March 31, 2016. The next step was a third-party certification process. In October 2017 Genzyme received confirmation from the FDA regarding Genzyme's compliance with the terms of the consent decree and compliance with applicable laws and regulations.

The Allston facility is required to engage a third-party expert to audit its manufacturing operations for an additional period of at least five years. More details about our manufacturing sites are given below at section ''D. Property, Plant and Equipment''.

B.9. Insurance and risk coverage

We are protected by five insurance programs, relying not only on the traditional corporate insurance and reinsurance market but also on our direct insurance company, Carraig Insurance DAC (Carraig).

These five key programs cover Property & Business Interruption; General & Product Liability; Stock & Transit; loss and liability arising from cyber and digital risks; and Directors & Officers Liability.

Carraig participates in our coverage for various lines of insurance including Property, Stock & Transit, Cyber/Digital, and General & Product Liability. Carraig is run under the supervision of the Irish and European regulatory authorities, is wholly owned by Sanofi, and has sufficient resources to meet those portions of our risks that it has agreed to cover.

Carraig sets premiums for our entities at market rates. Claims are assessed using the traditional models applied by insurance and reinsurance companies, and the company's reserves are regularly verified and confirmed by independent actuaries.

Our Property & Business Interruption program covers all our entities worldwide, in all territories where it is possible to use a centralized program operated by Carraig. By sharing risk between our entities, this approach enables us to set deductibles and cover appropriate to the needs of local entities before the market attachment point. It also incorporates a prevention program, including a comprehensive site visit schedule covering our production, storage, research and distribution facilities and standardized repair and maintenance procedures across all sites.

The Stock & Transit program protects all goods owned by Sanofi while they are in transit nationally or internationally whatever the means of transport, and all our inventories wherever they are located. Sharing risk between our entities through Carraig means that we can set deductibles at appropriate levels, for instance differentiating between goods that require temperature controlled distribution and those that do not. We have developed a prevention program with assistance from experts, implementing best practices in this area at our distribution sites.

Our Cyber/Digital insurance program protects our operations against loss originating from various sources, and against liability in respect of data security. Centralized through Carraig, the program enables us to set deductibles and cover appropriate to the needs of local entities before the market attachment point.

Our General & Product Liability program was renewed in 2020 for all our subsidiaries worldwide in all territories where it was possible to do so, despite reluctance in the insurance and reinsurance market to cover product liability risks for large pharma-biotech groups. For several years, insurers have been reducing product liability cover because of the difficulty of transferring risk for some products that have been subject to numerous claims. This applies to a few of our products and has led us to increase, year by year, the extent to which we self-insure.

The principal risk exposure for our pharmaceutical products is covered with low deductibles at country level, with a greater proportion of risk being retained. The level of risk self-insured by Sanofi (including via Carraig) before the market attachment point enables us to retain control over the management and prevention of risk. Our negotiations with third-party insurers and reinsurers are tailored to our specific risks. In particular, they allow for differential treatment of products in the development phase; for discrepancies in risk exposure between European countries and the United States; and for specific issues arising in certain jurisdictions, such as generics coverage in the United States. Coverage is adjusted every year to take account of the relative weight of new product liability risks, such as those relating to rare diseases or to healthcare products which do not require marketing approval.

Our cover for risks that are not specific to the pharma-biotech industry (general liability) is designed to address the potential impacts of our operations.

For all the insurance programs handled by Carraig, outstanding claims are covered by provisions for the estimated cost of settling all claims incurred but not paid at the balance sheet date, whether reported or not, together with all related claims handling expenses. Where there is sufficient data history from Sanofi or from the market for claims made and settled, management – with assistance from independent actuaries – prepares an actuarial estimate of our exposure to unreported claims for the risks covered. The actuaries perform an actuarial valuation of the company's IBNR (Incurred But Not Reported) and ALAE (Allocated Loss Adjustment Expense) liabilities at year end. Two ultimate loss projections (based upon reported losses and paid losses, respectively) are computed each year using various actuarial methods including the Bornhuetter-Ferguson method; those projections form the basis for the provisions set.

The Directors & Officers Liability program protects all legal entities under our control, and their directors and officers. Carraig is not involved in this program.

We also operate other insurance programs, but these are of much lesser importance than those described above.

All our insurance programs are backed by best in class insurers and reinsurers and are designed in such a way that we can integrate most newly acquired businesses without interruption of cover. Our cover has been designed to reflect our risk profile and the capacity available in the insurance market. By centralizing our major programs, we are able to provide world-class protection while limiting the premium increase in a global market with severe upward price pressure.

B.10. Health, Safety and Environment

Our manufacturing and research operations are subject to increasingly stringent health, safety and environmental (HSE) laws and regulations. These laws and regulations are complex and rapidly changing, and Sanofi invests the necessary sums in order to comply with them. This investment, which aims to respect health, safety and the environment, varies from year to year.

Applicable environmental laws and regulations may require us to eliminate or reduce the effects of chemical substance discharge at our various sites. The sites in question may belong to Sanofi, and may be currently operational, or may have been owned or operational in the past. In this regard, Sanofi may be held liable for the costs of removal or remediation of hazardous substances on, under or in the sites concerned, or on sites where waste from activities has been stored, without regard to whether the owner or operator knew of or under certain circumstances caused the presence of the contaminants, or at the time site operations occurred the discharge of those substances was authorized.

As is the case for a number of companies in the pharmaceutical, chemical and intense agrochemical industries, soil and groundwater contamination has occurred at some of our sites in the past, and may still occur or be discovered at others. In Sanofi's case, such sites are mainly located in the United States, Germany, France, Hungary, Italy and the United Kingdom. As part of a program of environmental surveys conducted over the last few years, detailed assessments of the risk of soil and groundwater contamination have been carried out at current and former Sanofi sites. In cooperation with national and local authorities, Sanofi regularly assesses the rehabilitation work required and carries out such work when appropriate. Long-term rehabilitation work is in progress or planned in Mount Pleasant, Portland in the United States; Frankfurt in Germany; Brindisi in Italy; Dagenham in the United Kingdom; Ujpest in Hungary; Beaucaire, Valernes, Limay, Neuville and Vitry in France; and on a number of sites divested to third parties and covered by contractual environmental guarantees granted by Sanofi.

We may also have potential liability for investigation and cleanup at several other sites. We have established provisions for the sites already identified and to cover contractual guarantees for environmental liabilities for sites that have been divested. In France specifically, we have provided the financial guarantees for environmental protection required under French regulations.

Potential environmental contingencies arising from certain business divestitures are described in Note D.22.d. to the consolidated financial statements. In 2020, Sanofi spent €70 million on rehabilitating sites previously contaminated by soil or groundwater pollution.

Due to changes in environmental regulations governing site remediation, our provisions for remediation obligations may not be adequate due to the multiple factors involved, such as the complexity of operational or previously operational sites, the nature of claims received, the rehabilitation techniques involved, the planned timetable for rehabilitation, and the outcome of discussions with national regulatory authorities or other potentially responsible parties, as in the case of multiparty sites. Given the long industrial history of some of our sites and the legacy obligations arising from the past involvement of Aventis in the chemical and agrochemical industries, it is impossible to quantify the future impact of these laws and regulations with precision. See "Item 3.D. Risk Factors — Environmental Risks of Our Industrial Activities".

We have established, in accordance with our current knowledge and projections, provisions for cases already identified and to cover contractual guarantees for environmental liabilities relating to sites that have been divested. In accordance with Sanofi standards, a comprehensive review is carried out once a year on the legacy of environmental pollution. In light of data collected during this review, we adjusted our provisions to approximately €713 million as of December 31, 2020 versus €737 million as of December 31, 2019. The terms of certain business divestitures, and the environmental obligations and retained environmental liabilities relating thereto, are described in Note D.22. to our consolidated financial statements.

To our knowledge, Sanofi did not incur any liability in 2020 for non-compliance with current HSE laws and regulations that could be expected to significantly jeopardize its activities, financial situation or operating income. We also believe that we are in substantial compliance with current HSE laws and regulations and that all the environmental permits required to operate our facilities have been obtained.

Regular HSE audits are carried out by Sanofi in order to assess compliance with standards (which implies compliance with regulations) and to initiate corrective measures (34 internal audits performed in 2020). Moreover, more than 100 specific visits were performed jointly with experts representing our insurers.

Sanofi has implemented a worldwide master policy on health, safety and environment to promote the health and well-being of the employees and contractors working on its sites and respect for the environment. We consider this master policy to be an integral part of our commitment to social responsibility. In order to implement this master policy, Sanofi key requirements have been drawn up in the key fields of HSE management, HSE leadership, safety in the workplace, process safety, occupational hygiene, health in the workplace and protection of the environment.However, despite these efforts, Sanofi may be unsuccessful in the implementation of its policy to reduce and mitigate the harmful effects of its activities on the health and safety of its employees, customers or the general public and on the environment more generally. See “Item 3.B. Risk Factors” for further information.

Health

From the development of compounds to the commercial launch of new drugs, Sanofi research scientists continuously assess the effect of products on human health. This expertise is made available to employees through two committees responsible for chemical and biological risk assessment. Sanofi’s COVALIS (*Comité des Valeurs Limites Internes Sanofi*) Committee is responsible for the hazard determination and classification of all active pharmaceutical ingredients and synthesis intermediates handled at Sanofi facilities. This covers all active ingredients handled in production at company sites or in processes sub-contracted for manufacture. Any important issues involving raw materials or other substances that lack established occupational exposure limits may also be reviewed. The COVALIS Committee determines the occupational exposure limits required within Sanofi. Our TRIBIO Committee is responsible for classifying all biological agents according to their degree of pathogenicity, and applies rules for their containment and the preventive measures to be respected throughout Sanofi. See “Item 3. Key Information — D. Risk Factors — Environmental Risks of Our Industrial Activities — Risks from the handling of hazardous materials could adversely affect our results of operations”.

Appropriate occupational hygiene practices and programs are defined and implemented in each site. These practices consist essentially of containment measures for collective and individual protection against exposure in all workplaces where chemical substances or biological agents are handled. All personnel are monitored with an appropriate medical surveillance program, based on the results of professional risk evaluations linked to their duties.

In addition, dedicated resources have been created to implement the EU Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH). To fully comply with the new European Regulation on Classification, Labeling and Packaging of chemicals, Sanofi has registered the relevant hazardous chemical substances with the European Chemicals Agency (ECHA).

Safety

Sanofi has rigorous policies to identify and evaluate safety risks and to develop preventive safety measures, and methods for checking their efficacy. Additionally, Sanofi invests in training that is designed to instill in all employees a sense of concern for safety, regardless of their duties. These policies are implemented on a worldwide scale to ensure the safety of all employees and to protect their health. Each project, whether in research, development or manufacturing, is subject to evaluation procedures, incorporating the chemical substance and process data communicated by the COVALIS and TRIBIO Committees described above. The preventive measures are designed primarily to reduce the number and seriousness of work accidents and to minimize exposures involving permanent and temporary Sanofi employees as well as our sub-contractors.

The French chemical manufacturing sites in Aramon, Sisteron and Vertolaye, as well as the plants located in the Hoechst Industry Park in Frankfurt, Germany, and the chemical production site in Budapest, Hungary, are listed Seveso III (from the name of the European directive that deals with potentially dangerous sites through a list of activities and substances associated with classification thresholds). In accordance with French law on technological risk prevention, the French sites are also subject to heightened security inspections due to the toxic or flammable materials stored on the sites and used in the operating processes.

Risk assessments of processes and installations are drawn up according to standards and internal guidelines incorporating the best state of the art benchmarks for the industry. These assessments are used to fulfill regulatory requirements and are regularly updated. Particular attention is paid to any risk-generating changes such as process or installation changes, as well as changes in production scale and transfers between industrial or research units.

We have specialized process safety-testing laboratories that are fully integrated into our chemical development activities, apply methods to obtain the physico-chemical parameters of manufactured chemical substances (intermediate chemical compounds and active ingredients) and apply models to measure the effect of potentially leachable substances in the event of a major accident. In these laboratories the parameters for qualifying hazardous reactions are also determined, in order to define scale-up process conditions while transferring from development stage to industrial scale. We use these data to enhance the relevance of our risk assessments.

We believe that the safety management systems implemented at each site, the hazard studies carried out and the risk management methods implemented, as well as our third-party property insurance policies covering any third-party physical damage, are consistent with legal requirements and the best practices in the industry, although no guarantee can be given that they will prevent accidents of various kinds.

Environment

We have committed to an ambitious policy aimed at limiting the direct and indirect impacts of our activities on the environment, throughout the life cycle of our products. We have identified five major environmental challenges relating to our businesses: greenhouse gas emissions and climate disruption; water; pharmaceuticals in the environment; waste; and biodiversity.

The initiatives already implemented since 2010 are continuing, and we have been keen to give them fresh impetus through the Planet Mobilization program. Reflecting our environment strategy out to 2025, the program sets more ambitious targets for reducing environmental impacts across the entire value chain. Planet Mobilization is a global project that involves all of the Company's resources in defining objectives and engaging with external partners.

Compared with 2015 figures, we are undertaking to halve our carbon emissions by the end of 2025 and reach carbon-neutral status by 2050 on our scope 1 & 2 (direct and indirect emissions for all activities). We have also set ourselves the target of achieving sustainable water resource management, especially at sites which are under hydric stress. On this new scope, by the end of 2020, we had reduced CO_2 emissions by 27% and water consumption by 21%.

Overall waste recycling at sites is already above 73% and is expected to be more than 90% by the end of 2025. The discharge rate had dropped to 7% at the end of 2020 and we have committed to move towards a maximum of 1% by 2025. Biodiversity management at our sites is also a priority, with the aim of making all employees aware of this challenge and implementing risk assessment and management plans at priority sites.

Finally, we are pursuing the policy we began in 2010 of managing pharmaceutical products in the environment throughout their life cycles. At the end of 2020, all priority chemical sites had been evaluated. The assessment program was extended to other sites, starting with the pharmaceutical production sites. Since 2017, ten sites have implemented the program.

In line with this approach, we have committed to the "Roadmap AMR 2020" initiative, which aims to combat microbial resistance to antibiotics. The initiative brings together thirteen of the major players in the pharmaceutical industry, and will involve co-producing reference guides and methodologies for sustainable management of antibiotics in the pharmaceutical sector. The initiative includes a specific commitment with respect to antibiotic production sites that are operated by signatories or their suppliers, involving firstly the definition and deployment of a shared framework for managing potential waste, and secondly the establishment of environmental thresholds. See "Cautionary statement regarding forward-looking statements" and "Item 3.D. Risk Factors".

C. Organizational Structure

C.1. Significant Subsidiaries

Sanofi is the holding company of a consolidated group consisting of over 250 companies. The table below sets forth our significant subsidiaries as of December 31, 2020. For a fuller list of the principal companies in our consolidated group, see Note F. to our consolidated financial statements, included in this annual report at Item 18.

Significant subsidiary	Date of incorporation	Country of incorporation	Principal activity	Financial and voting interest
Aventis Inc.	July 1, 1968	United States	Pharmaceuticals	100 %
Genzyme Corporation	November 21, 1991	United States	Pharmaceuticals	100 %
Genzyme Europe B.V.	October 24, 1991	Netherlands	Pharmaceuticals	100 %
Hoechst GmbH	July 8, 1974	Germany	Pharmaceuticals	100 %
Sanofi-Aventis Deutschland GmbH	June 30, 1997	Germany	Pharmaceuticals	100 %
Sanofi-Aventis Participations SAS	February 25, 2002	France	Pharmaceuticals	100 %
Sanofi-Aventis Singapore Pte Ltd	May 14, 1997	Singapore	Pharmaceuticals	100 %
Sanofi Biotechnology	December 23, 2013	France	Pharmaceuticals	100 %
Sanofi Foreign Participations B.V.	April 29, 1998	Netherlands	Pharmaceuticals	100 %
Sanofi Winthrop Industrie	December 11, 1972	France	Pharmaceuticals	100 %

Since 2009, we have transformed Sanofi through numerous acquisitions (see "A. History and Development of the Company" above), in particular those of Genzyme in April 2011, Merial in September 2009, Bioverativ in March 2018, Ablynx in June 2018, Synthorx in January 2020, and Principia in September 2020. The financial effects of the Genzyme acquisition are presented in Note D.1.3. to our consolidated financial statements for the year ended December 31, 2013, included in our annual report on Form 20-F for that year. The financial effects of the Merial acquisition are presented in Note D.1.3. to our consolidated financial statements for the year ended December 31, 2010, included in our annual report on Form 20-F for that year. At the end of December 2016, Sanofi Pasteur and MSD (known as Merck in the United States and Canada) ended their Sanofi Pasteur MSD joint venture. The financial effects of the resulting divestment/acquisition are presented in Note D.1.2. to our consolidated financial statements for the year ended December 31, 2016, included in our annual report on Form 20-F for that year. On January 1, 2017, Sanofi and Boehringer Ingelheim (BI) finalized the strategic transaction agreed in June 2016, involving the exchange of Sanofi's Animal Health business (Merial) for BI's Consumer Healthcare business. The financial effects of this transaction are presented in Note D.1. to our consolidated financial statements for the year ended December 31, 2017, included in our annual report on Form 20-F for that year. The financial effects of the Bioverativ and Ablynx acquisitions are presented in Note D.1.1. to our consolidated financial statements for the year ended December 31, 2018, included in our annual report on Form 20-F for that year. The financial effects of the Synthorx and Principia acquisitions are presented in Note D.1. to our consolidated financial statements for the year ended December 31, 2020, included in the present annual report on Form 20-F.

In certain countries, we carry on some of our business operations through joint ventures with local partners. In addition, we have entered into worldwide collaboration agreements with Regeneron relating to Zaltrap®, Praluent®, Dupixent®, Kevzara® and Libtayo®. For further information, refer to Note C. "Principal Alliances" to our consolidated financial statements.

C.2. Internal organization of activities

Sanofi and its subsidiaries collectively form a group organized around three activities: Pharmaceuticals (General Medicines and Specialty Care), Vaccines, and Consumer Healthcare.

Within Sanofi, responsibility for research and development (R&D) in their respective fields rests with Sanofi and Genzyme Corporation in Pharmaceuticals, and with Sanofi Pasteur and Sanofi Pasteur, Inc. in Vaccines. However, within our integrated R&D organization, strategic priorities are set and R&D efforts coordinated on a worldwide scale. In fulfilling their role in R&D, the aforementioned companies subcontract R&D to those of their subsidiaries that have the necessary resources. They also license patents, manufacturing know-how and trademarks to certain of their French and foreign subsidiaries. Those licensee subsidiaries manufacture, commercialize and distribute the majority of our products, either directly or via local distribution entities.

Our industrial property rights, patents and trademarks are mainly held by the following companies:

- Pharmaceuticals: Sanofi, Sanofi Mature IP, Sanofi Biotechnology SAS (France), Sanofi-Aventis Deutschland GmbH (Germany), Ablynx (Belgium), and Genzyme Corporation and Bioverativ Inc. (US);
- Vaccines: Sanofi Pasteur (France) and Sanofi Pasteur, Inc. (US).

For a description of our principal items of property, plant and equipment, see "- D. Property, Plant and Equipment" below. Our property, plant and equipment is held mainly by the following companies:

- in France: Sanofi Pasteur SA, Sanofi Chimie, Sanofi Winthrop Industrie, and Sanofi-Aventis Recherche & Développement;
- in the United States: Sanofi Pasteur, Inc., Genzyme Therapeutics Products LP, and Genzyme Corporation;
- in Germany: Sanofi-Aventis Deutschland GmbH;
- in Canada: Sanofi Pasteur Limited;
- in Belgium: Genzyme Flanders BVBA; and
- in Ireland: Genzyme Ireland Limited.

C.3. Financing and financial relationships between group companies

The Sanofi parent company raises the bulk of the Company's external financing and uses the funds raised to meet, directly or indirectly, the financing needs of its subsidiaries. The parent company operates a cash pooling arrangement under which any surplus cash held by subsidiaries is managed centrally. There is also a centralized foreign exchange risk management system in place, whereby the parent company contracts hedges to meet the needs of its principal subsidiaries.

Consequently, at December 31, 2020, the Sanofi parent company held 98% of our external financing and 92% of our surplus cash.

Sanofi European Treasury Center SA (SETC), a 100%-owned Sanofi subsidiary incorporated in 2012 under the laws of Belgium, is dedicated to providing financing and various financial services to our subsidiaries.

D. Property, plant and equipment

D.1. Overview

Our headquarters are located in Paris, France. See "- D.4. Office Space" below.

We operate our business through office premises and research, production and logistics facilities in approximately 90 countries around the world. Our office premises house all of our support functions, plus operational representatives from our subsidiaries and the Company.

A breakdown of our sites by use and by ownership status (owned versus leasehold) is provided below. This breakdown is based on surface area. All surface area figures are unaudited.

Breakdown of sites by use	
Industrial	61%
Research	13%
Offices	14%
Logistics	9%
Other	4%

Breakdown of sites by ownership status	
Leasehold	24%
Owned	76%

We own most of our research & development and production facilities, either freehold or under finance leases with a purchase option exercisable on expiration of the lease.

D.2. Description of our sites

Sanofi industrial sites

As part of the process of transforming Sanofi and creating Global Business Units, we are continuing to adapt the organization of the Industrial Affairs department in support of our new business model.

The Industrial Affairs department focuses on customer needs and service quality; the sharing of "Sanofi Manufacturing System" good manufacturing practices; and the development of a common culture committed to quality.

In 2020, Industrial Affairs modified its organization to align on the new Global Business Units structure comprising Specialty Care, General Medicines, Vaccines and Consumer Heath Care.

In February 2020, we announced a plan to create a major leading European company dedicated to the production and marketing to third parties of active pharmaceutical ingredients (API). This involves creating a standalone company combining our API commercial and development activities with six of our European API production sites: Brindisi (Italy), Frankfurt Chemistry (Germany), Haverhill (UK), Saint-Aubin-les-Elbeuf (France), Újpest (Hungary), and Vertolaye (France). This new company will help support and secure API manufacturing, and provides supply capacities for Europe and beyond.

The Industrial Affairs department is also responsible for Sanofi Global HSE and Global Supply Chain.

At the end of 2020, we were carrying out industrial production at 69 sites in 32 countries:

- 9 sites for our Specialty Care operations;
- 31 sites for our General Medicines operations;
- 6 sites for our Third-Party API operations;
- 12 sites for our Consumer Healthcare operations; and
- 11 sites for the industrial operations of Sanofi Pasteur in vaccines.

The quantity of units sold in 2020, including in-house and outsourced production, was 4.8 billion, comprising:

- Pharmaceuticals: 2.8 billion units;
- Consumer Healthcare: 1.7 billion units; and
- Vaccines: 176 million boxes.

We believe that our production facilities are in compliance with all regulatory requirements, are properly maintained and are generally suitable for future needs. We regularly inspect and evaluate those facilities with regard to environmental, health, safety and security matters, quality compliance and capacity utilization. For more information about our property, plant and equipment, see Note D.3. to our consolidated financial statements, included at Item 18. of this annual report, and section "B.8. Production and Raw Materials" above.

Our principal production sites by volume are:

- Le Trait (France), Frankfurt (Germany), Waterford (Ireland), Geel (Belgium) and Framingham (United States) for Specialty Care;
- Aramon, Sisteron and Ambarès (France), Frankfurt (Germany), Csanyikvölgy (Hungary), Lüleburgaz (Turkey), Campinas (Brazil), Jurong (Singapore) and Hangzhou (China) for General Medicines products;
- Compiègne and Lisieux (France), Cologne (Germany), Suzano (Brazil) and Ocoyoacac (Mexico) for Consumer Healthcare products; and
- Marcy-l'Étoile and Val-de-Reuil (France), Toronto (Canada), Swiftwater (United States) and Hyderabad (India) for vaccines.

Research & Development sites

In Pharmaceuticals, research and development activities are conducted at the following sites:

- four operational sites in France: Chilly-Mazarin/Longjumeau, Montpellier, Strasbourg and Vitry-sur-Seine/Alfortville;
- three sites in the rest of Europe (Germany, Belgium and the Netherlands), the largest of which is in Frankfurt (Germany);
- six sites in the United States: Bridgewater, Cambridge, Framingham/Waltham, Great Valley, San Francisco and San Diego; and
- in Asia, three sites in China (Beijing, Shanghai and Chengdu).

Vaccines research and development sites are:

- Swiftwater, Cambridge and Orlando (United States);
- Marcy-l'Étoile/Lyon (France); and
- Toronto (Canada).

D.3. Acquisitions, capital expenditures and divestitures

The carrying amount of our property, plant and equipment at December 31, 2020 was €9,365 million. During 2020, we invested €1,310 million (see Note D.3. to our consolidated financial statements, included at Item 18. of this annual report), mainly in increasing capacity and improving productivity at our various production and R&D sites.

Our principal acquisitions, capital expenditures and divestitures in 2018, 2019 and 2020 are described in Notes D.1. & D.2. ("Changes in the scope of consolidation"), D.3. ("Property, plant and equipment") and D.4. ("Goodwill and other intangible assets") to our consolidated financial statements, included at Item 18. of this annual report.

As of December 31, 2020, our firm commitments in respect of future capital expenditures amounted to €708 million. The principal locations involved were: for the Pharmaceuticals segment, the industrial facilities at Frankfurt (Germany); Le Trait, Maisons-Alfort, Compiègne, and Ambares (France); Cambridge (United States); Origgio, Anagni, Brindisi, and Scoppito (Italy); and for the Vaccines segment, the facilities at Toronto (Canada), Marcy-l'Étoile and Val de Reuil (France).

In the medium term and assuming no changes in the scope of consolidation, we expect to invest on average some €1.6 billion a year in property, plant and equipment. We believe that our own cash resources and the undrawn portion of our existing credit facilities will be sufficient to fund these expenditures.

Our principal ongoing capital expenditures are described below.

Specialty Care

Our Specialty Care industrial operations are organized around two end-to-end clusters. We have four dedicated biotechnology hubs: Paris/Lyon (France), Frankfurt (Germany), Geel (Belgium) and Boston Area (United States). The Bioatrium project, a joint venture between Sanofi and Lonza (Switzerland) set up in 2017 to increase bioproduction capacity, is proceeding on schedule. We also launched in 2020 the Lyon Gerland platform for Viral Vectors. Exploiting the innovative techniques on which biotech relies, including cell and microbiological culture and the development of viral vectors, calls for highly specific knowledge and expertise backed by dedicated production platforms to support global product launches.

The Waterford and Le Trait sites manufacture pre-filled Dupixent® syringes.

General Medicines

Our General Medicines industrial operations are organized through end-to-end clusters, with chemistry, pharmaceutical and injectable sites organized through a network of over 31 regional and local industrial sites in 21 countries, supporting growth in those markets.

This new organization encompasses a dedicated Launch Sites cluster from API manufacturing to finished goods packaging (Sisteron, Aramon, Ambarès, Scoppito).

The Frankfurt facility is our principal site for the manufacture of diabetes treatments.

Consumer Healthcare

The pharmaceutical industrial operations of our Consumer Healthcare (CHC) business are spread across a dedicated network. Global markets are supplied from our facilities at Compiègne (France) and Cologne (Germany). We have recently invested in projects to bring various manufacturing operations related to our acquisition of Boehringer Ingelheim's CHC business in-house, mainly to our sites at Compiègne (France) and Suzano (Brazil).

Vaccines (Sanofi Pasteur)

Sanofi Pasteur's industrial operations are in a major investment phase, preparing for the upcoming growth of our influenza and Polio/Pertussis/Hib franchises, plus the mid-term growth linked to our New Vaccines pipeline. A major investment was announced in 2020 with the new Evolutive Facility in France for the New Vaccines pipeline (Neuville-Sur-Saone). Other major investments are under way in France (including construction of a new influenza vaccine building at Val-de-Reuil), Canada (a new pertussis vaccine building), the US and Mexico.

Innovation and culture of industrial excellence

The ambition of our Industrial Affairs department is to continue to raise quality standards in Sanofi's production activities, and to remain a world leader and a benchmark in the global pharmaceutical industry. To achieve this goal, all our activities share a common culture of industrial excellence, enshrined in the Sanofi Manufacturing System. This sets out a series of priorities (such as customer service, constant improvement, site network optimization and transverse optimization) that constitute our industrial vision and will be crucial to our mutual success.

In terms of operational excellence, we continue to build on our Top Decile performance program, focused on core sites and fully leveraging digital opportunities.

D.4. Office space

As part of the transformation of Sanofi, we are undertaking major real estate programs with two core objectives: to bring our teams together on single sites in new workspaces that favor agility, cross-fertilization and communication, and to rationalize office space while achieving a responsible environmental footprint.

Projects completed in 2020 included the rationalization of our sites in Rotkreuz (Switzerland), Buenos Aires (Argentina), Mexico City (Mexico), and Hong Kong and Shanghai (China), plus the inauguration of Sanofi Business Services (SBS) platforms at Budapest (Hungary) and Santiago (Chile).

This transformation of workspaces to flexible mode has already reached over 21,000 of our people around the globe, and provides strong support for our various operations to attain their objectives. The rollout covers all regions worldwide, and a number of projects are currently under way. These include projects in the Greater Paris region (relocation of our headquarters to Avenue de la Grande Armée in the seventeenth arrondissement of Paris, and closure of the Croix-de-Berny site at Antony), and further projects in Russia, Australia and South Africa. Finally, we continue to divest orphan sites; during 2020, we sold around fifteen holdings of land or buildings no longer required for our operations, including a portfolio of over 1,200 plots of agricultural land and forest.

Item 4A. Unresolved Staff Comments

N/A

Item 5. Operating and Financial Review and Prospects

You should read the following discussion in conjunction with our consolidated financial statements and the notes thereto included in this annual report at Item 18.

Our consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and with IFRS endorsed by the European Union as of December 31, 2020.

The following discussion contains forward-looking statements that involve inherent risks and uncertainties. Actual results may differ materially from those contained in such forward-looking statements. See “Cautionary Statement Regarding Forward-Looking Statements” at the beginning of this document.

Unless otherwise stated, all financial variations in this item are given on a reported basis.

The discussion of our operating and financial review and prospects for the years ended December 31, 2019 and December 31, 2018, can be found in Part I, Item 5. of our Form 20-F filed on March 5, 2020, including a presentation of our consolidated income statements for the years ended December 31, 2019 and December 31, 2018 in “Item 5. — A.2. Results of operations” of our Form 20-F filed on March 5, 2020.

A. Operating Results

A.1. Significant Operating Information

A.1.1. 2020 Overview

During 2020, Sanofi continued to implement its new **“Play to Win”** strategy, involving major decisions and positive actions that will support and rebuild the competitive margins necessary for Sanofi to continue to deliver on its mission. The strategy is based on four major priorities: focus on growth, lead with innovation, accelerate efficiency, and reinvent how we work. For further information about our strategy, refer to “- Item 4. — B.1. Strategy”. Other significant events of the year are described below.

On January 23, 2020, Sanofi completed the acquisition of **Synthorx, Inc.**, a biotechnology company focused on prolonging and improving the lives of people suffering from cancer and autoimmune disorders, for $68 per share in cash, representing an aggregate equity value of approximately $2.5 billion (on a fully diluted basis).

On February 24, 2020, Sanofi announced its ambition to create a **leading European company dedicated to the production and marketing to third parties of active pharmaceutical ingredients (API)**, the essential molecules responsible for the beneficial effects used in the composition of any drug. The project involves creating a new standalone company combining Sanofi’s API commercial and development activities with six of its European API production sites: Brindisi (Italy), Frankfurt Chemistry (Germany), Haverhill (UK), Saint-Aubin-lès-Elbeuf (France), Újpest (Hungary), and Vertolaye (France). With increasing medicine shortages that critically impact patient care, the new entity is expected to contribute to securing API manufacturing and supply capacity for Europe and beyond. We expect that the new entity will rank as the world’s second-largest API company, with approximately €1 billion of sales anticipated by 2022 and 3,200 employees; it will be headquartered in France. An initial public offering on Euronext Paris is envisaged in 2022, if market conditions allow. Sanofi is fully committed to the long-term success of the new entity, in which it intends to retain a minority stake of approximately 30%. To provide optimal conditions for success, Sanofi intends the new company to be debt free in order to maximize its future investment capacities, and is committed to remaining an important customer of the new entity.

On February 28, 2020, the Sanofi subsidiary Aventis Inc. acquired from **Bristol-Myers Squibb** Investco LLC, E.R. Squibb & Sons LLC and Bristol-Myers Squibb Puerto Rico, Inc. (all subsidiaries of BMS) their respective equity interests in the three partnerships that organize the commercialization of Plavix® in the United States and Puerto Rico. As a result of those transactions, Sanofi obtained sole control and freedom to operate commercially with respect to Plavix® in the United States and Puerto Rico. Since March 2020, Sanofi has recognized in its consolidated financial statements the revenues and expenses generated by Plavix® in these two territories.

On April 6, 2020, Sanofi announced that it had finalized the planned restructuring related to **Praluent®** (alirocumab) with Regeneron Pharmaceuticals, Inc. (“Regeneron”). Effective April 1, 2020, Sanofi has sole responsibility for Praluent® outside the United States, while Regeneron has sole responsibility for Praluent® in the United States. The restructuring simplifies the antibody collaboration between the companies, increases efficiency, and streamlines operations for Praluent®. Although each company has responsibility for supplying Praluent® in its respective territory, the companies have entered into agreements to support manufacturing needs in the near term. Sanofi had previously announced its intention to restructure the antibody collaboration on Praluent® and Kevzara® (sarilumab) in December 2019.

On May 29, 2020, Sanofi announced the closing of its sale of 13 million shares of **Regeneron** common stock through a registered offering at a price of $515 per share. This included a previously-announced overallotment option, which was fully exercised by the underwriters. In addition, Sanofi announced the completion of Regeneron's repurchase of 9.8 million shares or approximately $5 billion in common stock directly from Sanofi. As a result of the offering, Sanofi has sold its entire equity investment in Regeneron (except for 400,000 Regeneron shares initially retained by Sanofi to support its ongoing collaboration with Regeneron) for total gross proceeds of $11.7 billion. Consequently, Sanofi’s equity interest in Regeneron ceased to be accounted for by the equity method. The registered offering and share repurchase will not affect the ongoing collaboration between Sanofi and Regeneron: the two companies have had a successful and long-standing clinical and commercial collaboration dating back to 2003 that has resulted in five approved treatments to date, with additional candidates currently in clinical development.

On June 16, 2020, Sanofi announced that it is investing in France to **increase its vaccine research and production capacities**, and to respond to future pandemic risks. In line with the corporate strategy presented in December 2019, Sanofi is investing €610 million to create a new flexible, digitalized production site and a research center in France, both dedicated to vaccines. Sanofi’s investment in vaccine production in France involves the creation of an Evolutive Vaccine Facility (EVF) in Neuville-sur-Saône. This state-of-the-art

industrial site will use the latest innovative vaccine production technologies. The project represents an investment of €490 million over a five-year period, and is expected to create 200 new jobs. Building this plant will enable Sanofi Pasteur, Sanofi's global vaccines entity, to be the first pharmaceutical manufacturer to benefit from such a facility, and will help secure vaccine supplies in France and the rest of Europe in the event of new pandemics. Sanofi is also investing €120 million to create a new R&D center in France, on the Sanofi Pasteur site at Marcy-l'Étoile. This state-of-the-art digitized facility will house biosecurity level 3 (BSL 3) laboratories for the development of vaccines against emerging diseases and pandemic risks, and aims to set a global standard for pre-clinical research and pharmaceutical and clinical development.

On June 23, 2020, Sanofi Pasteur and **Translate Bio** announced they had expanded their existing 2018 collaboration and license agreement to develop mRNA vaccines for infectious diseases. Under the terms of the expanded agreement, Translate Bio received a total upfront payment of $425 million, consisting of a $300 million cash payment and a private placement equity investment of $125 million at $25.59 per share, representing a 50% premium to the 20-day moving average share price prior to signing. Translate Bio will also be eligible for potential future milestones and other payments of up to $1.9 billion, including $450 million of milestones under the 2018 agreement. Of those potential milestones and other payments, approximately $360 million are anticipated over the next several years, inclusive of COVID-19 vaccine development milestones (under the collaboration announced on March 27, 2020 as described below). Translate Bio is also eligible to receive tiered royalty payments based upon worldwide sales of the developed vaccines. Sanofi Pasteur will pay for all costs during the collaboration term. Under this agreement Sanofi Pasteur will receive exclusive worldwide rights for the infectious disease vaccines developed.

In early July 2020, Sanofi entered into an exclusive license agreement with **Kiadis Pharma N.V.**, a clinical-stage biopharmaceutical company developing natural killer (NK) cell therapies for patients with potentially life-threatening diseases, for Kiadis' previously undisclosed K-NK004 program. The agreement covers Kiadis' proprietary CD38 knock out (CD38KO) K-NK therapeutic for combination with anti-CD38 monoclonal antibodies including Sarclisa®, Sanofi's recently approved therapy for patients with multiple myeloma. Sanofi also obtained exclusive rights to use Kiadis' K-NK platform for two undisclosed pre-clinical programs. As part of the agreement, Kiadis will receive a €17.5 million upfront payment and will be entitled to receive up to €857.5 million upon Sanofi attaining specified preclinical, clinical, regulatory and commercial milestones. Kiadis will also receive double-digit royalties based on commercial sales of approved products resulting from the agreement. On November 2, 2020, Sanofi and Kiadis entered into a definitive agreement under which Sanofi will make a public offer (subject to satisfaction of certain customary conditions) to acquire the entire share capital of Kiadis for €5.45 per share, representing an aggregate equity value of approximately €308 million (adjusted for the value of share warrants that may be exercised in shares or settled in cash based on the Black-Scholes valuation on or after the day immediately following the public announcement of change of control).

Also in early July 2020, Sanofi and **Kymera Therapeutics Inc.** signed a multi-program strategic collaboration agreement to develop and commercialize first-in-class protein degrader therapies targeting IRAK4 in patients with immune-inflammatory diseases. The companies will also partner on a second earlier stage program. Kymera will receive $150 million in cash upfront and may receive more than $2 billion in potential milestones, as well as royalty payments. Kymera retains the option to participate in US development and commercialization for both programs subject to its having an equal share in the costs, profits and losses, and to co-promote partnered products in the US.

On August 17, 2020, Sanofi and **Principia Biopharma Inc.**, a late-stage biopharmaceutical company focused on developing treatments for autoimmune diseases, entered into a definitive agreement under which Sanofi was to acquire all the outstanding shares of Principia for $100 per share in cash, representing an aggregate equity value of approximately $3.68 billion (on a fully diluted basis). The transaction was approved unanimously by the Boards of Directors of Sanofi and Principia, and was completed on September 28, 2020.

On December 9, 2020, Sanofi announced the signing of its first two **sustainability-linked** revolving credit facilities. The facilities are part of our strategy to secure long-term financing sources, and build in an adjustment mechanism that links the credit spread to the attainment of two sustainable development performance indicators: our contribution to polio eradication, and the reduction in our carbon footprint. What is innovative about those facilities is our commitment to invest a fixed annual contribution to fund environmental or social projects and maximize our impact on the two objectives, via the activities of the Sanofi Espoir Foundation or our Planet Mobilization program. If we meet our annual sustainable development targets, the lender banks will grant a reduction in our credit spread to support our contribution.

On December 10, 2020, Sanofi signed a renewed partnership agreement with the **World Health Organization** (WHO), extending a 20-year collaboration to fight some of the most neglected tropical diseases and supporting the WHO in its commitment to sustainably eliminate sleeping sickness before 2030. As part of this new five-year commitment, we will provide financial support for disease management, to include screening of populations, disease awareness campaigns, capacity building, and drug donations.

As well as continuing to deliver on its strategy, Sanofi played a leading role in the **fight against COVID-19** on multiple fronts during 2020:

- On February 18, 2020, Sanofi announced that it would leverage previous development work for a vaccine against severe acute respiratory syndrome (SARS) to attempt to unlock a fast path forward for developing a COVID-19 vaccine. Sanofi is collaborating with **BARDA** (the US Biomedical Advanced Research and Development Authority), part of the Office of the Assistant Secretary for Preparedness and Response within the US Department of Health and Human Services, expanding Sanofi's long-standing partnership with BARDA.
- On March 27, 2020, Sanofi Pasteur (our vaccines Global Business Unit) and **Translate Bio**, a clinical-stage messenger RNA (mRNA) therapeutics company, announced a collaboration to develop a novel mRNA vaccine for the virus responsible for COVID-19. This collaboration leverages an existing agreement from 2018 between the two companies to develop mRNA vaccines for infectious diseases. Translate Bio has begun to produce multiple mRNA constructs and will use its mRNA platform to discover, design, and manufacture a number of SARS-CoV-2 vaccine candidates. Sanofi will provide deep vaccine expertise and support from its external research networks to advance identified vaccine candidates for potential further development. On October 15, 2020, Sanofi and Translate Bio announced that preclinical evaluation of MRT5500 had demonstrated a favorable immune response profile against SARS-CoV-2. Those data support the continuation of clinical development for MRT5500, and the launch of a Phase I/II clinical trial is expected to start in the first quarter of 2021.
- On April 14, 2020, **Sanofi** and **GSK** announced that they had signed a letter of intent to develop an adjuvanted vaccine for COVID-19, using innovative technology from both companies to help address the pandemic. Sanofi is contributing its spike-protein COVID-19 antigen, which is based on recombinant DNA technology. GSK is contributing its pandemic adjuvant technology. On July 29, 2020,

Sanofi and GSK reached an agreement with the **UK government** for the supply of 60 million doses of their COVID-19 vaccine, subject to final contract. On July 31, 2020, Sanofi and GSK announced advanced discussions with the **European Commission** for the supply of up to 300 million doses of their COVID-19 vaccine, with the doses to be manufactured in European countries including France, Belgium, Germany and Italy. On the same date, Sanofi and GSK announced a collaborative effort with the US government to accelerate the development of the vaccine. The collaboration with the US Department of Health and Human Services and Department of Defense will help fund development activities and the scale-up of Sanofi and GSK manufacturing capabilities in the United States for the recombinant protein-based, adjuvanted vaccine, resulting in a significant increase in capacity for the two companies. The US government agreed to provide up to $2.1 billion, more than half of which is to support further development of the vaccine, including clinical trials, with the remainder used for manufacturing scale-up and delivery of an initial 100 million doses of the vaccine. Sanofi is to receive the majority of the funding from the US government, which has a further option for the supply of an additional 500 million doses in the longer term. The collaboration will help the US government's Operation Warp Speed goals, and provide millions of doses of a safe and effective COVID-19 vaccine. On September 22, 2020, Sanofi and GSK signed agreements with the **Government of Canada** for the supply of up to 72 million doses of an adjuvanted COVID-19 vaccine, beginning in 2021. On October 28, 2020, Sanofi and GSK signed a statement of intent with Gavi, the legal administrator of the **COVAX Facility**, a global risk-sharing mechanism for pooled procurement and equitable distribution of eventual COVID-19 vaccines. On December 11, 2020, Sanofi and GSK announced a delay in their adjuvanted recombinant protein-based COVID-19 vaccine program, in order to improve immune response in the elderly. **Interim Phase I/II results** showed an immune response comparable to patients who recovered from COVID-19 in adults aged 18 to 49 years, but an insufficient response in older adults demonstrated the need to optimize the concentration of antigen in order to provide high-level immune response across all age groups. Therefore, we initiated a new Phase II study with an improved antigen formulation in February 2021, with support from the US Biomedical Advanced Research and Development Authority (BARDA). A Phase III trial will follow, to start in the second quarter of 2021. The vaccine is now expected to be available in the fourth quarter of 2021, subject to successful completion of the development plan.

In Pharmaceuticals, highlights of our research and development activities in 2020 included launches of Phase III studies of **venglustat** (GZ402671), an orally administered glucosylceramide synthase inhibitor, in the treatment of GM2 gangliosidoses; **Sarclisa**® (isatuximab-irfc), in the treatment of smoldering multiple myeloma; **tolebrutinib** (SAR442168, a BTK inhibitor) in the treatment of multiple sclerosis; **SAR408701** (an antibody drug conjugate that binds to CEACAM-5), as a second and third line treatment for non small cell lung cancer; **amcenestrant** (SAR439859, a selective estrogen receptor degrader), as a treatment for breast cancer in combination with palbociclib; **Libtayo**® (cemiplimab) as a neoadjuvant treatment for squamous cell skin cancer; **Dupixent**® (dupilumab) in the treatment of allergic bronchopulmonary aspergillosis, chronic spontaneous urticaria, prurigo nodularis, and eosinophilic esophagitis in children; and **fitusiran** (siRNA therapeutic agent) in the treatment of hemophilia A and B in children aged 2 to 11 years.

In 2020, we obtained marketing authorizations for a number of our products. In the United States, the Food and Drug Administration (FDA) approved **Sarclisa**® (isatuximab-irfc) in combination with pomalidomide and dexamethasone (pom-dex) for the treatment of adults with relapsed refractory multiple myeloma (RRMM). The European Commission and the Japanese healthcare authorities (PMDA) also approved Sarclisa® for the treatment of adults with RRMM. The FDA and the European Commission approved **Dupixent**® (dupilumab) for children aged 6 to 11 years with moderate-to-severe atopic dermatitis. The Chinese National Medical Products Administration (NMPA) approved Dupixent® for the treatment of adults with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies, or when those therapies are not advisable. This came after the NMPA identified Dupixent® as an overseas medicine urgently needed in clinical practice, leading to an expedited review and approval process. Dupixent® was also approved by the PDMA in Japan for chronic rhinosinusitis with nasal polyposis. The NMPA approved **Aldurazyme**® in China for mucopolysaccharidosis type 1. **Soliqua**® was approved in Japan for the treatment of type 2 diabetes. The European Commission granted marketing approval for insulin aspart, a biosimilar used to improve blood sugar control in people with diabetes. In China, the NMPA approved **Toujeo**® for the treatment of type 1 and 2 diabetes. **MenQuadfi™**, a conjugate meningococcal vaccine to prevent invasive meningococcal infections (serogroups A, C, W and Y), was approved by the FDA for ages 2 and older, and by the European Commission for ages 12 months and older. Also approved by the European Commission were **Efluelda**®, an inactivated high-dose quadrivalent influenza vaccine; and **Supemtek**®, a quadrivalent (four-strain) recombinant influenza vaccine for the prevention of influenza in adults aged 18 years and older.

For further information about the pharmaceutical products and vaccines we sell, and about our research and development portfolio, refer to "- Item 4.B. — Business Overview".

Our net sales for 2020 amounted to €36,041 million, 0.2% lower than in 2019. At constant exchange rates (CER[(1)]), net sales rose by 3.3%. Solid performances for Dupixent®, and the Vaccines segment, and more generally for all franchises in our Specialty Care global business unit across all geographies, more than offset lower sales in our Diabetes and Cardiovascular & Established Prescription Products franchises.

Net income attributable to equity holders of Sanofi amounted to €12,314 million, compared with €2,806 million in 2019, mainly reflecting (i) the €7,382 million gain on the divestment of Regeneron shares following the transaction of May 29, 2020 (see Note D.1. to our consolidated financial statements, included at Item 18. of this annual Report on Form 20-F) and (ii) the impairment losses taken against intangible assets in 2019, which amounted to €3,604 million due to the impact of write-downs of Eloctate® assets. Earnings per share was €9.82, compared with €2.24 in 2019. Business net income[(2)] was €7,347 million, up 4.2% on 2019, while business earnings per share (business EPS[(2)]) was 3.9% higher than in 2019 at €5.86.

As of December 31, 2020, we had reduced our net debt[(3)] to €8,790 million (versus €15,107 million as of December 31, 2019), due in particular to cash inflows from investing activities during the year, and more specifically to the net proceeds from our sale of Regeneron shares on May 29, 2020. At the Annual General Meeting on April 30, 2021, we will ask our shareholders to approve a dividend of €3.20 per share for the 2020 financial year, representing a payout of 54.6% of our business net income.

(1) Non-GAAP financial measure: see definition in "- A.1.6. Presentation of Net Sales" below.
(2) Non-GAAP financial measure: see definition in "- A.1.5. Segment Information — 3. Business Net Income" below.
(3) Non-GAAP financial measure: see definition in "- B. Liquidity and Capital Resources" below.

A.1.2. Impacts of Competition from Generics and Biosimilars

Some of our flagship products continued to suffer sales erosion in 2020 under the impact of competition from generics and biosimilars. We do not believe it is possible to state with certainty what level of net sales would have been achieved in the absence of generic competition. A comparison of our consolidated net sales for the years ended December 31, 2020 and 2019 (see "- A.2. Results of Operations — Year Ended December 31, 2020 Compared with Year Ended December 31, 2019" below) for the main products affected by generic and biosimilar competition shows a loss of €525 million of net sales on a reported basis. Other parameters may have contributed to the loss of sales, such as a fall in the average selling price of certain products (e.g. Lantus®).

The table below sets forth the impact by product.

(€ million)	2020	2019 [(a)]	Change on a reported basis	Change on a reported basis (%)
Aprovel® Europe	100	113	(13)	-11.5%
Lantus® Europe	537	599	(62)	-10.4%
Lovenox® Europe	656	730	(74)	-10.1%
Plavix® Europe	129	142	(13)	-9.2%
Renagel®/Renvela® Europe	46	55	(9)	-16.4%
Lantus® United States	929	1,149	(220)	-19.1%
Lovenox® United States	30	33	(3)	-9.1%
Renagel®/Renvela® United States	64	133	(69)	-51.9%
Allegra® Japan	81	115	(34)	-29.6%
Amaryl® Japan	12	15	(3)	-20.0%
Aprovel® Japan	27	21	6	+28.6%
Lantus® Japan	21	25	(4)	-16.0%
Plavix® Japan	105	131	(26)	-19.8%
Taxotere® Japan	6	7	(1)	-14.3%
Total	**2,743**	**3,268**	**(525)**	**-16.1%**

(a) With effect from January 1, 2020, the geographical split of net sales is aligned on Sanofi's new organizational structure: Europe (including Israel and Ukraine), the United States, and Rest of the World. The presentation of 2019 figures has been amended to facilitate year-on-year comparisons.

We expect the erosion caused by generic competition to continue in 2021, with a negative impact on our net income. The products likely to be impacted in 2021 include those that already faced generic competition in 2020, but whose sales can reasonably be expected to be subject to further sales erosion in 2021 (see products listed in the table above). In addition, we expect generic competition for Jevtana® from the end of March 2021 in Europe.

In 2020, the aggregate consolidated net sales of those products in Europe, the United States and Japan were €2,743 million; this comprised €1,023 million in the United States (including €929 million in net sales of Lantus® and €64 million in net sales of Renagel®/Renvela®); €1,468 million in Europe; and €252 million in Japan. The negative impact on our 2021 net sales is likely to represent a substantial portion of those sales, but the actual impact will depend on a number of factors such as the prices at which the products are sold and potential litigation outcomes.

In China, the authorities have implemented a range of healthcare cost containment measures, including a Volume Based Procurement (VBP) program (see also "Item 4. — B.6.4. Pricing & Reimbursement"). A large number of molecules were selected to submit tenders under the VBP program, with the successful bidders being awarded a high level of market share in return for offering lower prices. Sanofi successfully tendered for Plavix® and Aprovel® family products in 2020, but decided not to submit a tender for Amaryl®. Consequently, net sales of those three products in China have decreased significantly since the VBP started at the end of 2019, with the increase in volumes for Plavix® and Aprovel® only partly offsetting the effect of lower prices (see also "Item 5. — A.2.1. Sales").

A.1.3. Purchase Accounting Effects

Our results of operations and financial condition for the years ended December 31, 2020, and 2019 have been significantly affected by our past acquisitions (acquisition of Aventis in August 2004, acquisition of Genzyme in April 2011, exchange of our Animal Health business (Merial) for Boehringer Ingelheim's Consumer Healthcare business in January 2017, acquisition of Bioverativ in 2018, and certain other transactions). See "- A.1.11. Critical accounting and reporting policies — Business combinations" below for an explanation of the impact of business combinations on our results of operations.

The Bioverativ business combination has generated significant amortization of intangible assets (€331 million in 2020, and €488 million in 2019) and impairment losses on intangible assets (€2,803 million in 2019). The Genzyme business combination has generated significant amortization of intangible assets (€549 million in 2020, and €727 million in 2019) and impairment losses on intangible assets (€163 million in 2019). The exchange of Merial for Boehringer Ingelheim's Consumer Healthcare business has generated amortization of intangible assets (€202 million in 2020, and €240 million in 2019) and impairment losses on intangible assets (€352 million in 2019, related to Zantac®).

In order to isolate the purchase accounting effects of all acquisitions and certain other items, we use a non-GAAP financial measure that we refer to as "business net income" (see definition in "- A.1.5. Segment Information — 3. Business Net Income" below).

A.1.4. Sources of Revenues and Expenses

Revenues. Revenue arising from the sale of goods is presented in the income statement within ***Net sales***. Net sales comprise revenue from sales of pharmaceutical products, consumer health care products, active ingredients and vaccines, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities. Returns, discounts, incentives and rebates are recognized in the period in which the underlying sales are recognized, as a reduction of sales revenue. See Note B.13.1. to our consolidated financial statements included at Item 18. of this annual report. We sell pharmaceutical products and vaccines directly, through alliances, and by licensing arrangements throughout the world. When we sell products directly, we record sales revenues as part of our consolidated net sales. When we sell products through alliances, the revenues reflected in our consolidated financial statements are based on the contractual arrangements governing those alliances. For more information about our alliances, see "- A.1.7. Financial Presentation of Alliances" below. When our products are sold by licensing arrangements, we receive royalty income that we record in ***Other revenues***. The sales of non-Sanofi products of our US based entity VaxServe are also presented in ***Other revenues***; see Note B.13.2. to the consolidated financial statements included at Item 18. of this annual report.

Cost of Sales. Our cost of sales consists primarily of the cost of purchasing raw materials and active ingredients, labor and other costs relating to our manufacturing activities, packaging materials, payments made under licensing agreements and distribution costs. We have license agreements under which we manufacture, sell and distribute products that are patented by other companies. When we pay royalties, we record them in ***Cost of sales***.

Operating Income. Our operating income reflects our revenues, our cost of sales and the remainder of our operating expenses, the most significant of which are research and development expenses and selling and general expenses. For our operating segments, we also measure our results of operations through an indicator referred to as "Business Operating Income," which we describe below under " A.1.5. Segment Information — 2/Business Operating Income."

A.1.5. Segment Information

1/ Operating segments

In accordance with IFRS 8 (Operating Segments), the segment information reported by Sanofi is prepared on the basis of internal management data provided to the Chief Executive Officer, who is the chief operating decision maker. The performance of those segments is monitored individually using internal reports and common indicators. The operating segment disclosures required under IFRS 8 are provided in Notes B.26. and D.35. ("Segment Information") to our consolidated financial statements, included at Item 18. of this annual report.

Sanofi has three operating segments: Pharmaceuticals, Vaccines, and Consumer Healthcare.

The Pharmaceuticals segment comprises, for all geographical territories, the commercial operations of the following global franchises: Specialty Care (Dupixent®, Multiple Sclerosis, Neurology, Other Inflammatory Diseases & Immunology, Rare Diseases, Oncology, and Rare Blood Disorders) and General Medicines (Diabetes, Cardiovascular and Established Prescription Products), together with research, development and production activities dedicated to the Pharmaceuticals segment. This segment also includes associates whose activities are related to pharmaceuticals. Following the transaction of May 29, 2020, Regeneron is no longer an associate of Sanofi (see Note D.1. to our consolidated financial statements). Consequently, the Pharmaceuticals segment no longer includes Sanofi's equity-accounted share of Regeneron's profits for all the periods presented in this Annual Report on Form 20-F.

The Vaccines segment comprises, for all geographical territories, the commercial operations of Sanofi Pasteur, together with research, development and production activities dedicated to vaccines.

The Consumer Healthcare segment comprises, for all geographical territories, the commercial operations for Sanofi's Consumer Healthcare products, together with research, development and production activities dedicated to those products.

Inter-segment transactions are not material.

The costs of Sanofi's global support functions (External Affairs, Finance, Human Resources, Legal Affairs, Information Solutions & Technologies, Sanofi Business Services, etc.) are mainly managed centrally at group-wide level. The costs of those functions are presented within the "Other" category. That category also includes other reconciling items such as retained commitments in respect of divested activities.

In 2020, Sanofi adapted its management reporting to reflect its new organizational structure. This resulted in cost reallocations between the Pharmaceuticals, Consumer Healthcare and Vaccines segments and the "Other" category, and product reallocations between Pharmaceuticals and Consumer Healthcare. Expenses relating to Global Medical Affairs, allocated to the "Other" category in the old management reporting structure, were reallocated to the Pharmaceuticals segment.

2/ Business operating income

We report segment results on the basis of "Business operating income". This indicator is used internally by Sanofi's chief operating decision maker to measure the performance of each operating segment and to allocate resources. For a definition of "Business operating income", and a reconciliation between that indicator and ***Income before tax and investments accounted for using the equity method***, refer to Note D.35. to our consolidated financial statements.

Following the transaction of May 29, 2020, Regeneron is no longer an associate of Sanofi (see Note D.1. to our consolidated financial statements). Consequently, the definition of the "Business operating income" indicator has been adjusted, and no longer includes Sanofi's share of the net income of Regeneron. This means that the ***Share of profit/(loss) from investments accounted for using the equity method*** line in the table reconciling ***Operating income*** (as shown in the income statement) to "Business operating income" no longer includes the equity-accounted share of profits from Regeneron. The comparatives presented for 2019 have been restated to reflect that adjustment. In addition, the gain arising on the divestment of the equity investment in Regeneron is not included in "Business operating income", with the exception of the gain on the remeasurement of the 400,000 retained shares at market value at the transaction date.

In addition, with effect from January 1, 2020 "Business operating income" includes depreciation charged against right-of-use assets recognized under IFRS 16 (Leases), applicable since January 1, 2019, and excludes rental expenses previously recognized under IAS 17. In the interests of consistency, the "Business operating income" and "Business operating income margin" figures presented for 2019 have been restated to include the effects of IFRS 16, and of certain expenses and income presented differently for segment reporting purposes to align on Sanofi's new 2020 management reporting structure (see "— A.1.5,1. — Operating Segments", above).

Our "Business operating income" for 2020 amounted to €9,762 million, versus €9,349 million in 2019, while our "Business operating income margin" was 27.1%, versus 25.9% in 2019. "Business operating income margin" is a non-GAAP financial measure, which we define as the ratio of our "Business operating income" to ***Net sales***.

Because our "Business operating income" and "Business operating income margin" are not standardized measures, they may not be directly comparable with the non-GAAP financial measures of other companies using the same or similar non-GAAP financial measures. Although management uses those non-GAAP measures to set goals and measure performance, they have no standardized meaning prescribed by IFRS.

3/ Business net income

We believe that understanding of our operational performance by our management and our investors is enhanced by reporting "Business net income". This non-GAAP financial measure represents "Business operating income", less net financial expenses and the relevant income tax effects.

On May 29, 2020, Sanofi sold its entire equity investment in Regeneron (except for 400,000 Regeneron shares retained by Sanofi) for gross sale proceeds of $11.7 billion (see Note D.1. to our consolidated financial statements). As a result, the definition of the non-GAAP financial measure "Business net income" has been adjusted such that ***Share of profit/(loss) from investments accounted for using the equity method*** now excludes the effects of applying the equity method to the investment in Regeneron. The effects of applying the equity method to the investment in Regeneron up to and including May 29, 2020 are now shown on a separate line in the table reconciling "Business net income" to ***Net income attributable to equity holders of Sanofi***. The figures presented for 2019 have been restated to reflect that adjustment.

In addition, with effect from January 1, 2020 "Business net income" includes depreciation charged against right-of-use assets recognized under IFRS 16 (Leases), applicable since January 1, 2019, and excludes rental expenses previously recognized under IAS 17.

"Business net income" for 2020 was €7,347 million, 4.2% higher than in 2019 (€7,050 million), and represented 20.4% of net sales (compared with 19.5% in 2019).

We also report "Business earnings per share" ("Business EPS"), a non-GAAP financial measure we define as "Business net income" divided by the weighted average number of shares outstanding. "Business EPS" was €5.86 for 2020, 3.9% higher than the 2019 figure of €5.64, based on an average number of shares outstanding of 1,253.6 million for 2020 and 1,249.9 million for 2019.

The table below reconciles our "Business operating income" to our "Business net income":

(€ million)	December 31, 2020	December 31, 2019 (a)
Business operating income	**9,762**	**9,349**
Financial income and expenses	(337)	(303)
Income tax expense	(2,078)	(1,996)
Business net income	**7,347**	**7,050**

(a) 2019 figures have been restated to exclude Sanofi's equity-accounted share of Regeneron's net profits, which amounted to €411 million (see Note D.1. to our consolidated financial statements) and to include the effects of IFRS 16 for comparative purposes.

We define "Business net income" as ***Net income attributable to equity holders of Sanofi*** determined under IFRS, excluding the following items:

- amortization and impairment losses charged against intangible assets (other than software and other rights of an industrial or operational nature);
- fair value remeasurements of contingent consideration relating to business combinations or divestments;
- other impacts associated with acquisitions (including impacts relating to investments accounted for using the equity method);
- restructuring costs and similar items (presented within the line item ***Restructuring costs and similar items)***;
- other gains and losses, including gains and losses on major disposals of non-current assets (presented within the line item ***Other gains and losses, and litigation***);
- the gain on the divestment of Regeneron shares on May 29, 2020, not including the gain on the remeasurement of the 400,000 retained shares at market value as of that date (see Note D.1. to our consolidated financial statements);
- other costs and provisions related to litigation (presented within the line item ***Other gains and losses, and litigation***);
- the tax effects of the items listed above, and the effects of major tax disputes;
- the effects of the discontinuation of accounting by the equity method for the investment in Regeneron (see Note D.1. to our consolidated financial statements); and
- the portion attributable to non-controlling interests of the items listed above.

The table below reconciles our "Business net income" to ***Net income attributable to equity holders of Sanofi***:

(€ million)	2020	2019 [(a)]
Net income attributable to equity holders of Sanofi	**12,314**	**2,806**
Amortization of intangible assets[(b)]	1,681	2,146
Impairment of intangible assets[(c)]	330	3,604
Fair value remeasurement of contingent consideration	(124)	(238)
Expenses arising from the impact of acquisitions on inventories	53	3
Restructuring costs and similar items	1,064	1,062
Other gains and losses, and litigation[(d)]	(136)	(327)
Gain on divestment of Regeneron shares on May 29, 2020[(e)]	(7,225)	—
Tax effects of the items listed above:	(264)	(1,857)
• *amortization and impairment of intangible assets*	*(541)*	*(1,409)*
• *fair value remeasurement of contingent consideration*	*39*	*(6)*
• *expenses arising from the impact of acquisitions on inventories*	*(8)*	—
• *restructuring costs and similar items*	*(293)*	*(311)*
• *gain on divestment of Regeneron shares on May 29, 2020*	*477*	—
• *other tax effects*	*62*	*(131)*
Share of items listed above attributable to non-controlling interests	(3)	(4)
Investments accounted for using the equity method: restructuring costs and expenses arising from the impact of acquisitions	(30)	165
Effect of discontinuation of equity method for investment in Regeneron[(f)]	(313)	(411)
Items relating to the Animal Health business[(g)]	—	101
Business net income	**7,347**	**7,050**
Average number of shares outstanding (million)	1,253.6	1,249.9
Basic earnings per share (€)	9.82	2.24
Reconciling items per share (€)	(3.96)	3.40
Business earnings per share (€)	5.86	5.64

(a) "Business net income" for 2019 has been restated to exclude Sanofi's share of profits from its equity investment in Regeneron, and to include the effects of IFRS 16 for comparative purposes.

(b) Includes amortization expense related to accounting for business combinations: €1,592 million in 2020 and €2,044 million in 2019.

(c) For 2020, this line includes impairment losses against in-house R&D programs within the Specialty Care GBU, and the discontinuation of certain R&D programs and collaboration agreements in Diabetes, in line with the strategy announced by Sanofi in December 2019. For 2019, this line includes impairment losses of €2,803 million against Eloctate® franchise assets; €352 million against Zantac®; and €280 million against in-house and partnered R&D programs.

(d) For 2020, this line mainly comprises the gain on the sale of the Seprafilm® activity to Baxter. For 2019, it consists mainly of a gain arising on settlement of litigation.

(e) This line includes the gain on the sale of (i) 13 million shares of Regeneron common stock in the registered public offering and (ii) the 9.8 million shares repurchased by Regeneron, but does not include the gain arising from the remeasurement of the 400,000 retained shares at market value as of May 29, 2020.

(f) "Business net income" no longer includes Sanofi's share of profits from its equity investment in Regeneron (see Note D.1. to our consolidated financial statements), which is reflected on this line.

(g) This line shows the residual impacts of the divestment of our Animal Health business.

The most significant reconciling items between "Business net income" and ***Net income attributable to equity holders of Sanofi*** relate to (i) the purchase accounting effects of our acquisitions and business combinations, particularly the amortization and impairment of intangible assets (other than software and other rights of an industrial or operational nature) and (ii) the impacts of restructurings or transactions regarded as non-recurring, where the amounts involved are particularly significant. We believe that excluding those impacts enhances an investor's understanding of our underlying economic performance, because it gives a better representation of our recurring operating performance.

We believe that eliminating charges related to the purchase accounting effect of our acquisitions and business combinations (particularly amortization and impairment of some intangible assets) enhances comparability of our ongoing operating performance relative to our peers. Those intangible assets (principally rights relating to research, development and commercialization of products) are accounted for in accordance with IFRS 3 (Business Combinations) and hence may be subject to remeasurement. Such remeasurements are not made other than in a business combination.

We also believe that eliminating the other effects of business combinations (such as the incremental cost of sales arising from the workdown of acquired inventories remeasured at fair value in business combinations) gives a better understanding of our recurring operating performance.

Eliminating restructuring costs and similar items enhances comparability with our peers because those costs are incurred in connection with reorganization and transformation processes intended to optimize our operations.

Finally, we believe that eliminating the effects of transactions that we regard as non-recurring and that involve particularly significant amounts (such as major gains and losses on disposals, and costs and provisions associated with major litigation and other major non-recurring items) improves comparability from one period to the next.

We remind investors, however, that "Business net income" should not be considered in isolation from, or as a substitute for, ***Net income attributable to equity holders of Sanofi*** reported in accordance with IFRS. In addition, we strongly encourage investors and potential investors not to rely on any single financial measure but to review our financial statements, including the notes thereto, carefully and in their entirety.

We compensate for the material limitations described above by using "Business net income" only to supplement our IFRS financial reporting and by ensuring that our disclosures provide sufficient information for a full understanding of all adjustments included in "Business net income".

Because our "Business net income" and "Business EPS" are not standardized measures, they may not be directly comparable with the non-GAAP financial measures of other companies using the same or similar non-GAAP financial measures.

A.1.6. Presentation of Net Sales

In the discussion below, we present our consolidated net sales for 2020, and 2019. We analyze our net sales by various categories including segment, Global Business Units, franchise, product, and geographical region. In addition to reported net sales, we analyze non-GAAP financial measures designed to isolate the impact on our net sales of currency exchange rates and changes in the structure of our group.

When we refer to changes in our net sales at constant exchange rates (CER), that means that we have excluded the effect of exchange rates by recalculating net sales for the relevant period using the exchange rates that were used for the previous period.

When we refer to changes in our net sales on a constant structure basis, that means that we eliminate the effect of changes in structure by restating the net sales for the previous period as follows:

- by including sales generated by entities or product rights acquired in the current period for a portion of the previous period equal to the portion of the current period during which we owned them, based on sales information we receive from the party from whom we make the acquisition;
- similarly, by excluding sales for a portion of the previous period when we have sold an entity or rights to a product in the current period; and
- for a change in consolidation method, by recalculating the previous period on the basis of the method used for the current period.

A presentation of consolidated net sales for 2019 compared with 2018 is available in our Form 20-F filed on March 5, 2020, Item 5., section "A.2.1. Net Sales".

As described below in section "A.2.1.Net Sales", to reflect the new organizational structure adopted by Sanofi on January 1, 2020, figures for 2019 disclosed in the present report have been restated to take account of transfers of products between Global Business Units.

Sanofi is now organized into three major Global Business Units (GBUs) that underpin the corporate strategy: the **Specialty Care** GBU (Dupixent®, Multiple Sclerosis, Neurology, Other Inflammatory Diseases & Immunology, Rare Diseases, Oncology, and Rare Blood Disorders); the **Vaccines** GBU; and the **General Medicines** GBU (Diabetes, Cardiovascular and Established Prescription Products). The **Consumer Healthcare** GBU has become a standalone commercial entity with its own manufacturing and R&D capabilities. Each GBU now includes its own contribution to emerging markets sales. The new structure has led to some products being transferred, and some franchises being combined. Some mature products formerly in the Oncology franchise (Zaltrap®, Mozobil®, Thymoglobulin®, Clolar®, Fludara®, Taxotere®, Eloxatin® and Campath®) have been transferred to the Established Prescription Products franchise in the General Medicines GBU. The Cardiovascular franchise (Praluent® and Multaq®) and the Established Prescription Products franchise have been combined. Some products formerly in the Consumer Healthcare GBU have been transferred to the General Medicines GBU and vice versa, with virtually no effect on the sales of the two GBUs. Finally, endocrinology products (Thyrogen®, Caprelsa®) have been transferred from the Rare Diseases franchise to the Established Prescription Products franchise.

In addition, with effect from January 1, 2020, the geographical split of net sales is aligned on Sanofi's new organizational structure: Europe, the United States, and Rest of the World. The Emerging Markets zone is now included in the Rest of the World region, apart from Israel and Ukraine which are now included in the Europe region. The presentation of our 2019 figures has been amended to facilitate year-on-year comparisons.

A.1.7. Financial Presentation of Alliances

We have entered into a number of alliances for the development, co-promotion and/or co-marketing of our products. We believe that a presentation of our two principal alliances is useful to an understanding of our financial statements.

The financial impact of the alliances on our income statement is described in "- Results of Operations — Year Ended December 31, 2020 Compared with Year Ended December 31, 2019", in particular in "- Net Sales", "- Other Revenues", "- Share of Profit/Loss from Investments Accounted for using the Equity Method" and "- Net Income Attributable to Non-Controlling Interests".

1/ Alliance arrangements with Regeneron Pharmaceuticals Inc. (Regeneron)

Collaboration agreements on human therapeutic antibodies

In November 2007, Sanofi and Regeneron signed two agreements (amended in November 2009) relating to human therapeutic antibodies: (i) the Discovery and Preclinical Development Agreement, and (ii) the License and Collaboration Agreement, relating to clinical development and commercialization. Under the License and Collaboration Agreement, Sanofi had an option to develop and commercialize antibodies discovered by Regeneron under the Discovery and Preclinical Development Agreement.

Discovery and development

Under the 2009 amended agreements, Sanofi funded the discovery and pre-clinical development of fully human therapeutic antibodies up to a maximum of $160 million per year through 2017. Because Sanofi decided not to exercise its option to extend the Discovery and Preclinical Development Agreement, that agreement expired on December 31, 2017.

Upon Sanofi's exercise of an option on an antibody under the Discovery and Preclinical Development Agreement, the antibody became a Licensed Product under the License and Collaboration Agreement, pursuant to which Sanofi and Regeneron co-develop the antibody with Sanofi initially being wholly responsible for funding the development program. On receipt of the first positive Phase III trial results for any antibody being developed under the License and Collaboration Agreement, the subsequent Phase III costs for that antibody are split 80% Sanofi, 20% Regeneron. Amounts received from Regeneron under those arrangements are recognized by Sanofi as a reduction in the line item ***Research and development expenses***. Co-development with Regeneron of the antibodies Dupixent®, Kevzara® and REGN3500 (SAR440340 – itepekimab) is ongoing under the License and Collaboration Agreement at this time.

Once a product begins to be commercialized, and provided that the share of quarterly results under the agreement represents a profit, Sanofi is entitled to an additional portion of Regeneron's profit-share (capped at 10% of Regeneron's share of quarterly profits) until Regeneron has paid 50% of the cumulative development costs incurred by the parties in the collaboration (see footnote g(ii) to the table provided in Note D.21.1. "Off balance sheet commitments relating to operating activities").

On the later of (i) 24 months before the scheduled launch date or (ii) the first positive Phase III trial results, Sanofi and Regeneron share the commercial expenses of the antibodies co-developed under the License and Collaboration Agreement.

Commercialization

Sanofi is the lead party with respect to the commercialization of all co-developed antibodies, and Regeneron has certain option rights to co-promote the antibodies. Sanofi recognizes all sales of the antibodies. Profits and losses arising from commercial operations in the United States are split 50/50. Outside the United States, Sanofi is entitled to between 55% and 65% of profits depending on sales of the antibodies, and bears 55% of any losses. The share of profits and losses due to or from Regeneron under the agreement is recognized within the line items ***Other operating income*** or ***Other operating expenses***, which are components of ***Operating income***. In addition, Regeneron is entitled to receive payments of up to $250 million contingent on the attainment of specified levels of aggregate sales on all antibodies outside the United States, on a rolling twelve-month basis.

As of September 30, 2020, sales of antibodies outside the United States exceeded $1.0 billion on a rolling twelve-month basis, triggering a payment by Sanofi to Regeneron of $50.0 million for the first sales milestone.

Amendments to the collaboration agreements

In January 2018, Sanofi and Regeneron signed a set of amendments to their collaboration agreements, including an amendment that allowed for the funding of additional programs on Dupixent® and REGN3500 (SAR440340) with an intended focus on extending the current range of indications, finding new indications, and improving co-morbidity between multiple pathologies.

Effective April 1, 2020, Sanofi and Regeneron signed a Cross License and Commercialization Agreement for Praluent®, whereby Sanofi obtained sole ex-US rights to Praluent®, and Regeneron obtained sole US rights to Praluent® along with a right to 5% royalties on Sanofi's sales of Praluent® outside the United States. Each party is solely responsible for the development, manufacturing and commercialization of Praluent® in their respective territories. Although each company has responsibility for supplying Praluent® in its respective territory, the companies have entered into agreements to support manufacturing needs for each other.

Sanofi and Regeneron continue to investigate restructuring their collaboration for Kevzara®.

The Zaltrap® Manufacturing and Supply Agreement terminates on December 31, 2021. Regeneron and Sanofi are discussing a potential extension of such agreement.

The terms of the collaboration relating to Dupixent® (dupilumab) and to SAR440340 (REGN3500) are unchanged.

Immuno-oncology (IO) collaboration agreements

On July 1, 2015, Sanofi and Regeneron signed two agreements – the IO Discovery and Development Agreement and the IO License and Collaboration Agreement (IO LCA) – relating to new antibody cancer treatments in the field of immuno-oncology. As part of the agreements, Sanofi made an upfront payment of $640 million to Regeneron.

The two companies agreed to invest approximately $1 billion from discovery through proof of concept (POC) development (usually a Phase IIa study) of monotherapy and novel combinations of immuno-oncology antibody candidates to be funded 25% by Regeneron ($250 million) and 75% by Sanofi ($750 million). The two companies also agreed to reallocate $75 million (spread over three years) to immuno-oncology antibody research and development from Sanofi's $160 million annual contribution under their existing antibody Discovery and Preclinical Development Agreement.

An Amended IO Discovery Agreement, effective from December 31, 2018, was signed on January 2, 2019. It narrows the scope of the existing discovery and development activities conducted by Regeneron ("IO Development Activities") under the original 2015 IO Discovery and Development Agreement to developing therapeutic bispecific antibodies targeting (i) BCMA and CD3 (the "BCMAxCD3 Program") and (ii) MUC16 and CD3 (the "MUC16xCD3 Program") through clinical proof-of-concept. Under the terms of the Amended IO Discovery Agreement, Sanofi paid Regeneron $462 million as consideration for (i) the termination of the 2015 IO Discovery Agreement, (ii) the prepayment for certain IO Development Activities regarding the BCMAxCD3 Program and the MUC16xCD3 Program, and (iii) the reimbursement of costs incurred by Regeneron under the 2015 IO Discovery Agreement during the fourth quarter of 2018. This gives Sanofi increased flexibility to advance its early-stage immuno-oncology pipeline independently, while Regeneron retains all rights to its other immuno-oncology discovery and development programs.

The ongoing development and commercialization collaboration on Libtayo® (cemiplimab) is unaffected by the amendments to the IO Discovery and Development Agreement.

Upon establishment of POC, or when the allocated funding has been expended, whichever is earlier, Sanofi can exercise its opt-in rights to further develop and commercialize under the IO LCA the two candidates derived from the amended IO Discovery Agreement. Sanofi has decided to opt-out with respect to the MUC16xCD3 program. If Sanofi exercises its opt-in rights with respect to the BCMAxCD3program, Sanofi will lead the development and global commercialization of the BCMAxCD3 candidate antibody and fund the development costs in full; Regeneron will refund 50% of those costs provided that the share of quarterly results under the IO LCA represents a profit, subject to a cap set at 10% of Regeneron's profit-share.

Libtayo® (cemiplimab)

Under the 2015 IO LCA as amended in January 2018, Sanofi and Regeneron committed funding of no more than $1,640 million, split on a 50/50 basis ($820 million per company), for the development of REGN2810 (cemiplimab, trademark Libtayo®), a PD-1 inhibitor antibody. Regeneron is responsible for the commercialization of Libtayo® in the United States, and Sanofi in all other territories. Sanofi has exercised its option to co-commercialize Libtayo® in the United States.

The IO LCA also provided for a one-time milestone payment of $375 million by Sanofi to Regeneron in the event that sales of a PD-1 product and any other collaboration antibody sold for use in combination with a PD-1 product were to exceed, in the aggregate, $2 billion in any consecutive 12-month period.

Under the IO LCA Sanofi and Regeneron share equally in profits and losses in connection with the commercialization of collaboration products, except that Sanofi is entitled to an additional share of profits capped at 10% of the share of Regeneron's quarterly profits in order to reimburse Sanofi for up to 50% of the clinical development costs funded by Sanofi under the IO Discovery Agreement, as amended.

In September 2018, the US Food and Drug Administration (FDA) approved Libtayo® (cemiplimab) for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation. Libtayo® is a fully human monoclonal antibody targeting the immune checkpoint receptor PD-1 (programmed cell death protein-1) and is the first and only treatment specifically approved and available for advanced CSCC in the US. In July 2019, the European Medicines Agency (EMA) granted marketing authorization for Libtayo® for patients with metastatic or locally advanced CSCC who are not candidates for surgery.

In addition to advanced CSCC, clinical trials are ongoing to investigate cemiplimab in non-small cell lung cancer, basal cell carcinoma, cervical cancer, head and neck squamous cell carcinoma, melanoma, colorectal cancer, prostate cancer, multiple myeloma, Hodgkin's disease and non-Hodgkin lymphoma. Those potential indications are still investigational, and the safety and efficacy of Libtayo® have not been evaluated by any regulatory authority for any of them.

Investor agreement

In January 2014, Sanofi and Regeneron amended the investor agreement that had existed between the two companies since 2007. Under the terms of the amendment, Sanofi accepted various restrictions. Sanofi is bound by certain "standstill" provisions, which contractually prohibit Sanofi from seeking to directly or indirectly exert control of Regeneron or acquiring more than 30% of Regeneron's capital stock (consisting of the outstanding shares of common stock and the shares of Class A stock). This prohibition remains in place until the earlier of (i) the later of the fifth anniversaries of the expiration or earlier termination of the Zaltrap® collaboration agreement with Regeneron (related to the development and commercialization of Zaltrap®) or the collaboration agreement with Regeneron on monoclonal antibodies (see "Collaboration agreements on human therapeutic antibodies" above), each as amended and (ii) other specified events.

Sanofi also agreed to vote as recommended by Regeneron's Board of Directors, except that it could elect to vote proportionally with the votes cast by all of Regeneron's other shareholders with respect to certain change-of-control transactions, and to vote in its sole discretion with respect to liquidation or dissolution, stock issuances equal to or exceeding 20% of the outstanding shares or voting rights of Regeneron's Class A Stock and Common Stock (taken together), and new equity compensation plans or amendments if not materially consistent with Regeneron's historical equity compensation practices. As soon as it had passed the threshold of 20% ownership of the capital stock, Sanofi exercised its right to designate an independent director, who was appointed to the Board of Directors of Regeneron. Sanofi began to account for its interest in Regeneron using the equity method in April 2014. On the conditions set out in the Amended Investor Agreement of January 2014, Sanofi's right to designate a Regeneron board member was contingent on Sanofi maintaining its percentage share of Regeneron's outstanding capital stock (measured on a quarterly basis) at a level no lower than the highest percentage level previously achieved, with the maximum requirement capped at 25%. In addition, Sanofi's interest in Regeneron was subject to a lock-up clause. Those restrictions were amended by the letter agreement of January 2018 (see below).

At Sanofi's request, pursuant to the Amended Investor Agreement, Regeneron appointed a new independent director, N. Anthony "Tony" Coles, M.D. to its Board of Directors in January 2017 as a Sanofi designee. The Amended Investor Agreement also gave Sanofi the right to receive certain reasonable information as might be agreed upon by the parties and which was a factor in Sanofi's ability to account for its investment in Regeneron using the equity method of accounting under IFRS.

In January 2018, Sanofi and Regeneron announced (i) amendments to their collaboration agreements on human therapeutic antibodies; (ii) amendments to the IO LCA on the development of cemiplimab (REGN2810); and (iii) a limited waiver and amendment of the Amended Investor Agreement (the Amended and Restated Investor Agreement) pursuant to a letter agreement (the "2018 Letter Agreement").

Pursuant to the 2018 Letter Agreement, Regeneron agreed to grant a limited waiver of the lock-up clause and the obligation to maintain the "Highest Percentage Threshold" in the Amended and Restated Investor Agreement between the companies, so that Sanofi could elect to sell a small percentage of the Regeneron common stock it owns to fund a portion of the cemiplimab and dupilumab development expansion. This waiver allowed Sanofi to sell up to an aggregate of 1.4 million shares of Regeneron common stock to Regeneron in private transactions through the end of 2020. If Regeneron decided not to purchase the shares, Sanofi would be allowed to sell those shares on the open market, subject to certain volume and timing limitations. Upon expiration of the limited waiver under the 2018 Letter Agreement, the Amended and Restated Investor Agreement would be amended to define "Highest Percentage Threshold" as the lower of (i) 25% of Regeneron outstanding shares of Class A Stock and Common Stock (taken together) and (ii) the higher of (a) Sanofi's percentage ownership of Class A Stock and Common Stock (taken together) on such termination date and (b) the highest percentage ownership of Regeneron outstanding shares of Class A Stock and Common Stock (taken together) Sanofi attains following such termination date.

As of December 31, 2019, Sanofi had sold Regeneron 530,172 shares of Regeneron stock out of the 1.4 million shares covered by the 2018 Letter Agreement.

In December 2019, Sanofi announced that on expiration of the lock-up term and as defined in the Amended and Restated Investor Agreement as amended by the 2018 Letter Agreement (i.e. in principle after December 20, 2020), Sanofi could dispose of its entire interest in Regeneron or of some of the shares of common stock held, on any single occasion or from time to time, via public offering or market transactions or a private sale, using derivatives or other means, at prices and on other terms acceptable to Sanofi depending on Sanofi's capital allocation priorities and alternative investment opportunities, market conditions, the price of Regeneron common stock, and any other factors judged relevant by Sanofi with respect to its investment in Regeneron. Those provisions were to be implemented in accordance with the Amended and Restated Investor Agreement as amended by the 2018 Letter Agreement, including the restrictions contained in Section 5 of the Amended and Restated Investor Agreement.

On May 29, 2020, Sanofi announced the closing of its sale of 13 million shares of Regeneron common stock in a registered offering and a private sale to Regeneron. As a result, Sanofi sold its entire equity investment in Regeneron, except for 400,000 Regeneron shares retained by Sanofi to partially fund investments allocated to the development programs for cemiplimab and dupilumab pursuant to the 2018 Letter Agreement (see Note D.1.).

On May 29, 2020, an amendment to the Investor Agreement became effective, which stipulates inter alia that (i) the "standstill" provisions in the Investor Agreement, which contractually prohibit Sanofi from seeking to directly or indirectly exert control of Regeneron, will continue to apply; (ii) Sanofi will no longer have the right to designate an independent board member on the Regeneron Board of Directors (but with no effect on the term of office of the current Sanofi designee); (iii) the voting commitments contained in the Investor Agreement will continue to apply to shares held by Sanofi.

The registered offering and share repurchase will not affect the ongoing collaboration between Sanofi and Regeneron: the two companies have had a successful and long-standing clinical and commercial collaboration dating back to 2003 that has resulted in five approved treatments to date, with additional candidates currently in clinical development.

As of December 31, 2020, Sanofi had sold an additional 120,234 shares of Regeneron stock out of the 400,000 shares retained as of May 29, 2020, per above, and consequently still holds 279,766 shares of Regeneron stock.

2/ Alliance arrangements with Bristol-Myers Squibb (BMS)

Two of Sanofi's leading products were jointly developed with BMS: the anti-hypertensive agent irbesartan (Aprovel®/Avapro®/Karvea®) and the anti-atherothrombosis treatment clopidogrel bisulfate (Plavix®/Iscover®).

On September 27, 2012, Sanofi and BMS signed an agreement relating to their alliance following the loss of exclusivity of Plavix® and Avapro®/Avalide® in many major markets.

Under the terms of this agreement, effective January 1, 2013, BMS returned to Sanofi its rights to Plavix® and Avapro®/Avalide® in all markets worldwide with the exception of Plavix® in the United States and Puerto Rico ("Territory B"), giving Sanofi sole control and freedom to operate commercially in respect of those products. In exchange, BMS received royalty payments on Sanofi's sales of branded and unbranded Plavix® and Avapro®/Avalide® worldwide (except for Plavix® in Territory B) until 2018, and also received a payment of $200 million from Sanofi in December 2018, part of which is for buying out the non-controlling interests (see Note D.18.). Rights to Plavix® in Territory B remained unchanged and continued to be governed by the terms of the original agreement until February 28, 2020.

In all of the territories managed by Sanofi (including the United States and Puerto Rico for Avapro®/Avalide®) as defined in the new agreement, Sanofi recognized in its consolidated financial statements the revenue and expenses generated by its own operations. Since January 2019 onwards, there has no longer been any share of profits reverting to BMS (previously presented within ***Net income attributable to non-controlling interests*** in the income statement).

In Territory B for Plavix®, which was managed by BMS, the Plavix® business was conducted through the Territory B partnerships, which were jointly owned by BMS and Sanofi. Sanofi recognized its share of profits and losses within the line item ***Share of profit/(loss) from investments accounted for using the equity method***.

On February 28, 2020, Sanofi purchased all BMS's interests (50.1%) in each of the Territory B partnerships for a cumulative purchase price of $12 million. Following a transition period, Sanofi has been commercializing Plavix® under its own label since July 1, 2020.

A.1.8. Impact of Exchange Rates

We report our consolidated financial statements in euros. Because we earn a significant portion of our revenues in countries where the euro is not the local currency, our results of operations can be significantly affected by exchange rate movements between the euro and other currencies, primarily the US dollar and, to a lesser extent, the Japanese yen, and currencies in emerging countries. We experience these effects even though certain of these countries do not account for a large portion of our net sales. In 2020, we earned 37.4% of our net sales in the United States. An increase in the value of the US dollar against the euro has a positive impact on both our revenues and our operating income. A decrease in the value of the US dollar against the euro has a negative impact on our revenues, which is not offset by an equal reduction in our costs and therefore negatively affects our operating income. A variation in the value of the US dollar has a particularly significant impact on our operating income, which is higher in the United States than elsewhere, and on the contribution to net income of our collaborations with Regeneron and BMS in the United States (see "- A.1.7. Financial Presentation of Alliances" above).

For a description of arrangements entered into to manage operating foreign exchange risks as well as our hedging policy, see "Item 11. Quantitative and Qualitative Disclosures about Market Risk", and "Item 3. Key Information — D. Risk Factors — Risks Related to Financial Markets — Fluctuations in currency exchange rates could adversely affect our results of operations and financial condition".

A.1.9. Divestments

On May 29, 2020, Sanofi announced the closing of its sale of 13 million shares of Regeneron common stock through a registered offering at a price of $515 per share. This included a previously-announced overallotment option, which was fully exercised by the underwriters. In addition, Sanofi announced the completion of Regeneron's repurchase of 9.8 million shares or approximately $5,000 million in common stock directly from Sanofi. As a result of the offering, Sanofi has sold its entire equity investment in Regeneron (except for 400,000 Regeneron shares retained by Sanofi to support its ongoing collaboration with Regeneron) for total sale proceeds (before transaction-related costs) of €10,575 million. Consequently, Sanofi's equity interest in Regeneron ceased to be accounted for by the equity method.

On November 26, 2019, Sanofi entered into a definitive agreement to sell Seprafilm® to Baxter. The sale was completed on February 14, 2020. Sanofi recognized a pre-tax gain of €129 million.

There were no material divestments in 2019.

For further details about the divestments mentioned above, see Note D.1. to our consolidated financial statements included at Item 18. of this annual report.

A.1.10. Acquisitions

On January 23, 2020, Sanofi acquired Synthorx Inc. ("Synthorx"), for $2.5 billion (€2.2 billion). The final purchase price allocation, resulted to the recognition of goodwill amounting to €930 million. Synthorx has no commercial operations, and has made a negative contribution of €106 million to Sanofi's consolidated net income in 2020. The cash outflow on this acquisition amounted to €2,245 million, and was recorded in the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** within the consolidated statement of cash flows.

Sanofi acquired Principia Biopharma Inc. ("Principia") on September 28, 2020, for $3.68 billion (€3.2 billion). The provisional purchase price allocation, resulted to the recognition of goodwill amounting to €913 million. Principia has no commercial operations, and has made a negative contribution of €45 million to Sanofi's consolidated net income in 2020. The cash outflow on this acquisition amounted to €2,972 million, and was recorded in the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** within the consolidated statement of cash flows.

The impacts of the acquisitions carried out in 2019 are not material to the Sanofi consolidated financial statements.

For further information about the acquisitions mentioned above, see Notes D.1. to our consolidated financial statements included at Item 18. of this annual report.

A.1.11. Critical Accounting and Reporting Policies

Our consolidated financial statements are affected by the accounting and reporting policies that we use. Certain of our accounting and reporting policies are critical to an understanding of our results of operations and financial condition, and in some cases the application of these critical policies can be significantly affected by the estimates, judgments and assumptions made by management during the preparation of our consolidated financial statements. The accounting and reporting policies that we have identified as fundamental to a full understanding of our results of operations and financial condition are the following:

1/ Revenue recognition

Our policies with respect to revenue recognition are discussed in Note B.13. to our consolidated financial statements included at Item 18. of this annual report. Revenue arising from the sale of goods is presented in the income statement within ***Net sales***. ***Net sales*** comprise revenue from sales of pharmaceutical products, consumer healthcare products, active ingredients and vaccines, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities. In accordance with IFRS 15 (Revenue from Contracts with Customers), such revenue is recognized when Sanofi transfers control over the product to the customer. Control refers to the ability to direct the use of, and obtain substantially all of the remaining benefits from, the products. For the vast majority of contracts, revenue is recognized when the product is physically transferred, in accordance with the delivery and acceptance terms agreed with the customer.

For contracts entered into by Sanofi Pasteur, transfer of control is usually determined by reference to the terms of release (immediate or deferred) and acceptance of batches of vaccine.

As regards contracts with distributors, Sanofi does not recognize revenue when the product is physically transferred to the distributor in case of products sold on consignment, or if the distributor acts as an agent. In such cases, revenue is recognized when control is transferred to the end customer, and the distributor's commission is presented within the line item ***Selling and general expenses*** in the income statement.

We offer various types of price reductions on our products. In particular, products sold in the United States are covered by various programs (such as Medicare and Medicaid) under which products are sold at a discount. Rebates are granted to healthcare authorities, and under contractual arrangements with certain customers. Some wholesalers are entitled to chargeback incentives based on the selling price to the end customer, under specific contractual arrangements. Cash discounts may also be granted for prompt payment. The discounts, incentives and rebates described above are estimated on the basis of specific contractual arrangements with our customers or of specific terms of the relevant regulations and/or agreements applicable for transactions with healthcare authorities, and of assumptions about the attainment of sales targets. We also estimate the amount of sales returns, on the basis of contractual sales terms and reliable historical data. Discounts, incentives, rebates and sales returns are recognized in the period in which the underlying sales are recognized within ***Net Sales***, as a reduction of gross sales. For additional details regarding the financial impact of discounts, incentives, rebates and sales returns, see Note D.23. to our consolidated financial statements included at Item 18. of this annual report.

Revenues from non-Sanofi products, mainly comprising royalty income from license arrangements and sales of non-Sanofi products by our US-based entity VaxServe, are presented within ***Other revenues***.

2/ Business combinations

As discussed in Note B.3. “Business combinations and transactions with non-controlling interests” to our consolidated financial statements included at Item 18. of this annual report, business combinations are accounted for by the acquisition method. The acquiree’s identifiable assets and liabilities that satisfy the recognition criteria of IFRS 3 (Business Combinations) are measured initially at their fair values as at the acquisition date, except for (i) non-current assets classified as held for sale, which are measured at fair value less costs to sell and (ii) assets and liabilities that fall within the scope of IAS 12 (Income Taxes) and IAS 19 (Employee Benefits). Business combinations completed on or after January 1, 2010 are accounted for in accordance with the revised IFRS 3 and the revised IAS 27 (Consolidated and Individual Financial Statements), now superseded by IFRS 10 (Consolidated Financial Statements). In particular, contingent consideration payable to former owners agreed in a business combination, e.g. in the form of payments upon the achievement of certain R&D milestones, is recognized as a liability at fair value as of the acquisition date irrespective of the probability of payment. If the contingent consideration was originally recognized as a liability, subsequent adjustments to the liability are recognized in profit or loss (see Note D.18. “Liabilities related to business combinations and non-controlling interests” to our consolidated financial statements included at Item 18. of this annual report).

3/ Impairment of goodwill and intangible assets

As discussed in Note B.6. “Impairment of property, plant and equipment, intangible assets, and investments accounted for using the equity method” and in Note D.5. “Impairment of intangible assets and property, plant and equipment” to our consolidated financial statements included at Item 18. of this annual report, we test our intangible assets for impairment periodically or when there is any internal or external indication of impairment. Such indicators could include primarily but not exclusively (i) increased market competition resulting from (for example) the introduction of a competitor’s product; (ii) earlier than expected loss of exclusivity; (iii) increased pricing pressure; (iv) restrictions imposed by regulatory authorities on the manufacture or sale of a product; (v) delay in the projected launch of a product; (vi) different from expected clinical trial results; (vii) higher than expected development costs or (viii) lower than expected economic performance.

We test for impairment on the basis of the same objective criteria that were used for the initial valuation. Our initial valuation and ongoing tests are based on the relationship of the value of our projected future cash flows associated with the asset to either the purchase price of the asset (for its initial valuation) or the carrying amount of the asset (for ongoing tests for impairment).

Significant underlying assumptions requiring the exercise of considerable judgement are applied in the future cash flow projections used to determine the recoverability of intangible assets, including primarily but not exclusively (i) therapeutic class market growth drivers; (ii) expected impacts from competing products (including but not exclusively generics and biosimilars); (iii) projected pricing and operating margin levels; (iv) likely changes in the regulatory, legal or tax environment; and (v) management’s estimates of terminal growth or attrition rates.

The recoverable amounts of intangible assets related to research and development projects are determined based on future net cash flows, which reflect the development stage of the project and the associated probability of success of marketization of the compound.

The projected cash flows are discounted to present value using a discount rate which factors in the risks inherent in cash flow projections.

Changes in facts and circumstances, assumptions and/or estimates may lead to future additional impairment losses or reversal of impairment previously recorded.

Key assumptions relating to goodwill impairment are the perpetual growth rate and the post-tax discount rate. A sensitivity analysis to the key assumptions is disclosed in Note D.5. “Impairment of intangible assets and property, plant and equipment” to our consolidated financial statements included at Item 18. of this annual report.

4/ Contingent consideration receivable

As described in Note B.8.1. and D.7.3. to our consolidated financial statements included at Item 18. of this annual report, contingent consideration receivable such as earn-outs on divestments, for example in the form of a percentage of future sales of the acquirer, are recognized as an asset at fair value as of the date of divestment. Subsequent remeasurements of the fair value of the asset are recognized in profit or loss.

5/ Pensions and post-retirement benefits

As described in Note B.23. “Employee benefit obligations” to our consolidated financial statements included at Item 18. of this annual report, we recognize our pension and retirement benefit commitments as liabilities on the basis of an actuarial estimate of the rights vested in employees and retirees at the end of the reporting period, net of the fair value of plan assets held to meet those obligations. We prepare this estimate at least on an annual basis taking into account financial assumptions (such as discount rates) and demographic assumptions (such as life expectancy, retirement age, employee turnover, and the rate of salary increases).

We recognize all actuarial gains and losses (including the impact of a change in discount rate) immediately through equity. A sensitivity analysis to the discount rate is set forth in Note D.19.1. “Provisions for pensions and other benefits” to our consolidated financial statements included at Item 18. of this annual report.

Depending on the key assumptions used, the pension and post-retirement benefit expense could vary within a range of outcomes and have a material effect on reported earnings. A sensitivity analysis to these key assumptions is set forth in Note D.19.1. “Provisions for pensions and other benefits” to our consolidated financial statements included at Item 18. of this annual report.

6/ Deferred taxes

As discussed in Note B.22. “Income tax expense” to our consolidated financial statements included at Item 18. of this annual report, we recognize deferred income taxes on tax loss carry-forwards and on temporary differences between the tax base and carrying amount of assets and liabilities. We calculate our deferred tax assets and liabilities using enacted tax rates applicable for the years during which we estimate that the temporary differences are expected to reverse. We do not recognize deferred tax assets when it is more likely than not that the deferred tax assets will not be realized. The recognition of deferred tax assets is determined on the basis of profit forecasts for each tax group, and of the tax consequences of the strategic opportunities available to Sanofi.

7/ Provisions for risks

Sanofi and its subsidiaries and affiliates may be involved in litigation, arbitration or other legal proceedings. These proceedings typically are related to product liability claims, intellectual property rights, compliance and trade practices, commercial claims, employment and wrongful discharge claims, tax assessment claims, waste disposal and pollution claims, and claims under warranties or indemnification arrangements relating to business divestitures. As discussed in Note B.12. “Provisions for risks” to our consolidated financial statements included at Item 18. of this annual report, we record a provision where we have a present obligation, whether legal or constructive, as a result of a past event; it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation; and a reliable estimate can be made of the amount of the outflow of resources. For additional details regarding the financial impact of provisions for risks see Notes D.19.3. “Other provisions” and D.22. “Legal and Arbitral Proceedings” to our consolidated financial statements included at Item 18. of this annual report.

8/ Provisions for restructuring costs

Provisions for restructuring costs include collective redundancy or early retirement benefits, compensation for early termination of contracts, and rationalization costs relating to restructured sites. Refer to Note D.19.2. to our consolidated financial statements included at Item 18. of this annual report.

Provisions are estimated on the basis of events and circumstances related to present obligations at the end of the reporting period and of past experience, and to the best of management’s knowledge at the date of preparation of the financial statements. The assessment of provisions can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions. Given the inherent uncertainties related to these estimates and assumptions, the actual outflows resulting from the realization of those risks could differ from our estimates.

A.2. Results of Operations - Year Ended December 31, 2020 Compared with Year Ended December 31, 2019

Consolidated income statements

(€ million)	2020	as % of net sales	2019	as % of net sales
Net sales	**36,041**	**100.0%**	**36,126**	**100.0%**
Other revenues	1,328	3.7%	1,505	4.2%
Cost of sales	(12,157)	(33.7%)	(11,976)	(33.2%)
Gross profit	**25,212**	**70.0%**	**25,655**	**71.0%**
Research and development expenses	(5,529)	(15.3%)	(6,018)	(16.7%)
Selling and general expenses	(9,390)	(26.1%)	(9,883)	(27.4%)
Other operating income	696		825	
Other operating expenses	(1,415)		(1,207)	
Amortization of intangible assets	(1,681)		(2,146)	
Impairment of intangible assets	(330)		(3,604)	
Fair value remeasurement of contingent consideration	124		238	
Restructuring costs and similar items	(1,064)		(1,062)	
Other gains and losses, and litigation	136		327	
Gain on Regeneron investment arising from transaction of May 29, 2020	7,382		—	
Operating income	**14,141**	**39.2%**	**3,125**	**8.7%**
Financial expenses	(390)		(444)	
Financial income	53		141	
Income before tax and investments accounted for using the equity method	**13,804**	**38.3%**	**2,822**	**7.8%**
Income tax expense	(1,813)		(139)	
Share of profit/(loss) from investments accounted for using the equity method	359		255	
Net income excluding the exchanged/held-for-exchange Animal Health business[(a)]	**12,350**	**34.3%**	**2,938**	**8.1%**
Net income/(loss) of the exchanged/held-for-exchange Animal Health business	—		(101)	
Net income	**12,350**	**34.3%**	**2,837**	**7.9%**
Net income attributable to non-controlling interests	36		31	
Net income attributable to equity holders of Sanofi	**12,314**	**34.2%**	**2,806**	**7.8%**
Average number of shares outstanding (million)	1,253.6		1,249.9	
Average number of shares after dilution (million)	1,260.1		1,257.1	
• Basic earnings per share (€)	9.82		2.24	
• Basic earnings per share (€) excluding the exchanged/held-for-exchange Animal Health business	9.82		2.33	
• Diluted earnings per share (€)	9.77		2.23	
• Diluted earnings per share (€) excluding the exchanged/held-for-exchange Animal Health business	9.77		2.31	

(a) The impacts of the divestment of the Animal Health business are presented separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations).

A.2.1. Net Sales

Consolidated net sales for the year ended December 31, 2020 amounted to €36,041 million, 0.2% lower than in 2019. Exchange rate fluctuations had a negative effect of 3.5 percentage points overall, due mainly to adverse trends in the euro exchange rate against the US dollar, Brazilian real, Argentinean peso and Turkish lira. At constant exchange rates (CER see definition below), net sales rose by 3.3%; solid performances for Dupixent®and Vaccines, and more generally for all franchises in our Specialty Care global business unit across all geographies, more than offset lower sales in our Diabetes and Cardiovascular & Established Prescription Products franchises.

Reconciliation of net sales to net sales at constant exchange rates

(€ million)	2020	2019	Change
Net sales	**36,041**	**36,126**	**-0.2%**
Effect of exchange rates	1,293		
Net sales at constant exchange rates	**37,334**	**36,126**	**+3.3%**

When we refer to changes in our net sales at constant exchange rates (CER), that means that we have excluded the effect of exchange rates by recalculating net sales for the relevant period using the exchange rates that were used for the previous period.

When we refer to changes in our net sales on a constant structure (CS) basis, that means that we eliminate the effect of changes in structure by restating the net sales for the previous period as follows:

- by including sales generated by entities or product rights acquired in the current period for a portion of the previous period equal to the portion of the current period during which we owned them, based on historical sales information we receive from the party from whom we make the acquisition;
- similarly, by excluding sales for a portion of the previous period when we have sold an entity or rights to a product in the current period; and
- for a change in consolidation method, by recalculating the previous period on the basis of the method used for the current period.

To facilitate analysis and comparisons with prior periods, some figures are given at constant exchange rates and on a constant structure basis (CER/CS).

1/ Net sales by Operating Segment and Global Business Unit

Our net sales comprise the net sales generated by our Pharmaceuticals, Vaccines and Consumer Healthcare segments.

The table below also presents an analysis of our net sales by Global Business Unit (GBU).

(€ million)	2020	2019 [(a)]	Change on a reported basis	Change at constant exchange rates
Specialty Care GBU	10,954	9,163	+19.5%	+22.4%
General Medicines GBU	14,720	16,537	-11.0%	-7.6%
Pharmaceuticals segment	**25,674**	**25,700**	**-0.1%**	**+3.1%**
Vaccines GBU/segment	**5,973**	**5,731**	**+4.2%**	**+8.8%**
Consumer Healthcare GBU/segment	**4,394**	**4,695**	**-6.4%**	**-1.9%**
Total net sales	**36,041**	**36,126**	**-0.2%**	**+3.3%**

(a) To reflect the new organizational structure adopted by Sanofi on January 1, 2020, figures for 2019 have been restated to take account of transfers of products between GBUs, as described below.

With effect from the start of 2020, Sanofi is organized into three major Global Business Units that underpin the corporate strategy: the **Specialty Care GBU** (Dupixent®, Multiple Sclerosis, Neurology, Other Inflammatory Diseases & Immunology, Rare Diseases, Oncology, and Rare Blood Disorders), the **Vaccines GBU**, and the **General Medicines GBU** (Diabetes, Cardiovascular and Established Prescription Products). The **Consumer Healthcare GBU** is now a standalone commercial entity with its own manufacturing and R&D capabilities. Each GBU now includes its own contribution to emerging markets sales. The new structure has led to some products being transferred, and some franchises being combined. Some mature products formerly in the Oncology franchise (Zaltrap®, Mozobil®, Thymoglobulin®, Clolar®, Fludara®, Taxotere®, Eloxatin® and Campath®) have been transferred to the Established Prescription Products franchise in the General Medicines GBU. The Cardiovascular franchise (Praluent® and Multaq®) and the Established Prescription Products franchise have been combined. Some products formerly in the Consumer Healthcare GBU have been transferred to the General Medicines GBU and vice versa, with virtually no effect on the sales of the two GBUs. Finally, endocrinology products (Thyrogen®, Caprelsa®) have been transferred from the Rare Diseases franchise to the Established Prescription Products franchise.

2/ Net sales by Franchise, Geographical Region[(a)] and Product

(€ million)	Net sales	Change (CER)	Change (reported)	United States	Change (CER)	Europe	Change (CER)	Rest of the world	Change (CER)
Dupixent®	3,534	+73.9%	+70.4%	2,808	+72.1%	386	+89.2%	340	+73.1%
Aubagio®	2,045	+10.6%	+8.8%	1,448	+9.0%	473	+14.7%	124	+15.8%
Lemtrada®	113	-58.7%	-59.8%	60	-59.6%	30	-68.4%	23	-28.6%
Kevzara®	236	+30.3%	+27.6%	123	+8.7%	75	+70.5%	38	+57.7%
Total Multiple Sclerosis, Neurology, Other Inflammatory Diseases & Immunology	**2,394**	**+3.9%**	**+2.1%**	**1,631**	**+2.5%**	**578**	**+4.9%**	**185**	**+13.1%**
Cerezyme®	690	+4.5%	-2.5%	177	-1.6%	249	-3.5%	264	+16.6%
Cerdelga®	234	+16.0%	+13.6%	128	+10.2%	92	+22.7%	14	+30.8%
Myozyme®/Lumizyme®	948	+6.0%	+3.3%	359	+10.9%	389	+0.5%	200	+8.5%
Fabrazyme®	817	+3.2%	+0.5%	406	+1.0%	200	+8.6%	211	+2.8%
Aldurazyme®	234	+8.5%	+4.5%	52	+3.9%	80	+1.3%	102	+17.0%
Total Rare Diseases	3,011	+5.7%	+1.9%	1,122	+4.7%	1,010	+2.7%	879	+10.4%
Jevtana®	536	+12.2%	+10.7%	246	+17.9%	187	+10.6%	103	+2.9%
Fasturtec®	152	+12.3%	+10.1%	96	+10.1%	42	+10.5%	14	+36.4%
Libtayo®	67	+331.3%	+318.8%	—	—	61	+306.7%	6	+700.0%
Sarclisa®	43	—	—	26	—	9	—	8	—
Total Oncology	798	+27.1%	+25.1%	368	+24.6%	299	+34.5%	131	+19.3%
Alprolix®	466	+15.0%	+13.1%	320	+8.7%	—	—	146	+32.1%
Eloctate®	638	-5.7%	-6.7%	445	-12.6%	—	—	193	+15.6%
Cablivi®	113	+105.4%	+101.8%	72	+117.6%	41	+86.4%	—	—
Total Rare Blood Disorders	1,217	+7.1%	+5.6%	837	+0.1%	41	+86.4%	339	+22.2%
Specialty Care GBU	**10,954**	**+22.4%**	**+19.5%**	**6,766**	**+24.8%**	**2,314**	**+16.7%**	**1,874**	**+21.0%**
Lantus®	2,661	-8.5%	-11.7%	929	-17.7%	537	-9.8%	1,195	+0.5%
Toujeo®	933	+8.4%	+5.7%	267	-5.9%	374	+9.6%	292	+23.1%
Apidra®	332	+1.7%	-3.5%	32	-28.3%	131	-1.5%	169	+12.8%
Amaryl®	272	-15.9%	-18.6%	2	—%	16	-11.1%	254	-16.2%
Admelog®/insuline lispro Sanofi®	188	-23.2%	-24.8%	166	-28.1%	20	+33.3%	2	—%
Soliqua®/Suliqua®	161	+36.1%	+32.0%	100	+17.2%	24	+38.9%	37	+129.4%
Total Diabetes	4,709	-4.8%	-7.9%	1,501	-15.6%	1,206	-2.4%	2,002	+3.2%
Plavix®	916	-30.1%	-31.3%	10	—	129	-9.2%	777	-33.5%
Lovenox®	1,351	+4.5%	-0.6%	30	-6.1%	656	-9.3%	665	+22.0%
Renagel®/Renvela®	238	-23.2%	-24.2%	64	-51.9%	46	-16.4%	128	+4.0%
Aprovel®	554	-15.9%	-17.8%	22	-15.4%	100	-11.5%	432	-16.8%
Synvisc®/Synvisc-One	192	-35.6%	-37.9%	131	-37.0%	20	-23.1%	41	-36.1%
Mozobil®	214	+10.6%	+8.1%	123	+9.6%	55	+7.8%	36	+18.8%
Thymoglobulin®	316	-8.2%	-10.7%	191	-1.0%	29	-21.6%	96	-16.0%
Taxotere®	160	-6.3%	-8.0%	—	-100.0%	2	-50.0%	158	-5.8%
Eloxatin®	198	-0.5%	-2.5%	1	-116.7%	2	—%	195	-3.9%
Praluent®	261	+2.3%	+1.2%	106	-4.5%	121	+8.9%	34	+2.9%
Multaq®	312	-8.4%	-10.1%	274	-5.1%	24	-41.5%	14	+27.3%
Generics	932	-2.9%	-13.2%	161	+8.6%	100	-27.3%	671	-0.8%
Other Established Prescription Products	4,367	-6.3%	-9.5%	255	-15.3%	2,015	-3.8%	2,097	-7.4%
Total Cardiovascular & Established Prescription Products	10,011	-8.8%	-12.4%	1,368	-11.4%	3,299	-6.7%	5,344	-9.4%
General Medicines GBU	**14,720**	**-7.6%**	**-11.0%**	**2,869**	**-13.6%**	**4,505**	**-5.6%**	**7,346**	**-6.3%**
Total Pharmaceuticals	**25,674**	**+3.1%**	**-0.1%**	**9,635**	**+10.2%**	**6,819**	**+0.9%**	**9,220**	**-1.8%**
Polio/Pertussis/Hib Vaccines	2,106	+12.6%	+8.2%	412	+11.3%	331	+6.3%	1,363	+14.6%
Adult Booster Vaccines	467	-14.9%	-17.1%	247	-20.3%	150	-10.7%	70	-1.3%
Meningitis/Pneumonia Vaccines	559	-15.0%	-18.0%	392	-20.3%	1	-50.0%	166	+1.2%
Influenza Vaccines	2,472	+37.9%	+30.7%	1,575	+29.9%	441	+93.9%	456	+30.6%
Travel & Other Endemics Vaccines	301	-43.2%	-44.2%	73	-48.3%	47	-64.4%	181	-29.9%
Total Vaccines	**5,973**	**+8.8%**	**+4.2%**	**2,759**	**+5.9%**	**973**	**+15.4%**	**2,241**	**+9.9%**
Allergy, Cough & Cold	1,096	-5.3%	-7.8%	361	+13.0%	305	-15.9%	430	-9.4%
Pain	1,225	+2.3%	-4.3%	181	-0.5%	539	—%	505	+5.4%
Digestive	858	-8.6%	-12.9%	86	-43.9%	319	-0.9%	453	-2.6%
Nutritionals	611	+4.7%	-1.6%	43	+15.8%	127	-0.8%	441	+5.3%
Total Consumer Healthcare	**4,394**	**-1.9%**	**-6.4%**	**1,071**	**-1.6%**	**1,359**	**-4.3%**	**1,964**	**-0.4%**
Total Sanofi	**36,041**	**+3.3%**	**-0.2%**	**13,465**	**+8.2%**	**9,151**	**+1.5%**	**13,425**	**+0.2%**

(a) With effect from January 1, 2020, the geographical split of net sales is aligned on Sanofi's new organizational structure: Europe, the United States, and Rest of the World. In addition, Israel and Ukraine are now included in the Europe region. The presentation of 2019 figures has been amended to facilitate year-on-year comparisons.

3/ Net sales – Pharmaceuticals Segment

In 2020, net sales for the Pharmaceuticals segment amounted to €25,674 million, down 0.1% on a reported basis but up 3.1% at constant exchange rates (CER). The year-on-year reported-basis decrease of €26 million reflects adverse exchange rate effects of €791 million, and the following effects at constant exchange rates:

- sales growth for Dupixent® (+€1,533 million), the Oncology franchise (+€173 million), the Rare Diseases franchise (+€169 million), the Multiple Sclerosis, Neurology, Other Inflammatory Diseases and Immunology franchise (+€91 million) and the Rare Blood Disorders franchise (+€82 million); and
- lower sales for the Cardiovascular & Established Prescription Products (-€1,011 million) and Diabetes (-€246 million) franchises.

Comments on the performances of our major Pharmaceuticals segment products are provided below.

SPECIALTY CARE GBU

Dupixent®

Dupixent® (developed in collaboration with Regeneron) generated net sales of €3,534 million in 2020, up 70.4% on a reported basis and 73.9% at constant exchange rates. In the United States, sales of Dupixent® reached €2,808 million in 2020, boosted by continuing strong demand in the treatment of atopic dermatitis in adults and adolescents and a rapid ramp-up in children aged 6 to 11 years (approved in May 2020), plus ongoing adoption of the product for the treatment of asthma. In Europe, the product posted 2020 net sales of €386 million, up 89.2% CER, driven by continuing growth in atopic dermatitis in key markets and by launches in asthma in new European markets. In the Rest of the World region, Dupixent® posted net sales of €340 million (+73.1% CER); that includes €192 million in Japan (+46.6% CER), where the sales impact of strong demand was tempered by price cuts imposed by the government in April 2020. In China, Dupixent® was approved in June 2020 in the treatment of moderate-to-severe atopic dermatitis in adults, and will be listed on the NRDL (National Reimbursement Drug List) as of March 2021. In China the product has generated post-launch sales of €12 million.

Multiple Sclerosis, Neurology, Other Inflammatory Diseases and Immunology

In 2020, the **Multiple Sclerosis, Neurology, Other Inflammatory Diseases and Immunology** franchise generated net sales of €2,394 million, representing growth of 2.1% on a reported basis and 3.9% CER, driven by higher sales of Aubagio® and Kevzara®.

Aubagio® posted net sales of €2,045 million in 2020, up 10.6% CER, boosted by sales in the United States (+9.0% CER at €1,448 million) and Europe (+14.7% CER at €473 million). That growth is driven by demand, as well as price increases in the United States and Germany.

In 2020, net sales of **Lemtrada®** amounted to €113 million, down 58.7% CER, on a decline in sales in the United States (-59.6% CER at €60 million) and Europe (-68.4% CER at €30 million). This reflects tougher competition worldwide, and the effects of the COVID-19 pandemic given the product's mode of administration and mechanism of action.

In 2020, net sales of **Kevzara®** (developed in collaboration with Regeneron) came to €236 million, up 30.3% CER, driven by sales of the product in Europe (+70.5% CER at €75 million), the Rest of the World region (+57.7% CER at €38 million), and the United States (+8.7% CER at €123 million). The growth trend reflects increasing adoption of Kevzara®, the development of the product's therapeutic class in mature markets, and a relatively modest impact from COVID-19. Because the Phase II/III clinical trials conducted by Sanofi and Regeneron in the United States and elsewhere on the potential use of Kevzara® in hospitalized mechanically ventilated COVID-19 patients failed to meet their primary and secondary endpoints, neither Sanofi nor Regeneron anticipate conducting any further clinical trials of Kevzara® as a treatment for COVID-19 at this stage.

Rare Diseases

In 2020, net sales for the **Rare Diseases** franchise totaled €3,011 million, up 1.9% on a reported basis and 5.7% at constant exchange rates (CER). In Europe, net sales for the franchise rose by 2.7% CER to €1,010 million. In the United States, net sales advanced by 4.7% CER to €1,122 million. There was a strong performance in the Rest of the World region (+10.4% CER at €879 million), reflecting demand and a favorable sequence of tender bids.

Net sales of **Myozyme®/Lumizyme®**, for the treatment of **Pompe disease**, were up 6.0% CER in 2020 at €948 million, driven by sales growth in the United States (+10.9% CER at €359 million) and the Rest of the World region (+8.5% CER at €200 million), reflecting a rise in the number of patients diagnosed with and treated for Pompe disease. In Europe, net sales of the product in 2020 were stable year-on-year at €389 million.

In 2020, net sales for the **Gaucher disease** franchise (**Cerezyme®** and **Cerdelga®**) reached €924 million, a rise of 7.1% CER. Cerezyme® sales were up 4.5% CER at €690 million, helped by a solid performance in the Rest of the World region (+16.6% CER at €264 million) reflecting a favorable sequence of shipments. Sales of Cerdelga® increased by 16.0% CER to €234 million, fueled by Europe (+22.7% CER at €92 million) and the United States (+10.2% CER at €128 million) as new patients adopted the product.

Net sales of the **Fabry disease** treatment **Fabrazyme®** in 2020 were €817 million (+3.2% CER), propelled by Europe (+8.6% CER at €200 million). In the United States, sales of the product were stable year-on-year at €406 million. In the Rest of the World region, net sales of Fabrazyme® rose by 2.8% CER to €211 million, despite competition and price cuts in Japan. In May 2020, Fabrazyme® was launched in China, where it is the first product to have been approved for Fabry disease.

Oncology

In 2020, net sales for the **Oncology** franchise amounted to €798 million, up 25.1% on a reported basis and 27.1% CER, driven by the launches of Sarclisa® and Libtayo® and by growth for key established products across all three regions.

Jevtana® posted net sales of €536 million in 2020, up 12.2% CER, boosted by growth in the United States (+17.9% CER at €246 million) and Europe (+10.6% CER at €187 million). Sales were lifted by publication of results from the CARD trial evaluating the product in metastatic castration-resistant prostate cancer at the European Society of Medical Oncology and in the New England Journal of Medicine (NEJM) in September 2019. In Europe, we expect generic competition for Jevtana® from the end of March 2021. In the United States, generic manufacturers of cabazitaxel are currently prevented from obtaining final approval from the Food and Drug Administration (FDA) until September 26, 2021. In addition, Sanofi has filed patent infringement suits against all generic manufacturers of cabazitaxel, asserting

patents with an expiration date of October 2030. Sanofi has entered into settlement agreements with some of the defendants and the suit against the remaining defendants is still ongoing.

Libtayo® (developed in collaboration with Regeneron), approved for patients with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for surgery or curative radiotherapy, reported net sales of €67 million outside the United States in 2020. Libtayo® has been launched in 18 countries outside the United States. In the United States, Libtayo® sales are consolidated by Regeneron under the terms of the alliance between Sanofi and Regeneron (see Note C.1. "Alliance arrangements with Regeneron Pharmaceuticals, Inc. (Regeneron)" to our consolidated financial statements, included at Item 18. of this Annual Report on Form 20-F).

In 2020, **Sarclisa®** (isatuximab-irfc) was approved by the FDA, the European Commission and the Japanese health authorities (PDMA) for the treatment of adults with relapsed or refractory multiple myeloma (RRMM), and has reported sales of €43 million since then. In the United States, where the product launch was hampered by COVID-19 lockdown measures, sales reached €26 million in 2020. Sarclisa® has now been launched in 12 countries including the United States, Japan, the United Kingdom, the Netherlands, Canada, Sweden, Switzerland and France.

Rare Blood Disorders

In 2020, the **Rare Blood Disorders** franchise generated net sales of €1,217 million, up 5.6% on a reported basis and 7.1% at constant exchange rates. Solid performances from Cablivi® and Alprolix® more than offset lower sales of Eloctate® in the United States. Excluding industrial sales of Alprolix® and Eloctate® to Swedish Orphan Biovitrum AB (Sobi), which commercializes the two products in Europe, Russia, the Middle East and some North African countries, sales for the Rare Blood Disorders franchise rose by 2.2% CER in 2020. Industrial sales to Sobi were higher in 2020 due to amendments to the supply agreement (Sobi accounted for 17% of Alprolix® sales and 11% of Eloctate® sales in 2020). We expect these sales to be significantly lower in 2021.

Eloctate®, indicated in the treatment of hemophilia A, generated net sales of €638 million in 2020, down 5.7% CER, reflecting lower sales in the United States (-12.6% CER at €445 million) due to competitive pressures. In the Rest of the World region, sales of Eloctate® rose by 15.6% CER to €193 million, with increased sales to Sobi more than offsetting lower sales in Japan (-6.3% CER at €90 million) due to competitive pressures and price cuts. Excluding industrial sales to Sobi, net sales of Eloctate® were down 9.8% in 2020.

In 2020, net sales of **Alprolix®**, indicated in the treatment of hemophilia B, amounted to €466 million, up 15.0% CER. In the United States, sales of the product reached €320 million, up 8.7% CER, reflecting transfers of patients from shorter-acting treatments and migration to prophylactic treatments. In the Rest of the World region, net sales of Alprolix® advanced by 32.1% CER to €146 million on increased sales to Sobi. Excluding industrial sales to Sobi, net sales of Alprolix® increased by 7.4% in 2020.

Cablivi®, which treats acquired thrombotic thrombocytopenic purpura (aTTP) in adults, posted net sales of €113 million in 2020, mainly in the United States (€72 million), and in Europe (€41 million). In Europe, the product is sold in several countries and has been granted a temporary authorization for use (ATU) in France. In July 2020, the International Society on Thrombosis and Haemostasis (ISTH) published for the first time guidelines on the treatment of TTP. These recommend treatment with Cablivi® in combination with plasma exchange and immuno-suppressants for adults with a first event or relapse of aTTP.

GENERAL MEDICINES GBU

Diabetes

In 2020, net sales for the **Diabetes** franchise were €4,709 million, down 7.9% on a reported basis and 4.8% at constant exchange rates. This mainly reflects a decrease in sales for the franchise in the United States (-15.6% CER at €1,501 million), especially of insulin glargines (Lantus® and Toujeo®) and Admelog®, and lower sales of Amaryl® in China.

Net sales of **Lantus®** in 2020 were down 8.5% CER at €2,661 million. In the United States, the product saw net sales decrease by 17.7% CER to €929 million, due largely to a drop in the average net selling price. In Europe, net sales of Lantus® were €537 million (-9.8% CER), reflecting competition from biosimilars and patients switching to Toujeo®. In the Rest of the World region, net sales of Lantus® held steady in 2020 at €1,195 million, with the impact of COVID-19 in non-reimbursable markets offset by a solid performance in China.

In 2020, **Toujeo®** posted net sales of €933 million, up 8.4% CER, driven by the Rest of the World region (+23.1% CER at €292 million) and Europe (+9.6% CER at €374 million), as patients switched from Lantus® and the number of new patients treated rose. In the United States, net sales of Toujeo® decreased by 5.9% due to lower average selling prices in the country, though the impact was partly cushioned by higher volumes. Toujeo® was launched in China in the fourth quarter of 2020.

Net sales of **Amaryl®** were €272 million in 2020, down 15.9% CER due to lower sales in China (-36.0% at €86 million). This reflects the second wave of the Volume Based Procurement (VBP) program that includes glimepiride (the international proprietary name for Amaryl®). As previously indicated, Sanofi decided not to submit a tender bid for Amaryl® and expected a significant drop in sales of the product in China.

Net sales of **Admelog®** (injectable insulin lispro) were down 23.2% CER at €188 million, on lower sales in the United States (-28.1% CER at €166 million) as a result of the previously-announced downward price adjustment of 44% granted to wholesalers on July 1, 2019.

In 2020, net sales of **Soliqua® 100/33 – Suliqua®** (insulin glargine 100 units/ml and lixisenatide 33 mcg/ml injectable) rose by 36.1% CER to €161 million. Sales of the product increased in all geographies, especially the Rest of the World region (+129.4% CER at €37 million) due to a number of product launches. In the United States, net sales reached €100 million (+17.2% CER versus 2019).

Cardiovascular & Established Prescription Products

In 2020, net sales for the **Cardiovascular & Established Prescription Products** amounted to €10,011 million, down 12.4% on a reported basis and 8.8% at constant exchange rates, largely as a result of lower sales of Plavix® and of Aprovel® family products in China due to net price adjustments following the nationwide rollout of the VBP program in December 2019. The decrease in the franchise's net sales in 2020 was exacerbated by negative effects of the COVID-19 crisis, especially in the Rest of the World region.

In 2020, net sales of **Lovenox®** were €1,351 million, a rise of 4.5% CER. Lower sales in Europe (-9.3% CER at €656 million), as a result of competition from biosimilars in a number of countries, was more than offset by sales growth in the Rest of the World region (+22.0% CER at €665 million), due largely to recent recommendations on the use of low molecular weight heparins in hospitalized COVID-19 patients.

Net sales of **Plavix®** in 2020 were €916 million, a decrease of 30.1% CER, mainly due to lower sales in China (-52.5% CER at €341 million), where net price adjustments under the VBP program (see above) were only partly offset by volume growth. In Japan, sales of Plavix® were down 19.8% CER at €105 million, following the price cuts introduced in October 2019. Following the transaction of February 28, 2020 and the amendments to the terms of the alliance between Sanofi and BMS (see Note C.2. “Alliance arrangements with Bristol-Myers Squibb (BMS)” to our consolidated financial statements, included at Item 18. of this Annual Report on Form 20-F), sales of Plavix® in the United States and Puerto Rico, previously made by BMS, are now consolidated within the net sales of Sanofi. Over the period, net sales of Plavix® in the United States amounted to €10 million.

Net sales of **Aprovel®/Avapro®** were €554 million in 2020, down 15.9% CER, mainly due to lower sales in China (-33.4% CER at €190 million) as a result of net price adjustments under the VBP program (see above) that were only partly offset by volume growth.

As previously announced, implementation of the VBP program therefore led to a sharp decrease in sales of Plavix® and of Aprovel® family products in 2020. Over the same period, sales of those products by volume increased by nearly 78% in China, in line with our full-year forecasts (60%+ growth).

In 2020, net sales of **Praluent®** (developed in collaboration with Regeneron) rose by 2.3% CER to €261 million. Lower sales in the United States (-4.5% CER at €106 million) were more than offset by sales growth in Europe (+8.9% CER at €121 million). Since April 1, 2020, as a result of the restructuring of Sanofi's collaboration agreements with Regeneron (see Note C.1. “Alliance arrangements with Regeneron Pharmaceuticals Inc. (Regeneron)” to our consolidated financial statements, included at Item 18. of this Annual Report on Form 20-F), Sanofi has sole responsibility for Praluent® outside the United States, while Regeneron has sole responsibility for Praluent® in the United States. The two companies have entered into agreements to meet short-term manufacturing imperatives. Since then, sales of Praluent® in the United States recognized by Sanofi correspond to industrial sales made to Regeneron; such sales are expected to be on a limited scale in 2021. Praluent® was launched in China in the second quarter of 2020.

4/ Net sales - Vaccines Segment/GBU

In 2020, the Vaccines segment posted net sales of €5,973 million, up 4.2% on a reported basis and 8.8% CER. Positive factors were growth in sales of influenza vaccines across all geographies (+37.9% CER at €2,472 million), and a solid performance for Polio/Pertussis/Hib vaccines (+12.6% CER at €2,106 million), especially in the Rest of the World region (+14.6% CER at €1,363 million). Those effects more than offset the negative impact of COVID-19 on sales of travel vaccines (-43.2% CER at €301 million), adult booster vaccines (-14.9% CER, at €467 million), and Menactra® (-15.0% CER, at €559 million).

Sales of **influenza vaccines** rose by 37.9% CER in 2020 to €2,472 million, driven by strong demand in both the northern and southern hemispheres boosted by the effects of the COVID-19 pandemic. In the United States, sales were up 29.9% at €1,575 million, lifted by increased sales of differentiated influenza vaccines. In Europe, sales increased by 93.9% to €441 million, driven largely by the launches of Efluelda® (a high-dose quadrivalent influenza vaccine approved in April 2020) and Supemtek® (a quadrivalent recombinant influenza vaccine). Net sales in the Rest of the World region (+30.6% CER at €456 million) include the effects of sales growth in China. In 2020, shipment of Sanofi influenza vaccines reached an all-time high of over 250 million doses.

In 2020, **Polio/Pertussis/Hib (PPH) vaccines** generated net sales of €2,106 million, up 12.6% CER, driven by sales in the Rest of the World region (+14.6% CER at €1,363 million), and especially by sales growth for Pentaxim® in China. In the United States, net sales of PPH vaccines were up 11.3% CER at €412 million, driven by sales growth for Pentacel®. In Europe, net sales of PPH vaccines rose by 6.3% CER to €331 million.

Net sales of **Meningitis/Pneumonia vaccines** for 2020 were €559 million, a decrease of 15.0% CER. Sales of Menactra® in the United States were down 20.3% CER at €392 million due to the adverse effects of the COVID-19 pandemic on vaccinations, while sales in the Rest of the World region were relatively stable (+1.2% CER at €166 million).

In 2020, sales of **adult booster vaccines** decreased by 14.9% to €467 million, mainly due to the impact of the COVID-19 pandemic on Adacel® in the United States and Repevax® in Europe.

Net sales of **travel and other endemics vaccines** in 2020 were €301 million, down 43.2% CER, reflecting the substantial reduction in travel during the pandemic.

5/ Net sales – Consumer Healthcare Segment/GBU

In 2020, net sales for the **Consumer Healthcare** (CHC) segment decreased by 6.4% on a reported basis and 1.9% at constant exchange rates to €4,394 million. This reflects the negative effects of the Zantac® product recall, reduced incidence of some seasonal pathologies due to public health measures, divestments of non-strategic brands, and product suspensions due to tighter regulatory requirements (especially in Europe). In 2020, sales were down year-on-year in the Digestive category (-8.6% CER at €858 million) and the Allergy, Cough & Cold category (-5.3% CER at €1,096 million). Those effects were partly offset by higher sales in the Pain category (+2.3% CER at €1,225 million) and the Nutritionals category (+4.7% CER at €611 million). Excluding Zantac®, CHC net sales were stable year-on-year.

In September 2019, the US Food and Drug Administration (FDA) and the Canadian health authorities announced publicly that ranitidine-based medicines, including **Zantac®**, might contain low levels of N-nitrosodimethylamine (NDMA), and that manufacturers had been asked to conduct tests. Inconsistencies in the results of preliminary tests on the active ingredient used in the products we sell in the United States and Canada led Sanofi to voluntarily recall Zantac® in October 2019. On April 1, 2020, the FDA ordered the immediate withdrawal from the US market of all ranitidine-based medicines.

In **Europe**, CHC net sales were down 4.3% CER in 2020 at €1,359 million; this reflects lower sales in the Allergy, Cough & Cold category due to lockdown measures, divestments of non-strategic brands, and product suspensions due to regulatory changes.

In the **United States**, CHC net sales amounted to €1,071 million in 2020, down 1.6% CER. A good performance from the Allergy (Allegra® and Xyzal®) and Nutritionals portfolios only partially offset the €77 million negative impact of the Zantac® recall. Excluding the impact of the Zantac® recall, full-year 2020 US sales would have increased by 5.7%.

In the **Rest of the World** region, CHC net sales were slightly lower (-0.4% CER) at €1,964 million in 2020. Growth in the Pain category (+5.4% CER at €505 million) and in Nutritionals (+5.3% CER at €441 million) did not fully offset lower sales in the Allergy, Cough & Cold category (-9.4% CER at €430 million) and the Digestive category (-2.6% CER, at €453 million).

6/ Net sales by Geographical Region

The table below sets forth our net sales for 2020 and 2019 by geographical region:

(€ million)	2020	2019 [(a)]	Change on a reported basis	Change at constant exchange rates
United States	13,465	12,756	+5.6%	+8.2%
Europe[(b)]	9,151	9,082	+0.8%	+1.5%
Rest of the World	13,425	14,288	-6.0%	+0.2%
of which China	2,454	2,704	-9.2%	-7.7%
of which Japan	1,735	1,908	-9.1%	-9.5%
of which Brazil	836	1,013	-17.5%	+5.6%
of which Russia	641	673	-4.8%	+6.7%
Total net sales	**36,041**	**36,126**	**-0.2%**	**+3.3%**

(a) With effect from January 1, 2020, the geographical split of net sales is aligned on Sanofi's new organizational structure: Europe, the United States, and Rest of the World. The presentation of 2019 figures has been amended to facilitate year-on-year comparisons.
(b) Israel and Ukraine are now included in the Europe region.

In 2020, net sales in the **United States** reached €13,465 million, up 5.6% on a reported basis and 8.2% at constant exchange rates. This reflects a strong performance from Dupixent® (+72.1% CER at €2,808 million) and influenza vaccines (+29.9% CER at €1,575 million), more than offsetting lower sales for the Diabetes franchise, for the Cardiovascular & Established Prescription Products franchise (-11.4% CER at €1,368 million), and for Menactra® (-20.3% CER at €392 million).

In **Europe**, net sales advanced by 0.8% on a reported basis and 1.5% at constant exchange rates in 2020 to €9,151 million. A substantial increase in sales of influenza vaccines (+93.9% CER at €441 million), plus strong performances by Dupixent® (+89.2% CER at €386 million) and the Oncology franchise (+34.5% CER at €299 million) offset a decrease in sales for the Cardiovascular & Established Prescription Products franchise (-6.7% CER at €3,299 million).

In the **Rest of the World** region, net sales for 2020 were down 6.0% on a reported basis but rose slightly (by 0.2%) at constant exchange rates, to €13,425 million. The unfavorable effects of the VBP program in China were offset by the performances of Vaccines, Dupixent®, Lovenox® and Rare Diseases franchise products. In **China**, net sales were 7.7% lower at €2,454 million due to the VBP program, despite strong growth in Vaccines and Consumer Healthcare plus the launch of Dupixent®. In **Japan,** 2020 net sales were down 9.5% at €1,735 million; lower sales in Established Prescription Products, Consumer Healthcare, Plavix® and the Diabetes franchise were only partly offset by the performance of Dupixent®.

A.2.2. Other Income Statement Items

1/ Other revenues

Other revenues decreased by 11.8% to €1,328 million in 2020 (versus €1,505 million in 2019). This line item mainly comprises VaxServe sales of non-Sanofi products (down 10.8% at €1,136 million in 2020, versus €1,273 million in 2019, recorded within the Vaccines segment), and revenues associated with the distribution of Eloctate® and Alprolix® (primarily in Europe) under our agreements with Swedish Orphan Biovitrum AB.

2/ Gross profit

Gross profit for 2020 amounted to €25,212 million compared with €25,655 million in 2019, a decrease of 1.7%. Gross margin (the ratio of gross profit to net sales) was slightly lower than in 2019 (70.0% in 2020, versus 71.0% in 2019).

Gross margin for the Pharmaceuticals segment decreased in 2020 to 73.1% (versus 74.4% in 2019). Positive factors for gross margin in the year included good performances from the Specialty Care GBU and industrial productivity gains. However, these only partially offset significant adverse price effects, due mainly to downward price adjustments for Plavix® and the Aprovel® family in China, and trends in net selling prices for Diabetes franchise products in the United States.

Gross margin for the Vaccines segment was unchanged in 2020 at 63.4%.

For the Consumer Healthcare segment, gross margin fell slightly in 2020 to 67.1% (versus 67.2% in 2019), due mainly to the adverse effect of exchange rates.

3/ Research and development expenses

Research and development (R&D) expenses amounted to €5,529 million, versus €6,018 million in 2019, a decrease of 8.1%. Cost control and a reduction in R&D expenses in Diabetes enabled Sanofi to reallocate resources to priority development projects (Specialty Care, Vaccines, and the acquisitions of Principia and Synthorx). R&D expenses represented 15.3% of net sales in 2020, versus 16.7% in 2019.

4/ Selling and general expenses

Selling and general expenses amounted to €9,390 million (26.1% of net sales), compared with €9,883 million in 2019 (27.4% of net sales). The year-on-year reduction of 5.0% was attributable mainly to global cost containment measures, and to the reallocation of resources to the Specialty Care and Vaccines GBUs.

5/ Other operating income and expenses

Other operating income amounted to €696 million in 2020 (versus €825 million in 2019), and other operating expenses to €1,415 million, versus €1,207 million in 2019.

Overall, this represented a net expense of €719 million in 2020, compared with a net expense of €382 million in 2019.

(€ million)	2020	2019	Change
Other operating income	696	825	-129
Other operating expenses	(1,415)	(1,207)	-208
Other operating income/(expenses), net	**(719)**	**(382)**	**-337**

The overall negative change of €337 million was due mainly to higher net expenses relating to our pharmaceutical alliance partners (€907 million in 2020, versus €640 million in 2019), and above all an increase in the share of profits/losses generated by the alliance with Regeneron under our collaboration agreement (see Note C.1. to our consolidated financial statements for the year ended December 31, 2019), due mainly to increased sales of Dupixent®.

The contribution of our alliance with Regeneron to this line item is as follows:

(€ million)	2020	2019
Income & expense related to profit/loss sharing under the Monoclonal Antibody Alliance	(727)	(253)
Additional share of profit paid by Regeneron towards development costs	75	21
Reimbursement to Regeneron of selling expenses incurred	(349)	(449)
Total: Monoclonal Antibody Alliance	**(1,001)**	**(681)**
Immuno-Oncology Alliance	**89**	**62**
Other (mainly Zaltrap®)	**(14)**	**(14)**
Other operating income/(expenses), net related to the Regeneron Alliance	**(926)**	**(633)**

The amount analyzed in the table above does not include the €157 million gain arising from the remeasurement (based on quoted market price as of May 29, 2020) of the 400,000 shares of Regeneron common stock retained by Sanofi to support its ongoing collaboration with Regeneron. That amount is included within ***Other operating income and expenses*** in the segment results of the Pharmaceuticals segment (see Note D.35. to our consolidated financial statements, included at Item 18. of this Annual Report on Form 20-F).

6/ Amortization of intangible assets

Amortization charged against intangible assets amounted to €1,681 million in 2020, compared with €2,146 million in 2019.

This €465 million decrease was mainly due to a reduction in amortization expense generated by intangible assets recognized in connection with the acquisition of Bioverativ (€331 million, versus €488 million in 2019), following impairment losses taken against Eloctate® franchise assets in 2019, and with the acquisitions of (i) Genzyme (€549 million, versus €727 million in 2019) and (ii) Aventis (€104 million, versus €197 million in 2019) as some products reached the end of their amortization period.

7/ Impairment of intangible assets

For 2020, this line item shows net impairment losses of €330 million taken against intangible assets (versus €3,604 million in 2019), mainly on development programs in Specialty Care and the termination of various R&D projects and collaboration agreements in Diabetes, in line with the strategic roadmap unveiled in December 2019.

For 2019, this line item mainly comprises an impairment loss of €2,803 million against Eloctate® franchise assets, reflecting ongoing competitive pressure in the market for hemophilia treatments. It also includes impairment losses of €352 million taken against rights to Zantac® following the voluntary recall of this product in the United States and Canada, and €280 million of impairment losses taken against assets associated with internal or collaborative development projects.

8/ Fair value remeasurement of contingent consideration

Fair value remeasurements of contingent consideration recognized in acquisitions (in accordance with IFRS 3) represented a net gain of €124 million in 2020, versus a net gain of €238 million in 2019.

This line item mainly comprises remeasurements of contingent consideration (i) relating to the dissolution of the Sanofi Pasteur MSD joint venture (net gain of €80 million in 2020 and of €154 million in 2019); (ii) arising on the acquisition of Bioverativ (net gain of €53 million in 2020, versus net expense of €78 million in 2019; and (iii) payable to Bayer as a result of an acquisition made by Genzyme prior to the latter's acquisition by Sanofi (net expense of €9 million in 2020, versus a net gain of €214 million in 2019).

9/ Restructuring costs and similar items

Restructuring costs and similar items represented a total charge of €1,064 million in 2020, versus a charge of €1,062 million in 2019. The amount charged in 2020 includes employee-related expenses of €690 million, comprising separation costs further to the announcement of plans to adapt Sanofi's organization (primarily in Europe) in line with the new "Play to Win" strategy announced in December 2019. This line item also includes €149 million of asset write-downs and accelerated depreciation.

In 2019, restructuring costs and similar items included separation costs of €791 million, relating mainly to Europe, the United States and Asia.

10/ Other gains and losses, and litigation

Other gains and losses, and litigation showed a gain of €136 million in 2020, mainly comprising a gain on the sale of operations related to the Seprafilm® activity to Baxter for proceeds of €311 million. This compares with a gain of €327 million in 2019, mainly relating to a gain on settlement of litigation.

11/ Operating income

Operating income amounted to €14,141 million in 2020, compared with €3,125 million in 2019. This increase was mainly due to the recognition of the €7,382 million gain on the divestment of Sanofi's equity investment in Regeneron following the transaction of May 29, 2020. Operating income also increased year-on-year due to a reduction in impairment losses taken against intangible assets in the period compared with 2019, when impairment losses reached €3,604 million due mainly to write-downs of Eloctate® franchise assets.

12/ Financial income and expenses

Net financial expenses were €337 million in 2020, versus €303 million in 2019, an increase of €34 million.

The cost of our net debt (see the definition in "B. Liquidity and Capital Resources" below) increased to €225 million in 2020, compared with €172 million in 2019. Other movements in net financial expenses included:

- increases: the net change in "Other financial income and expenses" (expense of €4 million in 2020, versus a gain of €19 million in 2019); and
- decreases: a reduction in the net interest cost of pension plans, mainly in France and Germany (€59 million, versus €87 million in 2019).

13/ Income before tax and investments accounted for using the equity method

Income before tax and investments accounted for using the equity method reached €13,804 million in 2020, versus €2,822 million in 2019.

14/ Income tax expense

Income tax expense represented €1,813 million in 2020, versus €139 million in 2019, giving an effective tax rate based on consolidated net income of 13.1% in 2020, compared with 4.9% in 2019. The increase in income tax expense was mainly due to the tax effects of (i) the transaction involving Regeneron shares (€502 million in 2020), and (ii) the impairment loss of €2,803 million in 2019 against Eloctate® franchise assets, reflecting ongoing competitive pressure in the market for hemophilia treatments.

The effective tax rate on our business net income is a non-GAAP financial measure (see definition under "A.1.5. Segment information — 3. Business Net Income" above). It is calculated on the basis of business operating income, minus net financial expenses and before (i) the share of profit/loss from investments accounted for using the equity method and (ii) net income attributable to non-controlling interests. We believe the presentation of this measure, used by our management, is also useful for investors as it provides a means to analyze the effective tax cost of our current business activities. It should not be seen as a substitute for the effective tax rate based on consolidated net income.

When calculated on business net income, our effective tax rate was 22.0% in 2020, the same rate as in 2019.

The table below reconciles our effective tax rate based on consolidated net income to our effective tax rate based on business net income:

(as a percentage)	2020	2019
Effective tax rate based on consolidated net income	**13.1%**	**4.9%**
Tax effects:		
Amortization and impairment of intangible assets	1.3	4.3
Restructuring costs and similar items	1.1	5.3
Gain on sale of Regeneron shares on May 29, 2020	6.9	—
Other tax effects	(0.4)	7.5
Effective tax rate based on business net income	**22.0%**	**22.0%**

15/ Share of profit/(loss) from investments accounted for using the equity method

Investments accounted for using the equity method contributed net income of €359 million in 2020, versus €255 million in 2019. This line item mainly comprises our share of profits from Regeneron (€343 million in 2020, versus €245 million in 2019); the increase was attributable mainly to changes in the corporate profits of Regeneron after adjustment to align on our accounting policies. On May 29, 2020, Sanofi sold its entire equity investment in Regeneron (except for 400,000 Regeneron shares retained by Sanofi to support its ongoing collaboration with Regeneron), which then ceased to be accounted for by the equity method. The amount for 2020 therefore reflects the use of the equity method until that date.

16/ Net income excluding the exchanged/held-for-exchange Animal Health business

Net income excluding the exchanged/held-for-exchange Animal Health business amounted to €12,350 million in 2020, versus €2,938 million in 2019.

17/ Net income/(loss) of the exchanged/held-for-exchange Animal Health business

In accordance with IFRS 5, the line item ***Net income/(loss) of the exchanged/held-for-exchange Animal Health business*** shows an expense of €101 million for 2019, relating to the final settlement signed in September 2019 with Boehringer Ingelheim.

18/ Net income

Net income amounted to €12,350 million in 2020, compared with €2,837 million in 2019.

19/ Net income attributable to non-controlling interests

Net income attributable to non-controlling interests was €36 million in 2020, versus €31 million in 2019.

20/ Net income attributable to equity holders of Sanofi

Net income attributable to equity holders of Sanofi amounted to €12,314 million in 2020, compared with €2,806 million in 2019.

Basic earnings per share for 2020 was €9.82, versus €2.24 for 2019, based on an average number of shares outstanding of 1,253.6 million in 2020 and 1,249.9 million in 2019. Diluted earnings per share for 2020 was €9.77, versus €2.23 for 2019, based on an average number of shares after dilution of 1,260.1 million in 2020 and 1,257.1 million in 2019.

A.2.3. Segment Results

Our business operating income, as defined in Note D.35. ("Segment information") to our consolidated financial statements, amounted to €9,762 million in 2020, compared with €9,349 million in 2019, an increase of 4.4%. That represents 27.1% of our net sales, compared with 25.9% in 2017.

Following the transaction of May 29, 2020, Regeneron is no longer an associate of Sanofi (see Note D.1. to our consolidated financial statements). Consequently, the definition of the "Business operating income" indicator has been adjusted, and no longer includes Sanofi's share of the net income of Regeneron. This means that the ***Share of profit/(loss) from investments accounted for using the equity method*** line in the table reconciling ***Operating income*** (as shown in the income statement) to "Business operating income" no longer includes the equity-accounted share of profits from Regeneron. The comparatives presented for 2019 have been restated to reflect that adjustment. In addition, the gain arising on the divestment of the equity investment in Regeneron is not included in "Business operating income", with the exception of the gain on the remeasurement of the 400,000 retained shares at market value at the transaction date.

In addition, with effect from January 1, 2020 "Business operating income" includes depreciation charged against right-of-use assets recognized under IFRS 16 (Leases), applicable since January 1, 2019, and excludes rental expenses previously recognized under IAS 17. In the interests of consistency, the "Business operating income" and "Business operating income margin" figures presented for 2019 have been restated to include the effects of IFRS 16, and of certain expenses and income presented differently for segment reporting purposes to align on Sanofi's new 2020 operational structure (see "—A.1.5,1. — Operating Segments", above).

The table below sets forth our business operating income for the years ended December 31, 2020 and 2019:

(€ million)	December 31, 2020	December 31, 2019 [(a)]	Change
Pharmaceuticals	8,833	8,182	+8.0%
Consumer Healthcare	1,419	1,657	-14.4%
Vaccines	2,276	2,181	+4.4%
Other	(2,766)	(2,671)	+3.6%
Business operating income	**9,762**	**9,349**	**+4.4%**

(a) 2019 figures have been restated to (i) exclude Sanofi's equity-accounted share of Regeneron's net profits, which amounted to €411 million in 2019; (ii) include the effects of IFRS 16; and (iii) include the reallocation of some products from Pharmaceuticals to Consumer Healthcare (immaterial impact) and the reallocation of costs previously reported in "Other" to operating segments, for a net amount of €291 million.

Due to lack of available data and the over-complex adjustments that would be required (in particular to our reporting tools), 2018 figures have not been restated to reflect the changes arising from our new segment reporting model implemented early 2020. Segment results for 2018, restated to exclude Sanofi's share of profits from its equity investment in Regeneron, but using the previous segment reporting model, are presented in Item 18. — Consolidated Financial Statements — Note D.35.

B. Liquidity and Capital Resources

Our operations generate significant positive cash flows. We fund our day-to-day investments (with the exception of significant acquisitions) primarily with operating cash flow, and pay regular dividends on our shares.

"Net debt" is a non-GAAP financial indicator which is reviewed by our management, and which we believe provides useful information to measure our overall liquidity and capital resources. We define "net debt" as (i) the sum total of short term debt, long term debt, and interest rate derivatives and currency derivatives used to manage debt, minus (ii) the sum total of cash and cash equivalents and interest rate derivatives and currency derivatives used to manage cash and cash equivalents. Following the first-time application of IFRS 16 effective from January 1, 2019, net debt does not includes lease liabilities.

As of December 31, 2020 our net debt was €8,790 million, compared with €15,107 million as of December 31, 2019, due in particular to cash inflows from investing activities during the year, and more specifically to the net proceeds from our sale of Regeneron shares on May 29, 2020. See Note D.17.1. to our consolidated financial statements.

In order to assess our financing risk, we also use the "gearing ratio", a non-GAAP financial measure (see table in section "B.2. Consolidated Balance Sheet and Debt" below). We define the gearing ratio as the ratio of net debt to total equity. As of December 31, 2020, our gearing ratio was 13.9%, compared with 25.6% as of December 31, 2019.

Because our net debt and gearing ratio are not standardized measures, they may not be directly comparable with the non-GAAP financial measures of other companies using the same or similar non-GAAP financial measures. Despite the use of non-GAAP measures by management in setting goals and measuring performance, these are non-GAAP measures that have no standardized meaning prescribed by GAAP.

B.1. Consolidated Statement of Cash Flows

Generally, factors that affect our earnings – for example, pricing, volume, costs and exchange rates – flow through to cash from operations. The most significant source of cash from operations is sales of our branded pharmaceutical products and vaccines. Receipts of royalty payments also contribute to cash from operations.

Summarized consolidated statements of cash flows

(€ million)	2020	2019
Net cash provided by/(used in) operating activities	7,449	7,744
Net cash provided by/(used in) investing activities	3,588	(1,212)
Net cash inflow from the exchange of the Animal Health business for BI's Consumer Healthcare business	—	154
Net cash provided by/(used in) financing activities	(6,485)	(4,193)
Impact of exchange rates on cash and cash equivalents	(64)	9
Net change in cash and cash equivalents	**4,488**	**2,502**

Net cash provided by/used in operating activities represented a net cash inflow of €7,449 million in 2020, compared with €7,744 million in 2019.

Operating cash flow before changes in working capital for 2020 amounted to €7,774 million, compared with €8,163 million in 2019. Working capital requirements increased by €325 million in 2020, compared with an increase of €419 million in 2019. The main factors in 2020 were a €593 million rise in inventories (mainly of Dupixent®).

Net cash provided by/used in investing activities represented a net cash inflow of €3,588 million in 2020, compared with a net outflow of €1,212 million in 2019. The main movements in 2020 were a cash inflow of €10,370 million from the sale of Regeneron shares on May 29, 2020, and cash outflows related to the acquisitions of Synthorx (€2,245 million) and Principia (€2,972 million).

Acquisitions of property, plant and equipment and intangible assets amounted to €2,114 million, versus €1,816 million in 2019. There were €1,254 million of acquisitions of property, plant and equipment (versus €1,323 million in 2019), mostly (€755 million) in the Pharmaceuticals segment, primarily in industrial facilities. The Vaccines segment accounted for €404 million of acquisitions of property, plant and equipment during 2020. Acquisitions of intangible assets (€860 million, versus €493 million in 2019) mainly comprised contractual payments for intangible rights under license and collaboration agreements.

After-tax proceeds from disposals amounted to €918 million in 2020, the main items being (i) the sale to Baxter of the Seprafilm® activity for a selling price before taxes of €311 million; (ii) the divestment of some of our established prescription products for €97 million before taxes; and (ii) €167 million before taxes of contingent consideration received in connection with a past divestment. In 2019, after-tax proceeds from disposals amounted to €1,224 million, mainly arising on the divestment of our equity interests in Alnylam (€706 million) and MyoKardia (€118 million).

Net cash provided by/used in financing activities represented a net cash outflow of €6,485 million in 2020, compared with a net cash outflow of €4,193 million in 2019. The 2020 figure includes net debt repayments of €1,885 million including lease liabilities (versus €491 million in 2019); the dividend payout to our shareholders of €3,937 million (versus €3,834 million in 2019); and the effect of changes in our share capital (repurchases of our own shares, net of capital increases), representing a net cash outflow of €619 million in 2020 and a net cash inflow of €153 million in 2019.

The ***net change in cash and cash equivalents*** in 2020 was an increase of €4,488 million, versus an increase of €2,502 million in 2019.

"Free cash flow" for the year ended December 31, 2020 was €6,982 million, an increase on the 2019 figure of €6,014 million. This reflects our operational performance (including the effect of cost containment measures), and asset divestments made during the period.

"Free cash flow" is a non-GAAP financial indicator which is reviewed by our management, and which we believe provides useful information to measure the net cash generated from our operations that is available for strategic investments[1] (net of divestments[1]), for debt repayment, and for payments to shareholders. "Free cash flow" is determined from our "Business net income"[2] adjusted for depreciation, amortization and impairment, share of undistributed earnings from investments accounted for using the equity method, gains & losses on disposals, net change in provisions including pensions and other post-employment benefits, deferred taxes, share-based payment expense and other non-cash items. It also includes net changes in working capital, capital expenditures and other asset acquisitions[3] net of disposal proceeds[3], and payments related to restructuring and similar items. "Free cash flow" is not defined by IFRS, and is not a substitute for ***Net cash provided by operating activities*** as reported under IFRS. Management recognizes that the term "Free cash flow" may be interpreted differently by other companies and under different circumstances. The table below sets forth a reconciliation between ***Net cash provided by operating activities*** and "Free cash flow":

(€ million)	2020	2019 [(d)]
Net cash provided by operating activities	**7,449**	**7,744**
Acquisitions of property, plant and equipment and software	(1,329)	(1,405)
Acquisitions of intangible assets, equity interests and other non-current financial assets[(a)]	(562)	(576)
Proceeds from disposals of property, plant and equipment, intangible assets and other non-current assets, net of tax[(a)]	930	490
Repayments of lease liabilities[(b)]	(234)	(267)
Other items[(c)]	728	28
Free cash flow	**6,982**	**6,014**

(a) Free cash flow includes investments and divestments not exceeding a cap of €500 million per transaction.
(b) Following the application of IFRS 16, cash outflows relating to repayments of the principal portion of lease liabilities are included in free cash flow.
*(c) This line mainly comprises the reclassification of net foreign exchange gains and losses arising on financial monetary items, and on the related hedging instruments, to **Net cash provided by/(used in) financing activities**.*
(d) The presentation of the 2019 figure has been adjusted to take account of the first-time application of IFRS 16.

B.2. Consolidated Balance Sheet and Debt

Total assets were €114,529 million as of December 31, 2020, compared with €112,736 million as of December 31, 2019, an increase of €1,793 million.

Net debt was €8,790 million as of December 31, 2020, compared with €15,107 million as of December 31, 2019, due in particular to cash inflows from investing activities during the year, and more specifically to the net proceeds from our sale of Regeneron shares on May 29, 2020. "Net debt" is a non-GAAP financial measure which is reviewed by our management, and which we believe provides useful information to measure our overall liquidity and capital resources. We define "net debt" as (i) the sum total of short term debt, long term debt, and interest rate derivatives and currency derivatives used to manage debt, minus (ii) the sum total of cash and cash equivalents and interest rate derivatives and currency derivatives used to manage cash and cash equivalents.

(€ million)	2020	2019
Long-term debt	19,745	20,131
Short-term debt and current portion of long-term debt	2,767	4,554
Interest rate and currency derivatives used to manage debt	119	(117)
Total debt	**22,631**	**24,568**
Cash and cash equivalents	(13,915)	(9,427)
Interest rate and currency derivatives used to manage cash and cash equivalents	74	(34)
Net debt[(a)]	**8,790**	**15,107**
Total equity	63,147	59,108
Gearing ratio	**13.9 %**	**25.6 %**

To assess our financing risk, we use the "gearing ratio", a non-GAAP financial measure. This ratio (which we define as the ratio of net debt to total equity) reduced from 25.6% as of December 31, 2019 to 13.9% as of December 31, 2020. Analyses of debt as of December 31, 2020 and December 31, 2019, by type, maturity, interest rate and currency, are provided in Note D.17.1. to our consolidated financial statements.

We expect that the future cash flows generated by our operating activities will be sufficient to repay our debt. The financing arrangements in place as of December 31, 2020 at the Sanofi parent company level are not subject to covenants regarding financial ratios and do not contain any clauses linking fees to Sanofi's credit rating.

[1] Above a cap of €500 million per transaction.
[2] Non-GAAP financial measure, as defined in "- A.1.5. — Segment Information — 3. Business Net income" above.
[3] Not exceeding a cap of €500 million per transaction.

Other key movements in the balance sheet are described below.

Total **equity** was €63,147 million as of December 31, 2020, versus €59,108 million as of December 31, 2019. The year-on-year change reflects the following principal factors:

- increases: our net income for 2020 (€12,350 million); and
- decreases: the dividend paid to our shareholders in respect of the 2019 financial year (€3,937 million), currency translation differences (€3,978 million, mainly on the US dollar), and repurchases of our own shares (€822 million).

As of December 31, 2020, we held 8.28 million of our own shares, recorded as a deduction from equity and representing 0.658% of our share capital.

Goodwill and ***Other intangible assets*** (€62,785 million in total) increased by €1,694 million year-on-year, the main factors being:

- increases: movements associated with the acquisitions of Synthorx (€930 million of goodwill, €1,549 million of other intangible assets) and Principia (€913 million of goodwill and €2,534 million of other intangible assets); and
- decreases: amortization and impairment charged in the period (€2,162 million), and currency translation differences (€2,832 million).

Investments accounted for using the equity method (€201 million) decreased by €3,390 million following our sale of Regeneron shares in the transaction of May 29, 2020 (see Note D.1. to our consolidated financial statements).

Other non-current assets amounted to €2,734 million, a year-on-year increase of €231 million. This mainly reflects the reclassification of the 400,000 Regeneron shares initially retained following the transaction of May 29, 2020 into the “Equity instruments at fair value through other comprehensive income” category (see Notes D.1. and D.7. to our consolidated financial statements).

Net deferred tax assets amounted to €2,442 million as of December 31, 2020, versus €3,140 million as of December 31, 2019, a year-on-year decrease of €698 million. This was largely due to deferred taxes arising on the remeasurement of the acquired intangible assets of Synthorx and Principia.

Non-current provisions and other non-current liabilities (€7,536 million) showed a decrease of €105 million, mainly due to a reduction in provisions for pensions and other post-employment benefits.

Liabilities related to business combinations and to non-controlling interests (€605 million) were €195 million lower year-on-year. The main movements in this line item are payments and fair value remeasurements of contingent consideration payable to (i) Merck, further to the dissolution of the Sanofi Pasteur MSD joint venture at the end of 2016; (ii) the former shareholders of True North Therapeutics, as a result of an acquisition made by Bioverativ prior to the latter's acquisition by Sanofi in 2018; and (iii) Bayer, as a result of an acquisition made by Genzyme prior to the latter’s acquisition by Sanofi in 2011.

B.3. Liquidity

We expect that our existing cash resources and cash from operations will be sufficient to finance our foreseeable working capital requirements. At year-end 2020, we held cash and cash equivalents amounting to €13,915 million, substantially all of which were held in euros (see Note D.13. to our consolidated financial statements included at Item 18. of this annual report). As at December 31, 2020, €425 million of our cash and cash equivalents were held by captive insurance and reinsurance companies in accordance with insurance regulations.

We run the risk of delayed payments or even non-payment by our customers, who consist principally of wholesalers, distributors, pharmacies, hospitals, clinics and government agencies (see “Item 3.D. Risk Factors — 2. Risks Relating to Our Business — We are subject to the risk of non-payment by our customers”). Deteriorating credit and economic conditions and other factors in some countries have resulted in, and may continue to result in an increase in the average length of time taken to collect our accounts receivable in these countries. Should these factors continue, it may require us to re-evaluate the collectability of these receivables in future periods. We carefully monitor sovereign debt issues and economic conditions and evaluate accounts receivable in these countries for potential collection risks. We have been conducting an active recovery policy, adapted to each country and including intense communication with customers, negotiations of payment plans, charging of interest for late payments, and legal action. Over our business as a whole, the amount of trade receivables overdue by more than 12 months (which primarily consists of amounts due from public sector bodies) decreased from €105 million as of December 31, 2019 to €95 million as of December 31, 2020 (see Note D.10. to our consolidated financial statements).

In November 2011, Sanofi obtained the necessary corporate authorizations to purchase any or all of the outstanding Contingent Value Rights (“CVR”) and subsequently purchased CVRs in 2011. In 2012 following a tender offer initiated in September 2012 on the basis of the same corporate authorization, Sanofi purchased an additional 40,025,805 CVRs (for a total consideration of approximately $70 million), followed by a further 10,928,075 CVRs (for approximately $9 million) in 2013, 1,879,774 CVRs (for approximately $1 million) in 2014, and none between 2015 and 2020. In October 2019, the Trustee and Sanofi entered into an agreement to settle the action for $315 million (the “Settlement Agreement”), which was previously disclosed in a Form 6-K filed by Sanofi on October 31, 2019. Among other things, the Settlement Agreement provides that the CVRs will be delisted from the NASDAQ and extinguished, and the CVR Agreement will be terminated. The Settlement Agreement was approved by the probate court for Hennepin County, Minnesota on December 20, 2019; the time for appeals expired on March 3, 2020.

At year-end 2020, we had no commitments for capital expenditures that we consider to be material to our consolidated financial position. Undrawn confirmed credit facilities amounted to a total of €8,000 million at December 31, 2020. For a discussion of our treasury policies, see “Item 11. Quantitative and Qualitative Disclosures about Market Risk.”

We expect that cash from our operations will be sufficient to repay our debt. For a discussion of our liquidity risks, see “Item 11. Quantitative and Qualitative Disclosures about Market Risk.”

C. Off Balance Sheet Arrangements/Contractual Obligations and Other Commercial Commitments

We have various contractual obligations and other commercial commitments arising from our operations. Our contractual obligations and our other commercial commitments as of December 31, 2020 are shown in Notes D.3., D.17., D.18., and D.21. to our consolidated financial statements included at Item 18. of this annual report. Note D.21. to our consolidated financial statements discloses details of commitments under our principal research and development collaboration agreements. For a description of the principal contingencies arising from certain business divestitures, refer to Note D.22.d.) to our 2020 consolidated financial statements.

Sanofi's contractual obligations and other commercial commitments are set forth in the table below:

December 31, 2020		Payments due by period			
(€ million)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Future contractual cash flows relating to debt and debt hedging instruments[(a)]	24,502	3,078	6,855	2,728	11,841
Principal payments related to lease liabilities[(b)]	1,311	247	357	225	482
Other lease obligations (with a term of less than 12 months, low value asset leases and lease contracts committed but not yet commenced)[(c)]	950	39	118	118	675
Irrevocable purchase commitments[(d)]					
• given	*7,153*	*4,072*	*1,482*	*572*	*1,027*
• received	*(608)*	*(236)*	*(168)*	*(51)*	*(153)*
Research & development license agreements					
• Commitments related to R&D and other commitments	*500*	*261*	*217*	*10*	*12*
• Potential milestone payments[(e)]	*2,456*	*163*	*714*	*972*	*607*
• Obligations related to R&D license agreements reflected in the balance sheet	*148*	*44*	*24*	*16*	*64*
Obligations relating to business combinations[(f)]	1,043	228	351	192	272
Estimated benefit payments on unfunded pensions and post employment benefits[(g)]	1,134	61	99	102	872
Total contractual obligations and other commitments	**38,589**	**7,957**	**10,049**	**4,884**	**15,699**
Undrawn general-purpose credit facilities	**8,000**	**4,000**	**—**	**4,000**	**—**

(a) See Note D.17.1. to our consolidated financial statements included at Item 18. of this annual report.

(b) See Note D.17.2. to our consolidated financial statements included at Item 18. of this annual report.

(c) See Note D.21.1. to our consolidated financial statements included at Item 18. of this annual report.

(d) These comprise irrevocable commitments to suppliers of (i) property, plant and equipment, net of down payments (see Note D.3. to our consolidated financial statements included at Item 18. of this annual report) and (ii) goods and services.

(e) This line includes all potential milestone payments on projects regarded as reasonably possible, i.e. on projects in the development phase.

(f) See Note D.18. to our consolidated financial statements included at Item 18. of this annual report.

(g) See Note D.19.1. to our consolidated financial statements included at Item 18. of this annual report. The table above does not include ongoing annual employer's contributions to plan assets, estimated at €42 million for 2021.

We may have payments due to our current or former research and development partners under collaboration agreements. These agreements typically cover multiple products, and give us the option to participate in development on a product-by-product basis. When we exercise our option with respect to a product, we pay our collaboration partner a fee and receive intellectual property rights to the product in exchange. We are also generally required to fund some or all of the development costs for the products that we select, and to make payments to our partners when those products reach development milestones.

We have entered into collaboration agreements under which we have rights to acquire products or technology from third parties through the acquisition of shares, loans, license agreements, joint development, co-marketing and other contractual arrangements. In addition to upfront payments on signature of the agreement, our contracts frequently require us to make payments contingent upon the completion of development milestones by our alliance partner or upon the granting of approvals or licenses.

Because of the uncertain nature of development work, it is impossible to predict (i) whether Sanofi will exercise further options for products, or (ii) whether the expected milestones will be achieved, or (iii) the number of compounds that will reach the relevant milestones. It is therefore impossible to estimate the maximum aggregate amount that Sanofi will actually pay in the future under existing collaboration agreements.

Given the nature of its business, it is highly unlikely that Sanofi will exercise all options for all products or that all milestones will be achieved.

The main collaboration agreements relating to development projects are described in Note D.21.1. to our consolidated financial statements, included at Item 18. of this annual report. Milestone payments relating to development projects under these agreements included in the table above exclude projects still in the research phase (€6.7 billion in 2020, and €6.7 billion in 2019) and payments contingent upon the attainment of sales targets once a product is on the market (€8.1 billion in 2020, and €10.6 billion in 2019).

Item 6. Directors, Senior Management and Employees

A. Directors and Senior Management

Since January 1, 2007, Sanofi has separated the offices of Chairman and Chief Executive Officer. Annual evaluations conducted since that date have indicated that this governance structure is appropriate to Sanofi's current configuration. This arrangement was maintained with the appointment of Serge Weinberg to the office of Chairman firstly on May 17, 2010, then on May 6, 2011, again on May 4, 2015, and finally on April 30, 2019. The Board of Directors regards this governance structure as appropriate to the current context in which Sanofi operates and its share ownership structure, and as protecting the rights of all of its stakeholders.

The **Chairman** organizes and directs the work of the Board, and is responsible for ensuring the proper functioning of the corporate decision-making bodies in compliance with good governance principles. The Chairman coordinates the work of the Board of Directors with that of its Committees. He ensures that the Company's management bodies function properly, and in particular that the directors are able to fulfil their duties. The Chairman is accountable to the Shareholders' General Meeting, which he chairs.

In addition to these roles conferred by law, the Chairman:

- in coordination with the Chief Executive Officer, liaises between the Board of Directors and the shareholders of the Company;
- is kept regularly informed by the Chief Executive Officer of significant events and situations affecting the affairs of the Company, and may request from the Chief Executive Officer any information useful to the Board of Directors;
- may, in close collaboration with the Chief Executive Officer, represent the Company in high-level dealings with governmental bodies and with key partners of the Company and/or of its subsidiaries, both nationally and internationally;
- seeks to prevent any conflict of interest and manages any situation that might give rise to a conflict of interest. He also gives rulings, in the name of the Board, on requests to take up external directorships of which he may become aware or that may be submitted to him by a director;
- may interview the statutory auditors in preparation for the work of the Board of Directors and the Audit Committee; and
- strives to promote in all circumstances the values and image of the Company.

The Chairman is also required to develop and maintain a proper relationship of trust between the Board and the Chief Executive Officer, so as to ensure that the latter consistently and continuously implements the orientations determined by the Board.

In fulfilling his remit, the Chairman may meet with any individual, including senior executives of the Company, while avoiding any involvement in directing the Company or managing its operations, which are exclusively the responsibility of the Chief Executive Officer.

Finally, the Chairman reports to the Board on the fulfilment of his remit.

The Chairman carries out his duties during the entire period of his term of office, subject to the caveat that a director who is a natural person may not be appointed or reappointed once that director has reached the age of 70.

The **Chief Executive Officer** manages the Company, and represents it in dealings with third parties within the limit of the corporate purpose. The Chief Executive Officer has the broadest powers to act in all circumstances in the name of the Company, subject to the powers that are attributed by law to the Board of Directors and to the Shareholders' General Meeting and within the limits set by the Board of Directors.

The Chief Executive Officer must be less than 65 years old.

Limitations on the powers of the Chief Executive Officer set by the Board

With effect from March 6, 2018, the limitations on the powers of the Chief Executive Officer are specified in the Board Charter. Without prejudice to legal provisions regarding authorizations that must be granted by the Board (regulated agreements, guarantees, divestments of equity holdings or real estate, etc.), prior approval from the Board of Directors is required for transactions or decisions resulting in an investment or divestment, or an expenditure or guarantee commitment, made by the Company and its subsidiaries, in excess of:

- a cap of €500 million (per transaction) for transactions, decisions or commitments pertaining to a previously approved strategy; and
- a cap of €150 million (per transaction) for transactions, decisions or commitments not pertaining to a previously approved strategy.

When such transactions, decisions or commitments give rise to installment payments to the contracting third party (or parties) that are contingent upon future results or objectives, such as the registration of one or more products, attainment of the caps is calculated by aggregating the various payments due from signature of the contract until (and including) filing of the first application for marketing authorization in the United States or in Europe.

Attainment of the above caps is also assessed after taking into account all commitments to make payments on exercise of a firm or conditional option with immediate or deferred effect, and all guarantees or collateral to be provided to third parties over the duration of such commitments.

The prior approval procedure does not apply to transactions and decisions that result in the signature of agreements that solely involve subsidiaries and the Company itself.

Board of Directors

The Board of Directors lays down the orientations of the Company's activities and ensures that they are implemented, paying due consideration to social and environmental issues. Subject to those powers expressly attributed to Shareholders' General Meetings and within the limits set by the corporate purpose, it addresses any issue of relevance to the proper conduct of the Company's affairs and, through its deliberations, settles matters concerning the Company.

Each year, the Board of Directors conducts a review to ensure that there is an appropriate balance in its composition and in the composition of its Committees. In particular, the Board seeks to ensure gender balance and a broad diversity of competencies, experiences, nationalities and ages, reflecting our status as a diversified global business. The Board investigates and evaluates not only potential candidates, but also whether existing directors should seek reappointment. Above all, the Board seeks directors who show independence of mind and are competent, dedicated and committed, with compatible and complementary personalities.

As of December 31, 2020 our Board of Directors had 16 members, including two directors representing employees. 43% of the directors were women and 50% were non-French nationals.

Acting on proposals from the Chief Executive Officer and in liaison with the Compensation Committee and the Appointments, Governance and CSR Committee, the Board sets objectives for gender balance on Sanofi's executive bodies, and more generally ensures that an inclusion (non-discrimination) and diversity policy is applied within the Company. As of December 31, 2020, 27% of the 11 Executive Committee members were women, and 64% were non-French nationals.

The Board of Directors is also kept informed, in particular on the occasion of its annual discussion on professional and pay equality policy, on how the inclusion and diversity policy is cascaded down to "Senior Leaders" and "Executives" (the positions in Sanofi with the highest level of responsibility). In 2020, there were 2,219 "Senior Leaders" within Sanofi; of that total, 38.8% were women.

The rules and operating procedures of our Board of Directors are defined by law, by our Articles of Association, and by our Board charter (an English language version of which is reproduced in full as Exhibit 1.2 to this Annual Report on Form 20-F).

Term of Office

The term of office of directors is four years. Directors are required to seek reappointment by rotation, such that members of the Board are required to seek reappointment on a regular basis in the most equal proportions possible. Exceptionally, the Shareholders' Ordinary General Meeting may appoint a director to serve for a term of one, two or three years, in order to ensure adequate rotation of Board members. Each director standing down is eligible for reappointment. Should one or more directorships fall vacant as a result of death or resignation, the Board of Directors may make provisional appointments in the period between two Shareholders' General Meetings, in accordance with applicable laws.

Directors may be removed from office at any time by a Shareholders' General Meeting.

A natural person cannot be appointed or reappointed as a director once he or she reaches the age of 70. As soon as the number of directors aged over 70 represents more than one-third of the directors in office, the oldest director shall be deemed to have resigned; his or her term of office shall end at the date of the next Shareholders' Ordinary General Meeting.

Selection Process for Board Members

The Appointments, Governance and CSR Committee has a remit to organize a procedure for selecting future independent directors. Once the desired profile and skillset for a new director has been defined, a search for potential candidates is conducted by external consultants.

Once a shortlist has been established, the Committee interviews two or three candidates. After completing the interviews, the Committee makes a recommendation to the Board on the candidate with the best fit for the profile, supporting that recommendation with an explanation of how the interviews were conducted and giving reasons why a candidate was selected.

Independence of Board Members

Under the terms of the AFEP-MEDEF corporate governance code (the AFEP-MEDEF Code), a director is independent when he or she has no relationship of any kind whatsoever with the Company, its group or its senior management that may color his or her judgment. More specifically, a director can only be regarded as independent if he or she:

- is not (and has not been during the past five years):
  - an employee or executive officer of the Company;
  - an employee, executive officer or director of an entity consolidated by the Company; or
  - an employee, executive officer or director of the Company's parent, or of an entity consolidated by that parent (criterion 1);
- is not an executive officer of an entity in which (i) the Company directly or indirectly holds a directorship or (ii) an employee of the Company is designated as a director or (iii) an executive officer of the Company (currently, or who has held office within the past five years) holds a directorship (criterion 2);
- is not a customer, supplier, investment banker or corporate banker that is material to the Company or its group, or for whom the Company or its group represents a significant proportion of its business (criterion 3);
- has no close family ties with a corporate officer of the Company (criterion 4);
- has not acted as auditor for the Company over the course of the past five years (criterion 5);
- has not been a director of the Company for more than twelve years (criterion 6);
- does not receive variable compensation in cash or in the form of shares or any compensation linked to the performance of the Company or its group (criterion 7); or

- does not represent a shareholder that has a significant or controlling interest in the Company (criterion 8).

The influence of other factors such as the ability to understand challenges and risks, and the courage to express ideas and form a judgment, is also evaluated before it is decided whether a director can be regarded as independent.

In compliance with our Board Charter and pursuant to the AFEP-MEDEF Code, the Board of Directors' meeting of March 3, 2021 discussed the independence of the current directors. Of the sixteen directors present on that date, eleven were deemed to be independent directors by reference to the independence criteria used by the Board of Directors pursuant to the AFEP-MEDEF Code: Serge Weinberg, Bernard Charlès, Rachel Duan, Lise Kingo, Patrick Kron, Fabienne Lecorvaisier, Melanie Lee, Carole Piwnica, Gilles Schnepp, Diane Souza and Thomas Südhof.

Consequently, the proportion of independent directors is 79%. This compares with the AFEP-MEDEF recommendation of 50% in companies with dispersed ownership and no controlling shareholder (which is the case for Sanofi). In accordance with the recommendations of the AFEP-MEDEF Code, directors representing employees are excluded when calculating the proportion of independent directors.

	Serge Weinberg	Bernard Charlès	Rachel Duan	Lise Kingo	Patrick Kron	Fabienne Lecorvaisier	Melanie Lee	Carole Piwnica	Gilles Schnepp	Diane Souza	Thomas Südhof
Criterion 1: not an employee/executive officer in past 5 years	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Criterion 2: No cross-directorships	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Criterion 3: no significant business relationship	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Criterion 4: no close family ties	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Criterion 5: not an auditor	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Criterion 6: not held office for >12 years	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Criterion 7: no variable or performance-linked compensation	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Criterion 8: not a significant shareholder	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Deemed independent	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Failure to fulfil one of the criteria does not automatically disqualify a director from being independent.

The Board's conclusions on the situation of Serge Weinberg and on the business relationships review are set out below.

1/ Serge Weinberg

When the offices of Chairman of the Board and Chief Executive Officer were temporarily combined on October 29, 2014, the Board of Directors determined that Serge Weinberg – given his role as Chief Executive Officer – could no longer be regarded as independent. When the two offices were separated again in April 2015, the Board of Directors determined that Serge Weinberg could be regarded as independent and could therefore resume the chairmanship of the Appointments and Governance Committee (renamed the Appointments, Governance and CSR Committee in March 2019).

Under Article 9.6 of the AFEP-MEDEF Code, a non-executive officer cannot be regarded as independent if he or she receives variable compensation in cash or shares or any compensation linked to the performance of the Company or group. Serge Weinberg receives fixed compensation only, with no entitlement to variable compensation in either cash or shares.

2/ Business Relationships Review

In its examination of the independence of each director, the Board of Directors took into account the various relationships between directors and Sanofi and concluded that no relationships were of a kind that might undermine their independence. The Board of Directors noted that the Company and its subsidiaries had, in the normal course of business, over the past three years, sold products and provided services to, and/or purchased products and received services from, companies in which certain of the Company's directors who are classified as independent (or their close family members) were senior executives or employees during 2020. In each case, the amounts paid to or received from such companies over the past three years were determined on an arm's length basis and did not represent amounts that the Board regarded as undermining the independence of the directors in question.

Board Evaluation

Under the terms of the Board Charter, a discussion of the operating procedures of the Board and its committees must be included on the agenda of one Board meeting every year. The Charter also requires a formal evaluation to be performed at least every three years under the direction of the Appointments, Governance and CSR Committee, with assistance from an independent consultant if deemed necessary.

In 2018, a formal evaluation of the Board was conducted under the direction of the Appointments and Governance Committee (renamed the Appointments, Governance and CSR Committee in March 2019), with assistance from a specialist consultancy firm. The results of the 2018 evaluation showed a positive assessment of the way in which the Board and its Committees operate.

The 2019 and 2020 evaluations were conducted internally, using a detailed questionnaire sent to directors by the Secretary to the Board. Each director was allowed a few weeks to complete the questionnaire using a secure digital platform. At the end of that period, the responses were analyzed by the Secretary to the Board, and supplemented by one-on-one interviews. The results were then presented to, and discussed by, the Appointments, Governance and CSR Committee.

The results of the 2019 evaluation showed a positive assessment of the way in which the Board and its Committees operate. The areas for progress and vigilance identified were (i) more time should be devoted to long-term strategic thinking; (ii) greater attention should be paid to issues relating to CSR and human resources policy; (iii) the induction program for new directors should be enhanced; and (iv) work should progress on preparing succession plans for the Chairman of the Board and members of the Executive Committee.

The following actions were taken during 2020 to address those areas for progress and vigilance:

- a strategy seminar, expanded to include Executive Committee members, was held in October 2020, which included a progress report on the "Play to Win" strategy and presentations on R&D, General Medicines, Vaccines, Dupixent®, opportunities in Specialty Care, digital strategy, and the financial roadmap;
- the human resources policy was subject to a review led by Natalie Bickford (Chief People Officer), who joined the Executive Committee in August 2020, and presented to the Board; and
- an in-depth review of Sanofi's top 50 managers was conducted at the request of Paul Hudson in order to strengthen Executive Committee succession planning.

The results of the 2020 evaluation were presented to the Board on March 3, 2021, and highlighted the following points:

The vast majority of Board members believed that the way in which the Board operates had improved since the previous evaluation.

In particular, they stressed the quality of dialogue on strategy with the Chief Executive Officer, with the Strategy Seminar a high point.

Progress had also been made in the areas of Corporate Social Responsibility; the quality of the work done by the Scientific Committee; and the composition of the Board, with three new directors taking up office.

The areas for progress and vigilance identified and noted by the Board were:

- deeper analysis of the human resources policy and succession planning - on the latter point, succession planning for the Chairman needs to be continued and stepped up by the Appointments, Governance and CSR Committee and by the Board itself, with the current Chairman's term of office due to expire in 2023;
- even closer attention to risk management; and
- the remit of the Strategy Committee must be clarified.

Board members also mentioned the impact of COVID-19 on exchanges between directors, which had become less interactive given that circumstances called for more use of online tools.

They expressed a wish to return to two executive sessions per year after the end of the Chief Executive Officer's transition phase.

Succession Planning

The remit of the Appointments, Governance and CSR Committee includes preparing for the future of the Company's executive bodies, in particular through the establishment of a succession plan for executive officers.

The plan, which is reviewed at meetings of the Appointments, Governance and CSR Committee, addresses various scenarios:

- unplanned vacancy due to prohibition, resignation or death;
- forced vacancy due to poor performance, mismanagement or misconduct; and
- planned vacancy due to retirement or expiration of term of office.

Through its work and discussions, the Committee seeks to devise a succession plan that is adaptable to situations arising in the short, medium or long term, but which also builds in diversity – in all its facets – as a key factor.

To fulfill its remit, the Appointments, Governance and CSR Committee:

- provides the Board with progress reports, in particular at executive sessions;
- co-ordinates with the Compensation Committee. In that regard, having directors that sit on both Committees is a great advantage;
- works closely with the Chief Executive Officer to (i) ensure the plan is consistent with the Company's own practices and market practices, (ii) ensure high-potential internal prospects receive appropriate support and training, and (iii) check there is adequate monitoring of key posts likely to fall vacant;
- meets with key executives as needed; and
- involves the Chairman and the Chief Executive Officer insofar as each has a key role in planning for his own successor, though without them directing the process.

In fulfilling their remit, Committee members are acutely conscious of confidentiality issues.

Although aware that separating the offices of Chairman and Chief Executive Officer provides continuity of power, the Committee nonetheless assesses the situation of the Chairman as well as that of the executive team.

Serge Weinberg's current term of office expires at the end of the Annual General Meeting of Sanofi shareholders called to approve the financial statements for the year ended December 31, 2022, and cannot be renewed as he will have reached the age limit stipulated in the Articles of Association (an English language version of which is reproduced in full as Exhibit 1.2 to this Annual Report on Form 20-F). Consequently, succession planning for the Chairman of the Board is already under close review by the Appointments, Governance and CSR Committee.

Succession planning for the Chief Executive Officer is subject to regular review by the Appointments, Governance and CSR Committee.

Board Charter

Our Board Charter describes the rights and obligations of Board members; the composition, role and operating procedures of the Board of Directors and Board Committees; and the roles and powers of the Chairman and the Chief Executive Officer. It is prepared in accordance with the French Commercial Code and our Articles of Association.

An English-language version of our Board Charter is reproduced in full as Exhibit 1.2 to this Annual Report on Form 20-F.

Composition of the Board of Directors as of December 31, 2020

As of December 31, 2020, our Board of Directors comprised:

Director	Age	Gender	Nationality	Number of shares	Number of directorships in listed companies[a]	Independent	First appointed	Term expires	Years of Board service	AC	AGC	CC	SC	SciC
Serge Weinberg, Chairman of the Board	70	M	French	1,636	1	Yes	2009	2023 AGM	11		C		C	M
Paul Hudson, Chief Executive Officer	53	M	British	5,600	1	No	2019	2022 AGM	1				M	
Laurent Attal	63	M	French	1,000	1	No	2012	2024 AGM	8				M	M
Christophe Babule	55	M	French	1,000	2	No	2019	2022 AGM	1	M				
Bernard Charlès	63	M	French	1,000	2	Yes	2017	2021 AGM	3					
Rachel Duan	50	F	Chinese	1,000	2	Yes	2020	2024 AGM	1					
Lise Kingo	59	F	Danish	1,000	1	Yes	2020	2024 AGM	1					
Patrick Kron	67	M	French	1,000	3	Yes	2014	2022 AGM	6		M	C	M	
Fabienne Lecorvaisier	58	F	French	1,000	2	Yes	2013	2021 AGM	7	C				
Melanie Lee	62	F	British	1,000	1	Yes	2017	2021 AGM	3		M			M
Marion Palme[b]	38	F	German	110	1	No	2017	2021 AGM	3					
Carole Piwnica	63	F	Belgian	1,000	3	Yes	2010	2024 AGM	10			M		
Gilles Schnepp	62	M	French	1,000	3	Yes	2020	2022 AGM	1	M				
Christian Senectaire[b]	56	M	French	337	1	No	2017	2021 AGM	3					
Diane Souza	68	F	American	1,137	1	Yes	2016	2024 AGM	4	M		M		
Thomas Südhof	65	M	American/ German	1,170	1	Yes	2016	2024 AGM	4					C

Independent directors	Female directors	Non-French directors
79%	43%	50%

AC: Audit Committee.
AGC: Appointments, Governance and CSR Committee.
CC: Compensation Committee.
SC: Strategy Committee.
SciC: Scientific Committee.
C: Chairman/Chairwoman.
M: Member.
(a) Includes all non-executive and executive (and equivalent) directorships held in listed companies.
(b) Director representing employees.

Competencies of Board members

The Board of Directors, in liaison with the Appointments, Governance and CSR Committee, must ensure that the composition of the Board is balanced, diverse and fit for purpose.

In assessing its composition, the Board takes account of the new challenges facing Sanofi and the corporate strategy, and determines whether the qualities of serving directors are sufficient for the Board to deliver on its remit.

Over the past several years, the Board has adapted its composition in line with its roadmap by:

- bringing additional pharmaceutical industry and healthcare sector expertise onto the Board;
- further raising the proportion of non-French directors, especially those with experience of the Chinese market;
- developing its knowledge of CSR issues; and
- maintaining the level of core competencies, especially in accounting and finance.

The Board has completed an overview of the competencies currently represented. The matrix below[(a)] shows a comprehensive, balanced spread of the types of competencies required, both in general terms and by reference to our strategic ambitions (the matrix shows the number of directors possessing each of those competencies)[(b)]:

Scientific training	3
Healthcare/pharmaceutical industry experience	6
Senior executive role in international group[(c)]	10
Board membership in international group	6
International experience[(d)]	10
Mergers & acquisitions	8
Finance/Accounting	5

(a) Based on the composition of the Board as of February 28, 2021.
(b) The information shown excludes directors representing employees.
(c) Executive Committee member within an international group.
(d) Operational role within an international group.

The Annual General Meeting of April 30, 2021 will be asked to renew the terms of office of Fabienne Lecorvaisier and Melanie Lee. The two directors put forward for reappointment to the Board have the following competencies:

- Fabienne Lecorvaisier: senior executive role in international groups, Board membership in international groups, international experience, mergers and acquisitions, and finance/accounting; and
- Melanie Lee: scientific training and pharmaceutical industry experience.

At his own request, Bernard Charlès will not seek reappointment at the Annual General Meeting of April 30, 2021. Christian Brandts will be put forward for appointment as a director at that meeting. Barbara Lavernos will also be put forward for appointment as a director, replacing Laurent Attal who will resign from office due to his taking retirement.

The two proposed candidates have the following competencies:

- Christian Brandts, Director of the University Cancer Center Frankfurt and Professor of Translational Oncology: scientific training, Oncology specialist; and
- Barbara Lavernos, President of Research, Innovation and Technologies at L'Oréal: senior executive role in international groups.

Finally, the Annual General Meeting will be asked to ratify the decision taken at the Board meeting of May 22, 2020, to co-opt Gilles Schnepp as a director, following the resignation of Emmanuel Babeau from his office as a director. Gilles Schnepp brings financial expertise to the Board, as well as experience in Board membership and senior management roles with international groups.

The following pages provide key information about each director individually:

- directorships and appointments held during 2020 (directorships in listed companies are indicated by an asterisk, and each director's principal position is indicated in bold);
- other directorships held during the last five years; and
- education and professional experience.

Serge Weinberg

Date of birth:	February 10, 1951 (aged 70)
Nationality:	French
First elected:	December 2009
Last reappointment:	April 2019
Term expires:	2023
Business address:	Sanofi - 54, rue La Boétie - 75008 Paris - France

Directorships and appointments of Serge Weinberg

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	**In French companies** **Independent director and Chairman of the Board of Directors of Sanofi*:** • Chairman of the Strategy Committee of Sanofi • Chairman of the Appointments, Governance and CSR Committee of Sanofi • Member of the Scientific Committee of Sanofi	**In French companies** **Chairman of Weinberg Capital Partners:** • Chairman of Maremma • Manager of Alret
	In foreign companies None	**In foreign companies** None
Past directorships expiring within the last five years	**In French companies** None	**In French companies** • Permanent representative of Weinberg Capital Partners on the Board of Directors of ADIT (ended October 4, 2019) • Director of Madrigall (ended June 19, 2019) • Chairman of the Supervisory Boards of Financière Climater SAS (ended October 31, 2018) and Financière Tess SAS (ended October 4, 2019) • Chairman of Financière Piasa and Piasa Holding (ended October 5, 2018)
	In foreign companies None	**In foreign companies** • Chairman of Corum (Switzerland)

Education and professional experience

- Graduate in law, degree from the *Institut d'Études Politiques*
- Graduate of ENA (*École Nationale d'Administration*)

Since 2005	**Chairman of Weinberg Capital Partners**
1976-1982	*Sous-préfet* and then Chief of Staff of the French Budget Minister (1981)
1982-1987	Deputy General Manager of FR3 (French television channel) and then Chief Executive Officer of Havas Tourisme)
1987-1990	Chief Executive Officer of Pallas Finance
1990-2005	Various positions at PPR* group including Chairman of the Management Board for 10 years
2006-2009	Chairman of the Board of Accor*
2005-2010	Vice Chairman of the Supervisory Board of Schneider Electric*

Number of shares held

1,636 shares

Paul Hudson

Date of birth:	October 14, 1967 (aged 53)
Nationality:	British
First elected:	September 2019
Term expires:	2022
Business address:	Sanofi - 54, rue La Boétie - 75008 Paris - France

Directorships and appointments of Paul Hudson

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments		**In French companies**
	Chief Executive Officer of Sanofi*: • Chairman of the Executive Committee of Sanofi • Director of Sanofi • Member of the Strategy Committee of Sanofi	None
		In foreign companies
	None	None
Past directorships expiring within the last five years		**In French companies**
	None	None
		In foreign companies
	None	None

Education and professional experience

- Degree in economics from Manchester Metropolitan University, UK
- Diploma in marketing from the Chartered Institute of Marketing, UK
- Honorary Doctorate in Business Administration, Manchester Metropolitan University, UK

From September 1, 2019	**Chief Executive Officer of Sanofi***
2016-2019	CEO of Novartis Pharmaceuticals, member of Executive Committee
2006-2016	Various operational and managerial positions at AstraZeneca (including President, AstraZeneca US; Executive Vice President, North America; and Representative Director & President, AstraZeneca KK, Japan, President of AstraZeneca Spain, and Vice-President and head of Primary Care United-Kingdom).
Before 2006	Various operational and managerial positions at Schering-Plough, including Head of Global Marketing for biologicals. Various sales and marketing positions at GlaxoSmithKline UK and Sanofi-Synthélabo UK

Number of shares held

5,600 shares

Laurent Attal

Date of birth:	February 11, 1958 (aged 63)
Nationality:	French
First appointed:	May 2012
Last reappointment:	April 2020
Term expires:	2024
Business address:	Sanofi - 54, rue La Boétie - 75008 Paris - France

Directorships and appointments of Laurent Attal

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments		**In French companies**
	Director of Sanofi*: • Member of the Strategy Committee of Sanofi • Member of the Scientific Committee of Sanofi	**Director of *Fondation d'Entreprise L'Oréal***
		In foreign companies
	None	None
Past directorships expiring within the last five years		**In French companies**
	None	None
		In foreign companies
	None	None

Education and professional experience

- Doctor of medicine, dermatologist
- MBA from INSEAD (*Institut Européen d'Administration des Affaires*)

Since 2010[1]	**Executive Vice-President, Research and Innovation at L'Oréal***
Since 1986	Various positions within the L'Oréal* Group, including posts within the Active Cosmetics Division and as President and Chief Executive Officer of L'Oréal USA (United States)
Since 2002	Member of the Executive Committee of L'Oréal*

Number of shares held

1,000 shares

(1) Until January 31, 2021.

Christophe Babule

Date of birth:	September 20, 1965 (aged 55)
Nationality:	French
First appointed:	February 2019
Term expires:	2022
Business address:	Sanofi - 54, rue La Boétie - 75008 Paris, France

Directorships and appointments of Christophe Babule:

	Within the Sanofi group	Outside the Sanofi group
Current directorships and appointments	**Director of Sanofi*** • Member of the Audit Committee of Sanofi	**In French companies** **Director of the *L'Oréal pour les femmes* Foundation**
	None	**In foreign companies** **L'Oréal* Group:** • Director of L'Oréal USA Inc. (United States)
Past directorships expiring within the last five year	None	**In French companies** None
	None	**In foreign companies** None

Education and professional experience

- Graduate of HEC Paris: Master of Business Administration (MBA) in Finance

Since February 2019	**Executive Vice President, Chief Financial Officer at L'Oréal***
Since 1988	Various positions within the L'Oréal* Group, including as Director of Administration & Finance for China, then Mexico, Director of Internal Audit and Administration & Financial Director for the Asia Pacific Zone

Number of shares held

1,000 shares

Bernard Charlès

Date of birth:	March 30, 1957 (aged 63)
Nationality:	French
First elected:	May 2017
Term expires:	2021
Business address:	Sanofi - 54, rue La Boétie - 75008 Paris - France

Directorships and appointments of Bernard Charlès

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	**Independent director of Sanofi***	**In French companies** **Vice-Chairman of the Board of Directors and Chief Executive Officer of Dassault Systèmes***
	None	**In foreign companies** **Dassault Systèmes Group:** • Chairman of the Board of Directors of Dassault Systemes Corp. and Centric Software Inc. (United States) • Chairman of the Advisory Board (statutory body) of Dassault Systemes 3DExcite GmbH (Germany)
Past directorships expiring within the last five years	None	**In French companies** None
	None	**In foreign companies** **Dassault Systèmes Group:** • Chairman of the Board of Directors of Dassault Systemes Biovia Corp., **Dassault Systemes SolidWorks Corp.**, **Dassault Systemes Simulia Corp.,** (United States) and Dassault Systemes Canada Software Inc. (Canada)

Education and professional experience

- Graduate of *École Normale Supérieure* engineering school, Cachan (France)
- *Agrégé* and Ph.D. in mechanics, majoring in automation engineering and information science

Since 2016	**Vice-Chairman of the Board of Directors and Chief Executive Officer of Dassault Systèmes* (France)**
1983-1984	National Service as Scientific Advisor in the Ministry of Defense (France)
1986-1988	Founder of the New Technology, Research and Strategy division at Dassault Systèmes* (France)
1988-1994	Head of Strategy, Research and Development at Dassault Systèmes* (France)
Since 1995	Chief Executive Officer of Dassault Systèmes* (France)
2005	Knight of the *Légion d'honneur* (France)
2009	Member of the *Académie des Technologies* (France)
2012	Officer of the *Légion d'honneur* (France)
2017	Member of the National Academy of Engineering (United States)

Number of shares held

1,000 shares

Rachel Duan

Date of birth:	July 25, 1970 (aged 50)
Nationality:	Chinese
First elected:	April 2020
Term expires:	2024
Business address:	Sanofi - 54, rue La Boétie - 75008 Paris - France

Directorships and appointments of Rachel Duan

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments		**In French companies**
	Independent director of Sanofi*	**Independent director of AXA***
		In foreign companies
	None	None
Past directorships expiring within the last five years		**In French companies**
	None	None
		In foreign companies
	None	None

Education and professional experience

- MBA, University of Wisconsin-Madison (United States)
- Bachelor's degree in Economics and International Trade, Shanghai International Studies University (China)

2019-2020	Senior Vice President of GE* (United States) and President & CEO of GE Global Markets (China)
1996-2020	Various positions within the GE group in China and Japan, including in the Audit Department at GE Capital, management positions at Lean Six Sigma, and sales and marketing roles at GE Plastics in China and the Asia-Pacific region. Rachel Duan has also served as President & CEO of GE Advanced Materials China, and later in the Asia-Pacific region; as President & CEO of GE Healthcare China; and as President & CEO of GE China.

Number of shares held

1,000 shares

Lise Kingo

Date of birth:	August 3, 1961 (aged 59)
Nationality:	Danish
First elected:	April 2020
Term expires:	2024
Business address:	Sanofi - 54, rue La Boétie - 75008 Paris - France

Directorships and appointments of Lise Kingo

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	**Independent director of Sanofi***	**In French companies** None
		In foreign companies
	None	None
Past directorships expiring within the last five years	None	**In French companies** None
		In foreign companies
	None	None

Education and professional experience

- Bachelor's degree in Religions and Ancient Greek Art, University of Aarhus (Denmark)
- Bachelor's degree in Marketing and Economics, Copenhagen Business School (Denmark)
- Master's degree in Responsibility & Business, University of Bath (United Kingdom)
- Director Certification, INSEAD (France)

Since June 2020	Independent Director of Sanofi
1988-1999	Various positions at the Bioindustriel Novo Industry group, now Novozymes (Denmark), including Promotion Coordinator and Director, Corporate Environmental Affairs.
1995-2006	Member of the HRH Prince of Wales Cambridge University Faculty for Sustainability Leadership (United Kingdom)
1999-2002	Senior Vice President, Stakeholder Relations at Novo Holding (Denmark)
2002-2014	Executive Vice President Corporate Relations & Chief of Staff at Novo Nordisk A/S (Denmark)
2005-2009	Board Member and Deputy Chairman, GN Store Nord (Denmark)
2006-2015	Professor of Sustainable Development and Innovation at Vrije Universiteit Amsterdam (Netherlands)
2010-2014	Chair, Steno Diabetes Center (Denmark)
2012-2015	Independent Board director of Grieg Star Shipping (Norway)
2012-2015	Chair of the Danish Council for Corporate Social Responsibility (Denmark)
2013-2015	Member of the "Scale for Good" Advisory Panel, Tesco Plc, (United Kingdom)
2014-2015	Deputy Chair of the Danish Society for Nature Conservation (Denmark)
2015-2020	CEO & Executive Director of the United Nations Global Compact (United States)
2015-2020	Member of the Board of Principles for Responsible Investments, UN PRI (United Kingdom)
2020	Chair of Blueprint for Denmark Initiative (Denmark)
2020	Member of the Advisory Panel for Humanitarian and Development Coordination, Novo Nordisk Foundation (Denmark)

Number of shares held

1,000 shares

Patrick Kron

Date of birth:	September 26, 1953 (aged 67)
Nationality:	French
First appointed:	May 2014
Last reappointment:	May 2018
Term expires:	2022
Business address:	Sanofi - 54, rue La Boétie - 75008 Paris - France

Directorships and appointments of Patrick Kron

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments		**In French companies**
	Independent director of Sanofi*: • Chairman of the Compensation Committee of Sanofi • Member of the Appointments and Governance Committee of Sanofi (renamed the Appointments, Governance and CSR Committee effective March 8, 2019) • Member of the Strategy Committee of Sanofi	**Chairman of Imerys*** **Chairman of Truffle Capital SAS** **Chairman of PKC&I SAS:** • Permanent representative of PKC&I on the Supervisory Board of Segula Technologies
		In foreign companies
	None	**Director of Lafarge-Holcim* (Switzerland)**
Past directorships expiring within the last five years		**In French companies**
	None	**Interim Chief executive Officer of Imerys*** **Director of Bouygues***
		In foreign companies
	None	**ElvalHalcor (Greece)**

Education and professional experience

- Degree from *École Polytechnique* and *École Nationale Supérieure des Mines de Paris*

Since 2019	**Chairman of Imerys* (and Interim Chief Executive Officer from October 2019 to February 2020)**
Since 2016	Chairman of Truffle Capital SAS
Since 2016	Chairman of PKC&I SAS
1979-1984	Various positions at the French Ministry of Industry, including as project officer at the *Direction régionale de l'Industrie, de la Recherche et de l'Environnement* (DRIRE) and in the Ministry's general directorate
1984-1988	Operational responsibilities in one of the Pechiney Group's biggest factories in Greece, then manager of the Greek subsidiary of Pechiney
1988-1993	Various senior operational and financial positions within the Pechiney Group
1993	Member of the Executive Committee of the Pechiney Group
1993-1997	Chairman and Chief Executive Officer of Carbone Lorraine
1995-1997	Manager of the Food and Health Care Packaging Sector at Pechiney, and Chief Operating Officer of American National Can Company in Chicago (United States)
1998-2002	Chairman of the Managing Board of Imerys
2003-2016	Chief Executive Officer, then Chairman and Chief Executive Officer, of Alstom*

Number of shares held

1,000 shares

Fabienne Lecorvaisier

Date of birth:	August 27, 1962 (aged 58)
Nationality:	French
First appointed:	May 2013
Last reappointment:	2017
Term expires:	2021
Business address:	Sanofi - 54, rue La Boétie - 75008 Paris - France

Directorships and appointments of Fabienne Lecorvaisier

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments		**In French companies**
	Independent director of Sanofi*: • Chairwoman of the Audit Committee of Sanofi	**Air Liquide Group*:** • Director of Air Liquide International • Chairwoman and Chief Executive Officer of Air Liquide Finance • Director of Air Liquide Eastern Europe • Director of The Hydrogen Company **Director of ANSA (*Association Nationale des Sociétés par Actions*)**
		In foreign companies
	None	**Air Liquide Group*:** • Executive Vice President of Air Liquide International Corporation • Director of American Air Liquide Holdings, Inc. • Chairwoman of Air Liquide US LLC
Past directorships expiring within the last five years		**In French companies**
	None	**Air Liquide Group*:** • Director of Air Liquide France Industries, Aqualung International, Air Liquide Welding SA and SOAEO
		In foreign companies
	None	None

Education and professional experience

- Civil engineer, graduate of *École Nationale des Ponts et Chaussées*

Since July 2017	**Executive Vice President, Chief Financial Officer and Executive Committee member of Air Liquide***
1985-1989	Member of the Corporate Finance Department, then Mergers and Acquisitions Department of Société Générale*
1989-1990	Senior Banking Executive in charge of the LBO Department (Paris)/Corporate Finance Department (Paris and London) at Barclays
1990-1993	Assistant General Manager of Banque du Louvre, Taittinger Group
1993-2008	Various positions within Essilor* including Group Chief Financial Officer (2001-2007) and Chief Strategy and Acquisitions Officer (2007-2008)
Since 2008	Chief Financial Officer and Executive Committee member of Air Liquide*

Number of shares held

1,000 shares

Melanie Lee

Date of birth:	July 29, 1958 (aged 62)
Nationality:	British
First elected:	May 2017
Term expires:	2021
Business address:	Sanofi - 54, rue La Boétie - 75008 Paris - France

Directorships and appointments of Melanie Lee

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments		**In French companies**
	Independent director of Sanofi*: • Member of the Scientific Committee of Sanofi • Member of the Appointments, Governance and CSR Committee of Sanofi	None
		In foreign companies
	None	**Director of Think10 (United Kingdom)** **Director of Lee Smith Properties Ltd (United Kingdom)**
Past directorships expiring within the last five years		**In French companies**
	None	None
		In foreign companies
	None	**Director of Syntaxin Ltd.* (United Kingdom)** **Director of BTG plc.* (United Kingdom)** **Non-executive director of Lundbeck A/S (Denmark)** **Director of NightstaRx Ltd. (United Kingdom)** **Executive Director of Celltech plc**

Education and professional experience

- Degree in Biology, University of York
- Ph.D. from the National Institute for Medical Research, London
- Commander of the Order of the British Empire award in 2009 for services to medical science

Since 2018	**Chief Executive Officer of LifeArc (United Kingdom)**
1988-1998	Senior Biologist and subsequently Research Unit Head, Receptor Systems at Glaxo/GlaxoWellcome (United Kingdom)
2004-2007	Chairwoman of the Board of Directors of Cancer Research Technology Ltd. United Kingdom
1998-2009	Executive Director of Research at Celltech plc., and subsequently Executive Vice President, Research and President New Medicines at UCB Celltech (United Kingdom)
2003-2011	Deputy Chairwoman of Cancer Research U.K. (United Kingdom)
2009-2013	Chief Executive Officer and Director of Syntaxin Ltd.* (United Kingdom)
2014	Founder of NightstaRx Ltd. (United Kingdom)
2014	Named as one of the 'leading practical scientists' in the UK by the Science Council
2011-2015	Non-executive director of Lundbeck A/S (Denmark)
2014-2018	Chief Scientific Officer of BTG plc* (United Kingdom)
Since 2013	Director and Consultant, Think10 (United Kingdom)
2019	Bio Industry Association (BIA) lifetime achievement award

Number of shares held

1,000 shares

Carole Piwnica

Date of birth:	February 12, 1958 (aged 63)
Nationality	Belgian
First appointed:	December 2010
Last reappointment:	April 2020
Term expires:	2024
Business address:	Sanofi - 54, rue La Boétie - 75008 Paris - France

Directorships and appointments of Carole Piwnica

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments		**In French companies**
	Independent director of Sanofi*: • Member of the Compensation Committee of Sanofi (since 2019)	**Rothschild & Co*:** • Independent member of the Supervisory Board and of the Remuneration & Nomination Committee
		In foreign companies
	None	**Director of Amyris Inc* (United States)** **Managing Partner of Naxos S.A. (Switzerland)** **Chairman of Arianna S.A. (Luxembourg)**
Past directorships expiring within the last five years		**In French companies**
	• Member of the Audit Committee of Sanofi (until April 2018)	**Rothschild & Co*:** • Member of the Remuneration Committee **Eutelsat Communications*:** • Independent director • Chairwoman of the Nomination and Governance Committee
		In foreign companies
	None	**Director of Louis Delhaize* (Belgium), RecyCoal Ltd. (United Kingdom) and Big Red (United States)** **Director of Naxos UK Ltd (United Kingdom)** **Director of Elevance (United States) and i2O (United Kingdom)**

Education and professional experience

- Degree in law, *Université Libre de Bruxelles*
- Master of Laws, New York University
- Admitted to the Bar in Paris and New York

Since 2018	**Managing Partner of Naxos S.A. (Switzerland)**
1985-1991	Attorney at Proskauer, Rose (New York) and Shearman & Sterling (Paris) with practice in mergers and acquisitions
1991-1994	General Counsel of Gardini & Associés
1994-2000	Chief Executive Officer of Amylum France, then Chairwoman of Amylum Group
1998-2004	Director of Spadel (Belgium)
1996-2006	Director of Tate & Lyle Plc (United Kingdom)
1996-2006	Chairwoman of the Liaison Committee and director of the *Confédération Européenne des Industries Agro-Alimentaires* (CIAA)
2000-2006	Director and Vice-Chairwoman of Tate & Lyle Plc for Governmental Affairs (United Kingdom)
2000-2006	Chairwoman of the Export Commission and director of the *Association Nationale des Industries Alimentaires* (ANIA)
2006-2009	Member of the Ethical Committee of Monsanto* (United States)
1996-2010	Director of Toepfer GmbH (Germany)
2007-2010	Director of Dairy Crest Plc* (United Kingdom)
2003-2011	Director, Chairwoman of the Corporate Responsibility Committee and member of the Compensation Committee of Aviva Plc* (United Kingdom)
2007- 2018	Founder Director of Naxos UK Ltd (United Kingdom)

Number of shares held

1,000 shares

Gilles Schnepp

Date of birth:	October 16, 1958 (aged 62)
Nationality:	French
First appointed:	May 2020
Term expires:	2022
Business address:	Sanofi - 54, rue La Boétie - 75008 Paris - France

Directorships and appointments of Gilles Schnepp

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	**Independent director of Sanofi*:** • Member of the Audit Committee of Sanofi	**In French companies** **Member of the Board of Directors of Legrand*** **Member of the Board of Directors of Saint Gobain*** **Lead Independent Director on the Board of Directors of Danone** **In foreign companies** None
Past directorships expiring within the last five years	None	**In French companies** • Vice-Chairman of the Supervisory Board of PSA* **In foreign companies** None

Education and professional experience

- Graduate of HEC business school

2019-2021	**Vice-Chairman of the Supervisory Board of PSA**
Since 2020	Member of the Board of Directors of Legrand
Since 2009	Member of the Board of Directors of Saint Gobain
2006	Chairman & CEO of Legrand
2004-2006	CEO of Legrand
2001-2004	Deputy CEO of Legrand
1989-2001	Various positions within the Legrand group
1983	Merrill Lynch

Number of shares held

1,000 shares

Diane Souza

Date of birth:	July 3, 1952 (aged 68)
Nationality:	American
First appointed:	May 2016
Last reappointment:	April 2020
Term expires:	2024
Business address:	Sanofi - 54, rue La Boétie - 75008 Paris - France

Directorships and appointments of Diane Souza

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments		**In French companies**
	Independent director of Sanofi*: • Member of the Compensation Committee of Sanofi (since May 2016) • Member of the Audit Committee of Sanofi (since May 2018)	None
		In foreign companies
	None	**Amica Insurance Companies (United States):** • Member of the Board of Directors • Member of the Compensation and Investment Committees
Past directorships expiring within the last five years		**In French companies**
	None	None
		In foreign companies
	None	**UnitedHealth Group:** • Member of the Board of Directors of Unimerica Insurance Company, Unimerica Life Insurance Company of New York, National Pacific Dental, Inc., Nevada Pacific Dental, DBP Services of New York, IPA, Dental Benefits Providers of California, Inc., Dental Benefit Providers of Illinois, Inc., Dental Benefit Providers, Inc., Spectera, Inc. and Spectera of New York, IPA, Inc. United States **Farm Credit East (United States)** • Member of the Board of Directors

Education and professional experience

- Degree in Accounting from University of Massachusetts
- Honorary doctorate in Business Administration from University of Massachusetts Dartmouth
- Certified Public Accountant
- Diploma in Dental Hygiene from Northeastern University, Forsyth School for Dental Hygienists

1979	Audit Staff Accountant at Price Waterhouse (United States)
1980-1988	Various positions at Deloitte Haskins & Sells, from Audit Staff Accountant to Senior Tax Manager-in-Charge (United States)
1988-1994	Various positions at Price Waterhouse from Audit Staff Accountant to Head of the Northeast Insurance Tax Region (United States)
1994-2006	Various positions at Aetna Inc. including Deputy Vice President Federal and State Taxes; Vice President and Chief Financial Officer, Large Case Pensions; Vice President and Head of Global Internal Audit Services; Vice President, National Customer Operations; and finally Vice President, Strategic Systems & Processes (United States)
2007-2008	Principal consultant at Strategic Business Solutions, LLC (United States)
2008-2014	Chief Operating Officer of OptumHealth Specialty Benefits (2008), then Chief Executive Officer of UnitedHealthcare Specialty Benefits (United States)

Number of shares held

2,275 American Depositary Receipts, equivalent to 1,137 shares

Thomas Südhof

Date of birth:	December 22, 1955 (aged 65)
Nationality:	German and American
First elected:	May 2016
Last reappointment:	April 2020
Term expires:	2024
Business address:	Sanofi - 54, rue La Boétie - 75008 Paris - France

Directorships and appointments of Thomas Südhof

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	**Independent director of Sanofi*:** • Chairman of the Scientific Committee of Sanofi	**In French companies** None
	None	**In foreign companies** None
Past directorships expiring within the last five years	None	**In French companies** None
	None	**In foreign companies** **Independent director of Abide Therapeutics (United States) (since 2019)**

Education and professional experience

- Degree in medicine from the Faculty of Medicine of the University of Göttingen (Germany)
- Elected member of the National Academy of Sciences of the USA (2002)
- Elected member of the National Academy of Medicine (2007)
- Bernard Katz Prize of the Biophysical Society, jointly with Reinhard Jahn (2008)
- Elected member of the American Academy of Arts and Sciences (2010)
- Nobel Prize for Physiology or Medicine, jointly with James Rothman and Randy Schekman (2013)
- Albert Lasker Prize for Basic Medical Research, jointly with Richard Scheller (2013)
- Elected foreign member of the German Academy Leopoldina (2015)
- Elected foreign member of the Royal Society of London for Improving Natural Knowledge (2017)
- Elected member of the Norwegian Society of Sciences

Since 2008	**Avram Goldstein Professor of Molecular & Cellular Physiology, Neurosurgery, Psychiatry, and Neurology Department in the School of Medicine at Stanford University (United States)**
1978-1981	Research assistant at the Max Planck Institute for Biophysical Chemistry (Germany)
1979	Student on exchange clerkship program at Harvard Medical School (United States)
1981-1982	Intern at the University Hospital of Göttingen (Germany)
1983-1986	Postdoctoral Fellow, Dept. of Molecular Genetics, UT Southwestern Medical School (USA)
1986-2008	Professor and subsequently Chair of the Neuroscience Department at the University of Texas Southwestern Medical School (United States)
2011-2019	Co-founder and member of the Scientific Advisory Board of Circuit Therapeutics, Inc. (United States)
2013-2016	Member of the Review Board of Genentech Neuroscience (United States)
2014-2017	Co-founder and member of the Scientific Advisory Board of Bluenobel, Inc. (China)
2014-2018	Member of the Scientific Advisory Board of the Singapore National Research Foundation (Singapore)
2014-2018	Member of the Scientific Advisory Board of the Chinese Academy Institute of Biophysics (China)
2014-2018	Member of the Scientific Advisory Committee of the Institute of Cellular and Molecular Biology of A*Star (China)
2017-2018	Member of the Scientific Advisory Board of Abide (USA)
2017-2019	Member of the Scientific Advisory Board of C-Bridge Everest Medical (China)
Since 1986	Investigator at the Howard Hughes Medical Institute (United States)
Since 2002	Co-founder and member of the Scientific Advisory Board of REATA Pharmaceuticals (United States)
Since 2013	Member of the Scientific Advisory Board of the Shemyakin-Ovchinnikov Institute of Bio-Organic Chemistry (Russia)
Since 2014	Member of the Scientific Advisory Board of Elysium, Inc. (United States)
Since 2016	Member of the Scientific Advisory Board of Simcere, Inc. (China)
Since 2016	Member of the Scientific Advisory Board of the Picower Institute, MIT Boston (United States)
Since 2017	Member of the Scientific Advisory Board of the Chinese Academy of Sciences Institute of Guangzhou (China)
Since 2017	Member of the Scientific Advisory Board of Cytodel, Inc. (United States)

Since 2018	Member of the Scientific Advisory Board of Alector, Inc. (United States)
Since 2018	Chairman of the Scientific Advisory Board of Capital Medical University, Beijing (China)
Since 2018	Member of the Scientific Advisory Board of Jupiter, Inc. (United States)
Since 2019	Advisor to Camden Venture Partners (United States)
Since 2019	Member of the Scientific Advisory Board of the Chinese Institute for Brain Research, Beijing (China)
Since 2019	Member of the Scientific Advisory Board of the Neuroscience Department at the Institut Pasteur (France)
Since 2020	Member of the Scientific Advisory Board of NeuroCure, Charite, Berlin (Germany)
Since 2020	Co-founder and member of the Scientific Advisory Board of Boost, Inc. and FSVC7, Inc. (United States)
Since 2020	Member of the Scientific Advisory Board of Danaher Corporation (United States)

Number of shares held

2,340 American Depositary Receipts, equivalent to 1,170 shares

Marion Palme

Date of birth:	December 22, 1982 (aged 38)
Nationality:	German
First elected:	May 2017
Term expires:	2021
Business address:	Sanofi - 54, rue La Boétie - 75008 Paris - France

Directorships and appointments of Marion Palme

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	**Director representing employees of Sanofi***	**In French companies** None
	None	**In foreign companies** **Member of the German Industrial Union Mining, Chemistry, Energy (IG BCE) (Germany)**
Past directorships expiring within the last five years	**Member of the European Works Council**	**In French companies** None
	None	**In foreign companies** None

Education and professional experience

- Bachelor of Science in Chemical Engineering from Provadis School of International Management and Technology (2011)

Since 2005	**Laboratory Technician at the Frankfurt site (Germany)**
2002-2005	Apprenticeship as a laboratory technician at the Frankfurt site (Germany)

Number of shares held

110[(1)]

(1) In accordance with Article L. 225-25 of the French Commercial Code, directors representing employees are exempt from the obligation to hold shares.

Christian Senectaire

Date of birth:	October 9, 1964 (aged 56)
Nationality:	French
First elected:	May 2017
Term expires:	2021
Business address:	Sanofi - 54, rue La Boétie - 75008 Paris - France

Directorships and appointments of Christian Senectaire

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	**In French companies**	
	Director representing employees of Sanofi* Member of the Supervisory Board of the Sanofi Group Savings Scheme (PEG) Member of the Supervisory Board of the Sanofi Group Collective Retirement Savings Plan (PERCO)	None
	In foreign companies	
	None	None
Past directorships expiring within the last five years	**In French companies**	
	Alternate member of the Works Council at the Vertolaye site and of the Sanofi Chimie Works Council Titular member of the Sanofi Group Works Council Central Delegate for the CFDT union, Sanofi Chimie Deputy Group Delegate for the CFDT union, Sanofi France	**SAS Laboratoires Pichot:** • Member of the Compensation and Disclosure Committee
	In foreign companies	
	None	None

Education and professional experience

Since 2009	**Senior production technician at the Vertolaye site (France)**
Since 1987	Staff representative on the CFDT ticket (France)
1985-2009	Chemical industry machine operator at the Neuville site and then the Vertolaye site (France)
2019	Employee Director Certificate, University of Paris Dauphine
2019	CSR Manager Certificate – Sustainable Development (Elegia)

Number of shares held

337[(1)]

(1) In accordance with Article L. 225-25 of the French Commercial Code, directors representing employees are exempt from the obligation to hold shares.

Changes in the composition of the Board of Directors

The table below shows changes in the composition of the Board of Directors during 2019 and 2020, and the changes that will be submitted for approval at the Annual General Meeting of April 30, 2021:

	Annual General Meeting of April 30, 2019	Annual General Meeting of April 28, 2020	Annual General Meeting of April 30, 2021
End of term of office	None	Claudie Haigneré[(b)] Suet-Fern Lee[(c)]	Marion Palme[(e)] Christian Senectaire[(e)] Laurent Attal[(f)] Bernard Charlès[(g)]
Renewal of term of office	Serge Weinberg (independent director and Chairman of the Board of Directors) Suet-Fern Lee (independent director)	Laurent Attal Carole Piwnica Diane Souza Thomas Südhof	Fabienne Lecorvaisier Melanie Lee
Proposed new appointments	None	Rachel Duan (independent director) Lise Kingo (independent director)	Christian Brandts [(g)] (independent director) Barbara Lavernos [(f)]
Co-opted	Christophe Babule[(a)]	Paul Hudson[(d)]	Gilles Schnepp
Other	None	None	None

(a) Christophe Babule was co-opted by the Board of Directors on February 6, 2019 following the resignation of Christian Mulliez as a director.

(b) Claudie Haignéré's term of office expired at the end of the Annual General Meeting of April 28, 2020, and she was not proposed for reappointment because she had already served as a director of Sanofi for 12 years.

(c) Suet-Fern Lee resigned as a director on April 29, 2020.

(d) Paul Hudson was co-opted by the Board of Directors on October 30, 2019 following the resignation of Olivier Brandicourt as a director.

(e) The terms of office of the two directors representing employees will expire at the end of the Annual General Meeting of April 30, 2021. In accordance with Article 11 of our Articles of Association, one employee representative director will be designated by the trade union body which is the most representative, within the meaning of the applicable legislation, within the Company and those of its direct or indirect subsidiaries that have their registered office in French territory, and the other director will be designated by the European Works Council.

(f) Laurent Attal has announced that he will resign from his position as Director, effective as of the Annual General Meeting of April 30, 2021. The meeting will be asked to approve the appointment of Barbara Lavernos..

(g) Bernard Charlès, whose term of office expires at the next meeting, did not wish to have his term of office renewed. The meeting will be asked to approve the appointment of Christian Brandts.

If the terms of office of Fabienne Lecorvaisier and Melanie Lee were to be renewed, and the appointments of Christian Brandts and Barbara Lavernos approved, there would be no change in the number of Board members (16) or the proportion of independent directors (79%) calculated using currently applicable rules. The proportion of female directors would increase from 43% to 50% and the proportion of non-French directors would increase from 50% to 57%.

As of December 31, 2020, the members of our Board of Directors collectively held (directly, or via the employee share ownership fund associated with the Group savings scheme) 19,990 of our shares, representing 0.0015% of our share capital.

As of December 31, 2020, no corporate officer has been the subject of any conviction or court order, or been associated with any bankruptcy or winding-up order. As of this day, there is no potential conflict of interest between any corporate officer and Sanofi.

Under current French legislation, and given that employees own less than 3% of our share capital, the Board does not include a director representing employee shareholders.

Executive Committee

The Executive Committee is chaired by the Chief Executive Officer. The Committee meets at least twice a month.

There were substantial changes in the composition of the Executive Committee during 2020, with three members (Alan Main, David Loew and Caroline Luscombe) leaving and four new members (Natalie Bickford, Arnaud Robert, Thomas Triomphe and Julie van Ongevalle) joining.

As of February 28, 2021, the Executive Committee had 11 members, three of whom are women. In accordance with our Board Charter (as amended on December 16, 2020), the Board of Directors – in liaison with the Compensation Committee and the Appointments, Governance and CSR Committee, and on a proposal from the Chief Executive Officer – has established a policy on gender balance within Sanofi's executive bodies.

Paul Hudson

Chief Executive Officer

Date of birth: October 14, 1967.

Paul Hudson joined Sanofi as Chief Executive Officer on September 1, 2019.

Previously CEO of Novartis Pharmaceuticals (2016-2019), where he was a member of the Executive Committee, Paul has had an extensive international career in healthcare that spans the US, Japan and Europe.

Prior to Novartis, he worked for AstraZeneca, where he held several increasingly senior positions and most recently carried out the roles of President, AstraZeneca United States and Executive Vice President, North America.

He began his career in sales and marketing roles at GlaxoSmithKline UK and Sanofi-Synthélabo UK.

Paul holds a degree in economics from Manchester Metropolitan University in the UK and last year his alma mater awarded him an honorary Doctor of Business Administration for his achievements in industry. He also holds a diploma in marketing from the Chartered Institute of Marketing, also in the UK.

Paul Hudson is a citizen of the United Kingdom.

Natalie Bickford

Executive Vice President, Chief People Officer

Date of birth: July 16, 1970.

Natalie Bickford joined Sanofi on August 1, 2020.

She holds a degree in French and International Politics from the University of Warwick in the UK.

She has worked in HR and HR leadership for more than 20 years and brings a wealth of experience in consumer-facing industries to Sanofi.

Prior to joining Sanofi, Natalie was Group HR Director at Merlin Entertainments, the world's second largest location-based entertainment business, where she was responsible for 30,000 employees across Europe, North America, and Asia Pacific. She also held senior HR positions at Sodexo, AstraZeneca and Kingfisher Plc.

Natalie has a solid track record of transforming organizations, with a strong focus on inclusion and diversity. She was awarded "HR Diversity Champion of the Year" at the European Diversity Awards in November 2019. Natalie is also Board member of the Kronos Workforce Institute, a reflection of her deep interest in understanding and shaping the future of work.

Natalie Bickford is a citizen of the United Kingdom.

Olivier Charmeil

Executive Vice President, General Medicines

Date of birth: February 19, 1963.

Olivier Charmeil is a graduate of HEC (*Ecole des Hautes Etudes Commerciales*) and of the *Institut d'Etudes Politiques* in Paris. From 1989 to 1994, he worked in the Mergers & Acquisitions department of Banque de l'Union Européenne. He joined Sanofi Pharma in 1994 as head of Business Development. Subsequently, he held various positions within Sanofi, including Chief Financial Officer (Asia) of Sanofi-Synthélabo in 1999 and Attaché to the Chairman, Jean-François Dehecq, in 2000, before being appointed as Vice President, Development within the Sanofi-Synthélabo International Operations Directorate, where he was responsible for China and support functions. In 2003, Olivier Charmeil was appointed Chairman and Chief Executive Officer of Sanofi-Synthélabo France, before taking the position of Senior Vice President, Business Management and Support within the Pharmaceutical Operations Directorate. In this role, he piloted the operational integration of Sanofi-Synthélabo and Aventis. He was appointed Senior Vice President Asia/Pacific, Pharmaceutical Operations in February 2006; Operations Japan reported to him from January 1, 2008, as did Asia/Pacific and Japan Vaccines from February 2009. On January 1, 2011, Olivier Charmeil was appointed Executive Vice President Vaccines, and joined our Executive Committee.

In May 2015, Olivier Charmeil and André Syrota were appointed as Co-Leaders of "Medicine of the Future", an initiative developed by the French Minister for Economy, Industry and Digital Affairs, the French Minister for Social Affairs, Health and Women's Rights and the French Minister for National and Higher Education and Research. They have been tasked with assembling a group of industrialists and academics, with the objective of imagining how French industry can accelerate the launch and export of innovative industrial products, with an emphasis on new biotechnologies.

From June 2016 to December 2018, Olivier Charmeil served as Executive Vice President of our General Medicines and Emerging Markets Global Business Unit.

He took up the position of Executive Vice President China & Emerging Markets in January 2019. In February 2020 he was appointed to lead the General Medicines GBU, created out of the former Primary Care and China & Emerging Markets GBUs. He also serves as sponsor for China. Also in 2020, Olivier became a Board Member of the European Federation of Pharmaceutical Industries and Associations (EFPIA).

Olivier Charmeil is a citizen of France.

Jean-Baptiste Chasseloup de Chatillon

Executive Vice President, Chief Financial Officer

Date of birth: March 19, 1965.

Jean-Baptiste Chasseloup de Chatillon holds a Masters from Paris Dauphine University and studied Finance in the United Kingdom at Lancaster University.

Until recently, he served as Chief Financial Officer and Executive Vice President of the PSA Group. In that capacity, he was also a member of the Managing Board and Executive Committee. He held various management positions within the PSA Group in finance (Treasurer in Spain, Chief Financial Officer in the United Kingdom) and in sales and marketing (Citroen Belgium Managing Director). He was also Chairman of the Board of Banque PSA Finance (BPF) from 2012 to June 2016. He joined the Peugeot S.A. Managing Board in 2012.

He was appointed to his current position on October 1, 2018.

Jean-Baptiste Chasseloup de Chatillon is a citizen of France.

Karen Linehan

Executive Vice President, Legal Affairs and General Counsel

Date of birth: January 21, 1959.

Karen Linehan graduated from Georgetown University with Bachelor of Arts and Juris Doctorate degrees. Prior to practicing law, Ms. Linehan served on the congressional staff of the Speaker of the US House of Representatives from September 1977 to August 1986. Until December 1990, she was an Associate in a mid-size law firm in New York. In January 1991, she joined Sanofi as Assistant General Counsel of its US subsidiary. In July 1996, Ms. Linehan moved to Paris to work on international legal matters within Sanofi and she has held a number of positions within the Legal Department, most recently as Vice President – Deputy Head of Legal Operations.

She was appointed to her current position in March 2007.

Karen Linehan is a citizen of the United States of America and Ireland.

Philippe Luscan

Executive Vice President, Global Industrial Affairs

Date of birth: April 3, 1962.

Philippe Luscan is a graduate of the *École Polytechnique* (*X*) and the *École Nationale Supérieure des Mines de Paris* in Biotechnology. He began his career in 1987 as a Production Manager at Danone. In 1990, he joined Sanofi as Director of the Sanofi Chimie plant at Sisteron, France, and subsequently served as Industrial Director of Sanofi in the United States, as Vice President Supply Chain and as Vice President Chemistry from September 2006. He was appointed to his current position in September 2008. From January 2015 to September 2017, he was also Chairman of Sanofi in France.

Philippe Luscan is a citizen of France.

Julie Van Ongevalle

Executive Vice President, Consumer Healthcare

Date of birth: November 22, 1974.

Julie Van Ongevalle joined Sanofi on September 1, 2020.

She graduated from the *Institut Catholique des Hautes Etudes Commerciales* (Belgium) with a Master of Science in Commercial and Financial Sciences.

With over 20 years of international experience, Julie has a deep knowledge of consumers and digital, as well as a proven track record in brand building, from identifying growth opportunities to building and implementing delivery strategies.

Prior to joining Sanofi, Julie worked at the Estée Lauder Companies, where she held roles of increasing responsibility across the company, starting in 2004. As Global Brand President of the Origins brand from 2016, she led a global organization of 4,000 people, growing the company's market share across geographies. Prior to Origins, she spent eight years in the M.A.C. Cosmetics division, first as General Manager Benelux, then of the EMEA Region and finally North America.

Julie started her career as a marketing manager at GSK Consumer Healthcare and Clinique.

Julie Van Ongevalle is a citizen of Belgium.

John Reed

Executive Vice President, Global Head of Research and Development

Date of birth: October 11, 1958.

John Reed holds a B.A. in chemistry from the University of Virginia, Charlottesville and an M.D. and Ph.D. (Immunology) from the University of Pennsylvania School of Medicine.

He began his academic career as a member of the faculty at the University of Pennsylvania in 1988, following a post-doctoral fellowship in Molecular Biology at the Wistar Institute and a residency in Pathology & Laboratory Medicine at the Hospital of the University of Pennsylvania. John Reed subsequently held faculty appointments at several universities including the University of California, the University of Florida and ETH-Zurich.

In 1992, he joined the Sanford-Burnham Medical Research Institute in La Jolla, California, one of the largest independent non-profit biomedical research institutes in the United States. From 2002 to 2013, he served as CEO of the Institute. During his tenure, John Reed ran a highly productive laboratory that generated more than 900 research publications and over 130 patents, was awarded more than 100 research grants, and trained over 100 post-doctoral fellows. He is a Fellow of the American Association for the Advancement of Science (AAAS) and the recipient of numerous honors and awards for his accomplishments in biomedical research.

John Reed has served on multiple editorial boards of research journals, and was scientific founder or co-founder of four biotechnology companies. He has served on the Board of Directors for five publicly traded biopharmaceutical and biotechnology companies and on the governing boards for various non-profit biomedical research organizations.

From 2013 to 2018, John Reed was Global Head of Roche Pharmaceutical Research & Early Development, based at company headquarters in Basel, Switzerland. He was responsible for research through Phase IIb development for all therapeutic areas, overseeing R&D activities across seven global sites.

He assumed his current position as Executive Vice President, Global Head of Research & Development for Sanofi in July 2018.

John Reed is a citizen of the United States of America.

Arnaud Robert

Executive Vice President, Chief Digital Officer

Date of birth: May 23, 1973.

Arnaud holds an engineering degree from the *École Polytechnique de Montreal*, and a Masters in Engineering and PhD in Computer Science from the Swiss Institute of Technology, Lausanne.

A newcomer to the pharmaceutical sector, Arnaud has led digital transformations across multiple industries and brings solid expertise in e-commerce, customer experience, data and technology; for example, he led the launch of the Apple Watch Nike running app. He previously worked at The Walt Disney Company, Nike, Shaw Communications and most recently as Chief Digital Officer at Viking Cruises.

He was appointed as Chief Digital Officer, leading our digital, data and technology groups, on June 15, 2020.

Arnaud Robert is a citizen of Canada.

Bill Sibold

Executive Vice President, Sanofi Genzyme

Date of birth: October 29, 1966.

Bill Sibold holds an MBA from Harvard Business School and a B.A. in Molecular Biophysics and Biochemistry from Yale University. He has more than twenty-five years of experience in the biopharmaceutical industry. Bill Sibold began his career with Eli Lilly and then held a number of leadership positions within Biogen, including driving their US commercial operations in neurology, oncology and rheumatology. He also worked for Biogen in Australia and the Asia-Pacific region, and served as Chief Commercial Officer at Avanir Pharmaceuticals. Bill Sibold joined Sanofi in late 2011 as head of the MS franchise where he oversaw the successful launches of Aubagio® and Lemtrada®. From January 2016 to June 2017 he served as head of Sanofi Genzyme's Global Multiple Sclerosis, Oncology and Immunology organization, where he led preparation for the global launches of dupilumab and sarilumab.

Bill Sibold has headed up Sanofi Genzyme, our specialty care global business unit, since July 1, 2017. He has also served as sponsor for North America since February 2020.

Bill Sibold is a citizen of Canada and of the United States of America.

Thomas Triomphe

Executive Vice President, Head of **Sanofi Pasteur**

Date of birth: August 6, 1974.

Thomas Triomphe earned his MSc in industrial engineering from Ecole des Ponts Paritech and the IFP School and he also holds an MBA from INSEAD.

Thomas joined Sanofi Pasteur in 2004 and has since advanced within the company in several roles of increasing responsibility in sales and marketing at country, regional and global levels. From 2015 to 2018, he was Head of the Asia-Pacific Region, based in Singapore. Before that, he served as Head of Sanofi Pasteur Japan from 2012 to 2015. In 2010, he became Associate Vice President, Head of the Influenza-Pneumo Franchise after three years as Director for the same franchise, based in the United States. Earlier in his career, Thomas worked in banking and strategic consulting.

Thomas served as Vice President and Head of Franchise & Product Strategy for Sanofi Pasteur from January 2018, in which position he implemented the strategy for our vaccine franchises, in close collaboration with Industrial Affairs and R&D.

He was appointed to his current position on June 15, 2020.

Thomas Triomphe is a citizen of France.

B. Compensation

Compensation and other arrangements for corporate officers

Compensation policy for corporate officers

This section describes the compensation policy for corporate officers of Sanofi, as established pursuant to Article L. 22-10-8 of the French Commercial Code. That policy describes all the components of compensation awarded to corporate officers of Sanofi as consideration for holding office, and explains the process by which it is determined, divided, reviewed and implemented.

Our compensation policy for corporate officers has three distinct elements: (i) the compensation policy for directors; (ii) the compensation policy for the Chairman of the Board; and (iii) the compensation policy for the Chief Executive Officer.

Each of those policies is submitted for approval by our shareholders at the Annual General Meeting, in accordance with Article L. 22-10-8 II of the French Commercial Code. The compensation policy approved in any given year applies to any person holding corporate office in that year. Moreover, when a corporate officer is appointed between two Annual General Meetings, their compensation is defined applying the terms of the compensation policy approved by the most recent Annual General Meeting of shareholders.

Process for determining the compensation policy for corporate officers

The compensation policy for corporate officers is established by the Board of Directors, acting on the recommendation of the Compensation Committee. The Board of Directors applies the AFEP-MEDEF Code when determining the compensation and benefits awarded to our executive and non-executive corporate officers.

All members of the Compensation Committee are independent, and were chosen for their technical competencies and their good understanding of current standards, emerging trends and Sanofi's practices.

To fulfill their remit, the Committee regularly invites the Chief People Officer and the Head of Reward and Performance of the Group to attend their meetings, although the latter absent themselves when the Committee deliberates. Committee members also work with the Chairman and the Secretary to the Board, who have contacts with our principal institutional shareholders ahead of the Annual General Meeting.

In addition, the Chairman of the Committee:

- discusses the financial, accounting and tax impacts of the proposed compensation policy with the Chairman of the Audit Committee;
- plays an active role at meetings of the Appointments, Governance and CSR Committee and the Strategy Committee (to both of which he belongs), thereby gaining assurance that the proposed performance criteria are consistent and appropriate in light of Sanofi's strategic ambitions.

The compensation policy is not subject to annual review, although some arrangements for implementing the policy – such as the performance criteria applicable to the Chief Executive Officer's annual variable compensation, for example – are defined by the Board of Directors on an annual basis.

After consulting the Compensation Committee and as the case may be the other Board Committees, the Board of Directors may temporarily derogate from the approved compensation policy for the Chief Executive Officer in exceptional circumstances and to the extent that the changes are aligned on the corporate interest and necessary to safeguard the continuity or viability of Sanofi. Derogations from the approved policy are possible in respect of the performance conditions applied to the Chief Executive Officer's compensation, and may result in either an increase or a decrease in compensation. The circumstances in which it is possible to apply such a derogation are (i) a change in the structure of the Sanofi group or (ii) major events affecting the markets. Such derogation may only be temporary and must be properly substantiated. Moreover, it will remain subject to approval by the next General Meeting of Sanofi shareholders.

General principles and objectives

Our compensation policy is based on the following general principles:

- the policy must be simple;
- the policy must prioritize long-term performance;
- the level of compensation must be competitive, so that we can attract and retain talent;
- there must be a fair balance between the corporate interest, the challenges of delivering on our strategy, and the expectations of our stakeholders.

The Compensation Committee must ensure that trends in the compensation of corporate officers over the medium term are not uncorrelated with trends in the compensation of all our employees. In terms of annual variable compensation and equity-based compensation, the Compensation Committee aims to achieve convergence between the performance criteria applied to our Senior Leaders and those applied to the Chief Executive Officer.

Our equity-based compensation policy, which aims to align employee and shareholder interests and reinforce loyalty to Sanofi, is a critical tool for our worldwide attractiveness as an employer.

Acting on the recommendation of the Compensation Committee, the Board of Directors determines the performance conditions attached to equity-based compensation for all beneficiaries at Sanofi and its subsidiaries worldwide, thereby furthering the attainment of our objectives. Our equity-based compensation plan rules are made available to our shareholders on the governance page of our website (*www.sanofi.com*) in the same form as that distributed to our employees.

During 2018 and until June 2019, equity-based compensation awards to senior executives were in the form of performance shares and (for the Chief Executive Officer) performance shares and stock options. With effect from June 2019, the Chief Executive Officer can only be awarded performance shares. Awarding performance shares makes it possible to maintain a comparable level of employee incentivization while reducing the dilutive effect of equity-based compensation plans for existing shareholders. The Board has sought to standardize the terms of equity-based compensation awards within Sanofi, and has listened to feedback from some shareholders and proxy advisors who have concerns about stock options given their dilutive effect and potential unintended consequences.

The Board of Directors makes any grant of performance shares contingent on multiple, exacting multi-year performance criteria in order to ensure that our equity-based compensation plans incentivize overall performance. Failure to achieve those criteria over the entire performance measurement period results in a reduction or loss of the initial grant.

In order to align equity-based compensation with our long-term performance, performance is measured over three financial years (the "vesting period"). Awards of performance shares are also contingent on continued employment in the Sanofi group during the vesting period, followed by stringent lock-up obligations in the case of the Chief Executive Officer (see below).

The terms of prior awards cannot be reset subsequently, for instance with less exacting performance conditions.

Compensation policy for directors

Directors hold office for a four-year term, as specified in our Articles of Association.

The maximum annual amount of overall compensation that can be allocated to the directors was set by the Annual General Meeting of our shareholders on April 28, 2020 at €2,000,000 with effect from the 2020 financial year, the previous amount of €1,750,000 having been changed to reflect the growing number of non-French directors and to allow for a revaluation of the variable portion.

The arrangements for allocating the overall annual amount set by the Annual General Meeting between the directors are determined by the Board of Directors, acting on a recommendation from the Compensation Committee. Directors' compensation comprises (i) an annual fixed amount of €30,000, apportioned on a time basis for directors who assumed or left office during the year, and (ii) a variable amount,

allocated by the Board according to actual attendance at Board and Committee meetings. As required by the AFEP-MEDEF Code, directors' compensation is allocated predominantly on a variable basis.

The Board meeting held on March 4, 2020 raised the amount of compensation allocated to Directors per meeting (variable portion) with effect from the 2020 financial year, the first time those amounts had been changed since 2010. The table below shows how the variable amount payable to directors for attendance at Board and committee meetings is determined.

	Compensation per meeting			
	Directors resident in France	Directors resident outside France but within Europe	Directors resident outside Europe	Chairman/Chairwoman
Board of Directors	€5,500	€8,250	€11,000	N/A
Audit Committee	€8,250	€8,250	€8,250	€11,000
Compensation Committee	€5,500	€8,250	€11,000	€8,250
Appointments, Governance and CSR Committee	€5,500	€8,250	€8,250	Determined by reference to place of residence
Strategy Committee	€5,500	€8,250	€11,000	Determined by reference to place of residence
Scientific Committee	€5,500	€8,250	€11,000	Determined by reference to place of residence

Up to and including 2020, a director who participated by a teleconference or videoconference received a payment equivalent to half the amount received by a director resident in France attending in person. The Board meeting of March 3, 2021 decided that from 2021 onwards – in light of public health protection measures, the deployment of appropriate technical solutions, and practices adopted by other issuers – directors who take part via videoconference will receive compensation equivalent to that paid to a director resident in France attending in person. Committee Chairs will continue to receive the usual compensation in respect of the Committee they chair.

In any event, the Board continues to encourage directors to attend Board and Committee meetings in person, subject to strict compliance with public health protection measures.

As an exception, in certain cases two meetings held on the same day give entitlement only to a single payment:

- if on the day of a Shareholders' General Meeting, the Board of Directors meets both before and after the Meeting, only one payment is made for the two Board meetings;
- if on the same day a director participates in a meeting of the Compensation Committee and a meeting of the Appointments, Governance and CSR Committee, only the higher of the two payments is made to cover both meetings.

The introduction of a separate compensation scale depending on whether or not the director is a European resident is intended to take into account the significantly longer travel time required to attend meetings in person.

Directors do not receive any exceptional compensation or equity-based compensation and have no entitlement to a top-up pension plan.

Neither the Chairman of the Board nor the Chief Executive Officer receives any compensation for serving as a director.

Compensation policy for the Chairman of the Board of Directors

The term of office of the Chairman of the Board is the same as that of the other directors (four years), and the Chairman's term is aligned with his term of office as a director.

The compensation policy for the Chairman of the Board is discussed by the Compensation Committee, which then makes a recommendation to the Board of Directors. The Chairman of the Board is not a member of the Committee, and does not attend meetings where his compensation is discussed.

The compensation of the Chairman of the Board of Directors (where the office of Chairman is separate from that of Chief Executive Officer, as is currently the case) consists solely of fixed compensation and benefits in kind and excludes any variable or exceptional compensation, any awards of stock options or performance shares, and any compensation for serving as a director. The Board meeting of March 3, 2021 set the annual fixed compensation awarded to the Chairman of the Board at €800,000 gross, unchanged from 2020.

Where the office of Chairman is separate from that of Chief Executive Officer, the Chairman of the Board is not entitled to the Sanofi top-up defined-contribution pension plan.

Nor is he entitled to a termination benefit or a non-compete indemnity.

Executive officers of Sanofi do not receive any compensation for serving as directors. Consequently, the Chairman of the Board does not receive compensation for chairing Board meetings or meetings of the Appointments, Governance and CSR Committee or the Strategy Committee.

Compensation policy for the Chief Executive Officer

General principles

Our Chief Executive Officer is not appointed for a fixed term of office.

The compensation policy for the Chief Executive Officer is established by the Board of Directors, acting on the recommendation of the Compensation Committee. The compensation structure is not subject to annual review and is applicable for as long as it remains unchanged. The arrangements for implementing the policy may vary from year to year; a table showing the changes made to those arrangements in 2020 and 2019 is provided at the end of the present section.

The compensation of the Chief Executive Officer is determined with reference to compensation awarded to the chief executive officers of the following 12 leading global pharmaceutical companies: Amgen, AstraZeneca plc, Bayer AG, Bristol-Myers-Squibb Inc., Eli Lilly and Company Inc., GlaxoSmithKline plc, Johnson & Johnson Inc., Merck Inc., Novartis AG, Novo Nordisk, Pfizer Inc., and Roche Holding Ltd. This panel comprises companies that are comparable to Sanofi, with no limitation as to geographical region given that Sanofi operates in a particularly competitive international environment. The panel has been expanded so that pharmaceutical companies operating in the biotechnology field are better represented. Consistency with market practice is fundamental in order to attract and retain the talents necessary to our success. In 2020, on the basis of the information published as of the date of this Annual Report on Form 20-F, median fixed compensation of the chief executive officers of the aforementioned twelve leading global pharmaceutical companies was in the region of €1,374,000; the median of the annual variable compensation awarded was in the region of €2,279,000; and the median of the long-term compensation awarded (whether equity-based or in cash) represented around 760% of fixed compensation. Within this peer group, Paul Hudson's global compensation (fixed, variable and equity-based compensation) lies within the first quartile. The practices of the main CAC 40 companies are also taken into consideration.

On taking up office

When the Chief Executive Officer is an outside appointment, the Board of Directors may decide, acting on a recommendation from the Compensation Committee, to compensate the appointee for some or all of the benefits he may have forfeited on leaving his previous employer. In such a case, the terms on which the Chief Executive Officer is hired aim to replicate the diversity of what was forfeited, with a comparable level of risk (variable portion, medium-term equity-based or cash compensation).

During the term of office

Compensation structure

Our policy aims at achieving and maintaining a balance in the compensation structure between fixed compensation, benefits in kind, short-term variable cash compensation, and medium-term variable equity-based compensation.

The compensation policy for the Chief Executive Officer is designed to motivate and reward performance by ensuring that a significant portion of compensation is contingent on the attainment of financial, operational and extra-financial criteria that reflect Sanofi's objectives, and are aligned with the corporate interest and with the creation of shareholder value. Variable cash compensation and equity-based compensation are the two principal levers for action, and are intended to align the interests of the Chief Executive Officer with those of our shareholders and stakeholders.

During the meeting that follows the Board meeting held to close off the financial statements for the previous year, the Compensation Committee examines the levels of attainment of variable compensation for that year. In advance of that meeting, the Chief Executive Officer presents the Committee with a report containing narrative and quantitative information necessary to measure attainment of the objectives. The members of the Compensation Committee then discuss the information provided and report to the Board on those discussions, giving an evaluation of the Chief Executive Officer's performance against each of the criteria (determining the level of attainment for quantitative objectives, and evaluating the level of attainment for qualitative objectives).

Annual fixed compensation

The annual fixed compensation of the Chief Executive Officer is set at €1,300,000 gross.

The amount of fixed compensation is not subject to annual review. It may however be changed, provided that such changes are not material:

- on the appointment of a new Chief Executive Officer, to reflect the new appointee's competencies and/or then current market practice; and
- in exceptional circumstances, to take account of changes in (i) the role or responsibilities of the Chief Executive Officer, for example in terms of market conditions or the size of the Sanofi group or (ii) the performance level of Sanofi over a given period.

Annual variable compensation

Annual variable compensation is in a range between 0% and 250% of fixed compensation, with a target of 150%. It is subject to a range of varied and exacting performance criteria, both quantitative and qualitative. The criteria are reviewed annually in light of the strategic objectives determined by Sanofi. The Board of Directors sets the criteria for each year at the start of that year on the recommendation of the Compensation Committee. For 2021, the criteria are:

- 50% based on financial indicators published by the Company: sales growth, business net income, free cash flow and business operating income (BOI) margin and growth in key new assets, each accounting for 10%. Free cash flow and BOI margin were chosen because they are in line with the Company's strategic roadmap; and
- 50% based on specific individual objectives (1/3 being quantitative objectives), including one linked to corporate social responsibility criteria for Sanofi (partly quantifiable), underlining the Board's commitment to long-term value creation. The individual objectives set for variable remuneration for 2021 are described in "-Compensation and benefits of all kinds awarded to corporate officers in respect of 2021" below.

The percentage of variable compensation linked to the attainment of quantitative criteria may be scaled down regardless of actual performance, in order to give greater weight to the attainment of qualitative criteria. This flexibility can only operate to reduce the amount of variable compensation, and cannot compensate for underperformance on quantitative criteria.

The policy does not allow for the possibility of clawing back any annual variable compensation.

In accordance with Article L. 22-10-34 II. of the French Commercial Code, payment of annual variable compensation in a given year in respect of the previous year is contingent on a favorable shareholder vote at the Annual General Meeting.

Equity-based compensation

The Chief Executive Officer's equity-based compensation, which since June 2019 can only be in the form of performance shares, may not exceed 250% of his target short-term compensation (fixed plus variable).

The Chief Executive Officer's equity-based compensation is contingent upon attainment of exacting performance conditions measured over a three-year-period. Such awards are contingent upon both:

- internal criteria based upon business net income (BNI) and free cash flow (FCF); and
- an external criterion based upon total shareholder return (TSR) relative to a benchmark panel of twelve of the leading global pharmaceutical companies: Amgen, AstraZeneca plc, Bayer AG, Bristol-Myers-Squibb Inc., Eli Lilly and Company Inc., GlaxoSmithKline plc, Johnson & Johnson Inc., Merck Inc., Novartis AG, Novo Nordisk, Pfizer Inc., and Roche Holding Ltd.

The valuation of performance shares is calculated at the date of grant, and represents the difference between the quoted market price of the share on the date of grant and the present value of the dividends to be received over the next three years. Since 2020, a market condition is also taken into account. The parameters used to calculate the valuations are market parameters available in the financial press.

Each award to our Chief Executive Officer takes into account previous awards and his overall compensation. In any event, the maximum number of shares to be delivered may not be more than the number of performance shares initially awarded.

The award proposed by the Board of Directors in respect of 2021 is described in "—Compensation and benefits of all kinds awarded to corporate officers in respect of 2021" below.

Share ownership and lock-up obligation of the Chief Executive Officer

The Chief Executive Officer is bound by the same obligations regarding share ownership specified in our Articles of Association and Board Charter as our other corporate officers.

In addition, until he ceases to hold office the Chief Executive Officer is required to retain a quantity of Sanofi shares equivalent to 50% of any gain (net of taxes and social contributions) arising on the vesting of performance shares, calculated as of the date on which those shares vest. Those shares must be retained in registered form until he ceases to hold office.

In compliance with the AFEP-MEDEF Code and our Board Charter, the Chief Executive Officer must undertake to refrain from entering into speculative or hedging transactions.

Multi-year variable compensation

The Chief Executive Officer does not receive multi-year variable compensation.

Compensation for serving as a director

Executive officers of Sanofi do not receive any compensation for serving as directors. Consequently, the Chief Executive Officer does not receive compensation in his capacity as a director or as a member of the Strategy Committee.

Exceptional compensation

No exceptional compensation can be awarded to the Chief Executive Officer.

On leaving office

The Chief Executive Officer is entitled to a top-up defined-contribution pension plan, a termination benefit, and a non-compete indemnity.

Such arrangements are part of the overall compensation package generally awarded to executive officers; in line with recommendations of the AFEP-MEDEF code, there are very strict rules about how they are implemented. The termination benefit and non-compete indemnity are intended to compensate for the fact that the Chief Executive Officer may be dismissed at any time.

Each of those benefits is taken into account by the Board of Directors when fixing the overall compensation of the Chief Executive Officer.

Pension arrangements

The Chief Executive Officer is entitled to benefits under the top-up defined-contribution pension plan introduced within Sanofi on January 1, 2020. This is a collective plan falling within the scope of Article 82 of the French General Tax Code. It is also offered to members of our Executive Committee and all senior executives whose position is classified within the Sanofi grade scale as "Executive Level 1 or 2". The Chief Executive Officer's entitlement under this plan may be withdrawn by a decision of the Board of Directors, but not retroactively.

Under the terms of the plan, the Chief Executive Officer receives an annual contribution the amount of which (subject to attainment of a performance condition) may be up to 25% of his reference compensation (annual fixed and variable cash-based compensation only; all other compensation is excluded). The rights accruing under the plan are those that are generated by the capitalization contract taken out with the insurer, and vest even if the Chief Executive Officer does not remain with Sanofi until retirement. The Chief Executive Officer may elect for the rights to be transferable as a survivor's pension.

The performance condition is as follows:

- if the level of attainment for variable compensation is equal to or greater than the target (i.e. 150% of fixed compensation), 100% of the contribution is paid;
- if the level of attainment for variable compensation is less than 100% of fixed compensation, no contribution is paid; and
- between those two limits, the contribution is calculated on a prorata basis.

Because this performance condition is linked to the attainment of the performance criteria for annual variable compensation (which itself is determined with reference to the strategic objectives of Sanofi), it ensures that no pension contributions could be made in the event that the Chief Executive Officer fails to deliver.

The plan is wholly funded by Sanofi, which pays the full amount of the gross contributions. Because it is treated as equivalent to compensation, the contribution is subject to payroll taxes and employer's social security charges, and to income tax in the hands of the Chief Executive Officer; all of the above are charged on the basis of the bands, rates and other conditions applicable to compensation, paid and declared on his payslips for the contribution period.

Subject to (i) formal confirmation by the Board of Directors that the performance condition for the previous year has been met and (ii) approval of the Chief Executive Officer's compensation package for that year by the Annual General Meeting of our shareholders, the annual gross contribution will be paid as follows:

- 50% as a gross insurance premium to the fund manager; and
- 50% to the Chief Executive Officer, to indemnify him for the social security and tax charges for which he will become immediately liable.

In accordance with Article 39.5 *bis* of the French General Tax Code, deferred compensation as defined in section 4 of Article L. 22-10.9 of the French Commercial Code can be offset against corporate profits as a taxable expense up to a limit set at three times the annual social security ceiling per beneficiary.

The pension entitlement is not cumulative with (i) any termination benefit paid in the event of forced departure or (ii) any non-compete indemnity.

Termination arrangements

The termination benefit only becomes payable if the departure of the Chief Executive Officer is forced, i.e. in the event of removal from office or resignation linked to a change in strategy or control of the Company. Compensation for non-renewal of the term of office is irrelevant in the case of the Chief Executive Officer, because this office is held for an indefinite term.

In addition, no termination benefit is payable and the arrangement is deemed to have been rescinded in the following circumstances:

- removal from office for gross or serious misconduct (*faute grave ou lourde*);
- if the Chief Executive Officer elects to leave Sanofi to take up another position;
- if the Chief Executive Officer is assigned to another position within Sanofi; or
- if the Chief Executive Officer takes his pension.

Payment of the termination benefit is contingent upon fulfillment of a performance condition, which is deemed to have been met if the attainment rate for the individual variable compensation objectives exceeded 90% of the target; that condition is assessed over the three financial years preceding the Chief Executive Officer leaving office.

The amount of the termination benefit is capped at 24 months of the Chief Executive Officer's most recent total compensation on the basis of (i) the fixed compensation effective on the date of leaving office and (ii) the last variable compensation received prior to that date subject to fulfilment of the performance condition.

The amount of the termination benefit is reduced by any amount received as consideration for the non-compete undertaking, such that the aggregate amount of those two benefits may never exceed two years of total fixed and variable compensation.

Non-compete undertaking

In the event of his departure from the Company, the Chief Executive Officer undertakes, during the 12-month period following his departure, not to join a competitor of Sanofi as an employee or corporate officer, or to provide services to or cooperate with such a competitor.

In return for this undertaking, he receives an indemnity corresponding to one year's total compensation, based on his fixed compensation effective on the day he leaves office and on the last individual variable compensation he received prior to that date. This indemnity is payable in 12 monthly installments.

However, the Board of Directors reserves the right to release the Chief Executive Officer from that undertaking for some or all of that 12-month period. In such cases, the non-compete indemnity would not be due for the period of time waived by the Company.

Consequences of the Chief Executive Officer's departure for equity-based compensation

If the Chief Executive Officer leaves Sanofi for reasons other than resignation or removal from office for gross or serious misconduct (in which case any award of equity-based compensation is forfeited in full), the overall allocation percentage is prorated to reflect the amount of time the Chief Executive Officer remained with Sanofi during the vesting period.

If at any time prior to the expiration of the vesting period of his performance shares the Chief Executive Officer joins a competitor of Sanofi as an employee or corporate officer, or provides services to or cooperates with such a competitor, he irrevocably loses those performance shares regardless of any full or partial discharge by the Board of Directors of the non-compete undertaking relating to his office as Chief Executive Officer.

If the Chief Executive Officer retires at statutory retirement age prior to the expiration of the vesting period of his performance shares, the overall allocation rate will be apportioned on a prorata basis to reflect the amount of time for which the Chief Executive Officer remains in the employment of Sanofi during the vesting period. Further to the vote expressed by the shareholders at the 2020 Annual General Meeting on the compensation of the previous Chief Executive Officer (Olivier Brandicourt) for the 2019 financial year, the Board of Directors decided – on a recommendation from the Compensation Committee – to amend the compensation policy for the Chief Executive Officer on this point with effect from 2021. This change reflects feedback from some of our shareholders, and current market practice.

Summary of benefits awarded to the Chief Executive Officer on leaving office

The table below presents a summary of the benefits (as described above) that could be claimed by the Chief Executive Officer on leaving office, depending on the terms of his departure. The information provided in this summary is without prejudice to any decisions that may be made by the Board of Directors.

	Voluntary departure/Removal from office for gross or serious misconduct	Forced departure	Retirement
Termination benefit[a]	/	24 months of fixed compensation as of the date of leaving office + 24 months of most recent individual variable compensation received[d] – Amounts received as non-compete indemnity	/
Non-compete indemnity[b]	12 months of fixed compensation as of the date of leaving office + 12 months of most recent individual variable compensation received prior to leaving office	12 months of fixed compensation as of date of leaving office + 12 months of most recent individual variable compensation received prior to leaving office[e]	/
Top-up pension[c]	/	/	Annual contribution of up to 25% of reference compensation
Performance share plans not yet vested	Forfeited in full	Rights retained prorata to period of employment within Sanofi[f]	Rights retained prorata to period of employment within Sanofi[f]

(a) The amount of the termination benefit is reduced by any indemnity received as consideration for the non-compete undertaking, such that the aggregate amount of those two benefits may never exceed two years of total fixed and variable compensation.

(b) The Board of Directors may decide to release the Chief Executive Officer from the non-compete undertaking for some or all of the 12-month period. In that case, the non-compete indemnity would not be due, or would be scaled down proportionately.

(c) Defined-contribution pension plan, within the scope of Article 82 of the French General Tax Code. Subject to fulfillment of the performance condition, assessed annually.

(d) Subject to fulfillment of the performance condition assessed over the three financial years preceding the departure from office, as described above.

(e) Subject to the Board of Directors enforcing the non-compete undertaking, the amount of the termination benefit is reduced by any indemnity received as consideration for the non-compete undertaking, such that the aggregate amount of those two benefits may never exceed two years of total fixed and variable compensation.

(f) In this case, the Chief Executive Officer remains subject to the terms of the plans, including the performance conditions and the non-compete clause.

The table below summarizes adjustments made to how the compensation policy for the Chief Executive Officer is implemented, based on in-depth discussions with our shareholders.

2021	2020
• Annual variable compensation: – The quantitative component of the objectives (financial and non financial) has been changed from 60% to 67% (minimum). – Sanofi will now publish the level of attainment of non-financial objectives, on an ex post basis. • Equity-based compensation: – If the Chief Executive Officer takes retirement at the statutory retirement age before the end of the vesting period, the overall allocation rate is apportioned on a prorata basis to reflect the amount of time for which he remained in the employment of Sanofi during the vesting period.	• The Board of Directors may temporarily derogate from the approved compensation policy in exceptional circumstances as defined in the policy. • The Chief Executive Officer is only awarded performance shares – he is no longer awarded stock options; • For performance shares, the comparison is now made with a panel of 12 leading global pharmaceutical companies (instead of 10). • The performance condition applicable to the termination benefit has been modified. • Top-up pension plan arrangements have changed following the entry into force of Order no. 2019-1234 of July 3, 2019 on compensation arrangements for corporate officers of listed companies.

Arrangements in favor of executive officers in office as of December 31, 2020 (table No. 11 of the AFEP-MEDEF Code)

Executive officer	Contract of employment	Top-up pension plan	Indemnities or benefits payable or potentially payable on cessation of office	Indemnities payable under non-compete clause
Chairman of the Board	No	No	No	No
Chief Executive Officer	No	Yes	Yes	Yes

Compensation and benefits of all kinds paid during 2020 or awarded in respect of 2020 to corporate officers

The section below constitutes the report on compensation of corporate officers required by Article L. 225-37 of the French Commercial Code. The arrangements described therein will be submitted for approval by our shareholders at the Annual General Meeting called to approve the financial statements for the year ended December 31, 2020 pursuant to Article L. 22-10-34 of the French Commercial Code.

Because the Covid-19 pandemic did not have a major impact on the performance of Sanofi, we did not consider adjusting any elements of the compensation of corporate officers in respect of 2020.

Compensation elements and benefits of all kinds paid during 2020 or awarded in respect of 2020 to directors (table No 3 of the AFEP-MEDEF CODE)

The compensation policy for directors (as described above in the section entitled "— Compensation policy for directors") defines the fixed amount of compensation, and the principles for allocating the variable portion between directors, up to the limit of the overall amount approved by the Annual General Meeting.

Directors' compensation includes an annual fixed payment, apportioned on a time basis for directors who assumed or left office during the year; and a variable amount, allocated by the Board according to actual attendance at Board and Committee meetings. As required by the AFEP-MEDEF Code, directors' compensation is allocated predominantly on a variable basis.

For 2020, directors' compensation was determined in accordance with the compensation policy for directors as described above in the section entitled "— Compensation policy for directors".

The table below shows amounts paid in respect of 2020 and 2019 to each member of our Board of Directors, including those whose term of office ended during those years.

Directors' compensation for 2019, the amount of which was approved at the Board meeting of March 4, 2020, was partially paid in July 2019, with an additional payment made in 2020.

Directors' compensation for 2020, the amount of which was approved at the Board meeting of March 3, 2021, was partially paid in July 2020, with an additional payment to be made in 2021.

(€)	Compensation in respect of 2020			Compensation in respect of 2019			
Name	Fixed portion	Variable portion	Total amount (fixed + variable portion)	Fixed portion	Variable portion	Total gross compensation	Total gross compensation apportioned on a prorata basis *
Laurent Attal	30,000	79,750	109,750	30,000	117,500	147,500	140,051
Emmanuel Babeau[(a)]	15,000	42,625	57,625	30,000	90,000	120,000	113,940
Christophe Babule[(b)]	30,000	49,500	79,500	26,965	50,000	76,965	73,076
Bernard Charlès	30,000	44,000	74,000	30,000	55,000	85,000	80,708
Rachel Duan	20,000	24,750	44,750				
Claudie Haigneré	10,000	27,500	37,500	30,000	87,500	117,500	111,566
Lise Kingo	20,000	24,750	44,750				
Patrick Kron	30,000	93,500	123,500	30,000	137,500	167,500	159,041
Fabienne Lecorvaisier	30,000	110,000	140,000	30,000	115,000	145,000	137,678
Melanie Lee[(c)]	30,000	88,000	118,000	30,000	115,000	145,000	137,678
Suet-Fern Lee[(d)]	10,000	30,250	40,250	30,000	95,000	125,000	118,449
Christian Mulliez[(e)]				3,035	12,500	15,535	15,535
Marion Palme[(c)(f)]	30,000	33,000	63,000	30,000	50,000	80,000	75,960
Carole Piwnica[(c)]	30,000	57,750	87,750	30,000	110,000	140,000	132,930
Gilles Schnepp	18,300	27,500	45,800				
Christian Senectaire[(f)(g)]	30,000	44,000	74,000	30,000	57,500	87,500	83,081
Diane Souza[(d)]	30,000	104,500	134,500	30,000	205,000	235,000	223,133
Thomas Südhof[(d)]	30,000	115,500	145,500	30,000	125,000	155,000	147,173
Total	**423,300**	**996,875**	**1,420,175**	**420,000**	**1,422,500**	**1,842,500**	**1,750,000**
Total			**1,420,175**				**1,750,000**

* *Due to the high number of Board and committee meetings in 2019, the theoretical amount of compensation payable to directors exceeded the maximum amount set by the Annual General Meeting of our shareholders. Consequently, the amount payable to each director was scaled down on a pro rata basis.*

The amounts reported are gross amounts before taxes.

(a) Assumed office May 2, 2018.
(b) Assumed office February 6, 2019.
(c) Resident outside France but within Europe.
(d) Resident outside Europe.
(e) Left office February 6, 2019 and received his compensation without apportionment on a pro rata basis.
(f) Director representing employees.
(g) Compensation due to Christian Senectaire is paid directly to Fédération Chimie Energie CFDT.

Each of the two directors representing employees has a contract of employment with a Sanofi subsidiary, under which they receive compensation unrelated to their office as director. Consequently, that remuneration is not disclosed.

Variable compensation allocated to directors in respect of 2020 represented 70.20% of their total compensation.

Compensation and benefits of all kinds paid during 2020 or awarded in respect of 2020 to Serge Weinberg, Chairman of the Board of Directors

Serge Weinberg has held the office of Chairman of the Board of Directors since May 17, 2010. He has never had, and does not currently have, a contract of employment with Sanofi.

The Chairman of the Board also chairs the Appointments, Governance and CSR Committee and the Strategy Committee, and is a member of the Scientific Committee.

The remit of the Chairman of the Board is specified in the Board Charter, which is reproduced in its entirety in Exhibit 1.2. to this Annual Report on Form 20F.

During the course of 2020, the Chairman's activities included:

- chairing all the meetings of the Board of Directors (14 in 2020) and of the Committees of which he is a member (five meetings of the Appointments, Governance and CSR Committee, six meetings of the Strategy Committee and five meetings of the Scientific Committee), and participating in Committee meetings to which he was invited (Audit Committee and Compensation Committee);
- close monitoring of the proper implementation of the decisions taken by the Board;
- meetings with directors, including (i) on the appointment of Rachel Duan, Lise Kingo and Gilles Schnepp, to explain to them how the Board operates and answer their questions, (ii) in connection with the evaluation of the Board's operating procedures, and (iii) on matters relating to the projects presented to the Board;
- regular meetings with members of the senior management team;
- meetings with Sanofi employees;
- meetings with biotechs and medtechs in France and abroad;
- organizing a strategy seminar in October 2020; and
- representing Sanofi at events or official meetings with representatives of the public authorities and other stakeholders, in line with his remit as defined by the Board Charter.

The Chairman also has a role in explaining positions taken by the Board within its sphere of competence, especially in terms of strategy, governance and executive compensation. In furtherance of this role, Serge Weinberg drew on his experience of corporate communication in:

- answering letters from investors and shareholders;
- holding meetings with certain shareholders and proxy advisors; and
- attending a meeting of the Individual Shareholders Committee at Sanofi headquarters in March 2020, discussing what Sanofi had achieved in 2019 and answering questions about the Company's latest news, future prospects and dividend policy.

Those tasks were carried out after coordination with the Chief Executive Officer, and in close collaboration with our Investor Relations department.

Compensation awarded in respect of the 2020 financial year

On March 4, 2020, acting on a recommendation from the Compensation Committee, the Board of Directors determined the components of Serge Weinberg's compensation for the 2020 financial year, taking into account the nature of his duties and the level of his involvement in the work of the Board and in broader corporate governance matters.

For the 2020 financial year, Serge Weinberg's annual fixed compensation was €800,000 (bearing in mind that his compensation had remained unchanged since he first took office in 2010, the Board meeting of March 4, 2020 decided to raise his annual fixed compensation from €700,000 to €800,000 with effect from the 2020 financial year).

In line with our compensation policy for the Chairman of the Board, as approved by our shareholders at the Annual General Meeting of April 28, 2020, he did not receive any variable compensation and was not awarded any stock options or performance shares. He received no compensation for serving as a director, and no compensation from any company included in Sanofi's scope of consolidation within the meaning of Article L. 233-16 of the French Commercial Code.

The amount reported for benefits in kind (€7,715 in 2020) relates to a company car with a driver.

Serge Weinberg is not covered by the Sanofi defined-contribution pension plan.

Compensation, options and shares awarded to Serge Weinberg (table No. 1 of the AFEP-MEDEF Code)

(€)	2020	2019
Compensation awarded for the year (details provided in the following table)	807,715	708,040
Valuation of stock options awarded during the year	N/A	N/A
Valuation of performance shares awarded during the year	N/A	N/A
Valuation of other long-term compensation plans	N/A	N/A
Total	**807,715**	**708,040**

Compensation awarded to Serge Weinberg (table No. 2 of the AFEP-MEDEF Code)

	2020		2019	
(€)	Amounts due	Amounts paid	Amounts due	Amounts paid
Fixed compensation[(a)]	800,000	800,000	700,000	700,000
Annual variable compensation	N/A	N/A	N/A	N/A
Exceptional compensation	N/A	N/A	N/A	N/A
Compensation for serving as a director	N/A	N/A	N/A	N/A
Benefits in kind	7,715	7,715	8,040	8,040
Total	**807,715**	**807,715**	**708,040**	**708,040**

The amounts reported are gross amounts before taxes.

(a) Fixed compensation due in respect of a given year is paid during that year.

Compensation and benefits of all kinds paid during 2020 or awarded in respect of 2020 to Paul Hudson, Chief Executive Officer

Paul Hudson has served as Chief Executive Officer of Sanofi since September 1, 2019, and holds office for an indeterminate period.

Paul Hudson does not have a contract of employment with Sanofi, and receives no compensation from any company included in Sanofi's scope of consolidation within the meaning of Article L. 233-16 of the French Commercial Code.

Compensation awarded to Paul Hudson (table No.1 of the AFEP-MEDEF Code)

(€)	2020	2019[(a)]
Compensation awarded for the year (details provided in the following table)	5,633,092[(b)]	1,160,733
Valuation of performance shares awarded during the year[(c)]	5,708,520	0
Valuation of other long-term compensation plans - Sign-on bonus [(d)]	N/A	3,664,500
Total	**11,341,342[(b)]**	**4,825,233**

(a) Compensation awarded from September 1, 2019, when Paul Hudson took office, through December 31, 2019.
(b) See notes (b) and (d) under the table below (table No.2 of the AFEP-MEDEF Code).
(c) Valuation at the date of grant, subject to fulfillment of the performance conditions. This represents the difference between the quoted market price of the share on the date of grant and the present value of the dividends to be received over the next three years.
(d) Valuation at the grant date under IFRS, including a market condition, subject to the attainment of performance conditions.

The parameters used to calculate the valuations are market parameters available in the financial press.

Fixed and variable compensation awarded to Paul Hudson (table No. 2 of the AFEP-MEDEF Code)

	2020		2019	
(€)	Amounts due	Amounts paid	Amounts due	Amounts paid
Fixed compensation	1,300,000[c]	1,300,000[c]	433,333[c]	433,333[c]
Annual variable compensation[a]	2,213,250	650,000	650,000[c]	—
Cash bonus (sign-on bonus) [b]	1,951,000[b]	N/A	N/A	N/A
Exceptional compensation	N/A	N/A	N/A	N/A
Compensation for serving as a director	N/A	N/A	N/A	N/A
Benefits in kind	168,842	168,842	77,400	77,400
Total	**5,633,092(d)**	**2,118,842**	**1,160,733**	**510,733**

The amounts reported are gross amounts before taxes.

(a) Variable compensation in respect of a given year is determined at the start of the following year and paid after the Annual General Meeting in that year, subject to shareholder approval.

(b) Cash bonus in respect of the 2020 financial year (First Tranche of the Phantom Stock Units plan), vesting of which is subject to performance conditions (see separate section below). The Board meeting of March 3, 2021 formally noted the attainment level of the performance conditions, and the overall allocation rate. Paul Hudson was awarded 25,000 Phantom Stock Units in respect of 2020. The amount mentioned in this table is provided by way of indication with reference to the average opening price of the Sanofi share with reference to the average opening price of the Sanofi share on Euronext Paris during the 20 trading days immediately preceding March 3, 2021, date of the Board meeting which has determined the components of the Chief Executive Officer's compensation. The final valuation of the 25,000 Phantom Stock Units will be determined as of March 30, 2021 (the vesting date of the First Tranche). It will be equal to the total number of Phantom Stock Units multiplied by the value of the Sanofi share with reference to the average opening price of the Sanofi share on Euronext Paris during the 20 trading days immediately preceding the vesting date, and will be communicated on the Sanofi corporate website. Payment of the bonus is contingent on Paul Hudson remaining in post as of March 30, 2021 and is subject to approval by the Annual General Meeting to be held on April 30, 2021.

(c) Fixed compensation due in respect of a given year is paid during that year. For 2019, the amount was apportioned on a pro rata basis for the period from September 1 through December 31, 2019.

(d) Indicative amount; see note (b) above.

Fixed and variable compensation

On March 4, 2020, acting on a recommendation from the Compensation Committee, the Board of Directors determined the components of Paul Hudson's compensation for the 2020 financial year.

The Chief Executive Officer's annual compensation for 2020 comprised (i) annual fixed gross compensation of €1,300,000 and, in line with our compensation policy for the Chief Executive Officer, as approved by our shareholders at the Annual General Meeting of April 28, 2020, (ii) annual variable compensation in a range from 0% to 250% of his annual fixed compensation, with a target of 150%, and subject to both quantitative and qualitative criteria.

The objectives applicable to annual variable compensation are 40% based on financial indicators (sales growth, business net income, free cash flow and BOI margin, each accounting for a quarter), and 60% based on specific individual objectives. For 2020, the individual objectives set by the Board were:

- Growth of key new assets (10%) – *quantitative objective*;
- Business transformation (15%) – *qualitative objective*;
- Organization and people (10%) – *qualitative objective*;
- Pipeline (10%) – *quantitative objective*; and
- CSR (15%) – *qualitative objective*.

At the start of 2020, the Board established a precise matrix for determining each individual objective. For confidentiality reasons, neither the level of attainment required (target) for the quantitative criteria nor the details of the qualitative criteria can be disclosed; however, they were pre-determined on a precise basis. In evaluating those criteria, the performance of major global pharmaceutical companies is always taken into account.

Acting on a recommendation from the Compensation Committee, the Board of Directors meeting of March 3, 2021 reviewed the attainment level of each criterion and sub-criterion. The Board's conclusions are summarized in the table below.

	Criterion	Type	Weight	Target/ Maximum (as % of fixed compensation)	Attainment rate	Comments	Payout (as % of fixed compensation)
Financial objectives (40%)	Sales growth	Quantitative	10%	15% / 25%	92.4%	Confidential target, performance below budget	13.9%
	Business net income[(a)]	Quantitative	10%	15% / 25%	106.3%	Confidential target, performance above budget	15.9%
	Free cash flow	Quantitative	10%	15% / 25%	135%	Confidential target, performance well above budget	20.3%
	Business operating income margin	Quantitative	10%	15% / 25%	113.4%	Confidential target, performance above budget	17%
Individual objectives (60%)	Growth in new key assets	Quantitative	10%	15% / 25%	105.5%	Sales above budget for Dupixent®, in line with budget for Vaccines and China	15.8%
	Business transformation	Qualitative	15%	22.5% / 37.5%	115%	Transformation under way in CHC, Industrial Affairs (especially EuroApi spin-out and launch of Evolutive Vaccine Facility) and Digital	25.9%
	Organization and people	Quantitative	10%	15% / 25%	120%	Executive Committee streamlined and refreshed; evaluation of 50 critical posts and development plan for 100 top talents; realignment of compensation on priorities	18%
	Pipeline	Quantitative	10%	15% / 25%	140%	Pipeline additions ahead of forecast; advances on six priority assets in line with plan; productivity gains ahead of objectives.	21%
	CSR	Qualitative	15%	22.5% / 37.5%	100%	Definition of a more ambitious CSR strategy	22.5%
Total			**100%**	**150%/ 250%**			**170.3%**

(a) For a definition, see "Item 5 - Operating and Financial Review and Prospects - Business Net Income".

Acting on a recommendation from the Compensation Committee, the Board of Directors meeting of March 3, 2021 set Paul Hudson's variable compensation for 2020 at €2,213,250, equivalent to 170.3% of his fixed compensation.

Payment of Paul Hudson's variable compensation in respect of the 2020 financial year is contingent on approval of his compensation package by the shareholders in an Ordinary General Meeting, on the terms stipulated in Article L. 22-10-34 II of the French Commercial Code.

Phantom stock units

Having waived all equity-based compensation not yet vested on leaving his previous employer, Paul Hudson was awarded on joining Sanofi a medium-term incentive plan under which he can be paid a cash bonus subject to continuous presence and performance conditions. Under the terms of the plan, which compensates for around 50% of the incentive plans that Paul Hudson has waived, he is awarded phantom stock units, vesting of which is contingent on (i) his continuous presence and (ii) attainment of performance conditions, with the attainment level of those conditions to be determined for half of the award, i.e. 25,000 phantom stock units, as of March 30, 2021 (the "First Tranche") and for the other half of the award, i.e. 25,000 phantom stock units, as of March 30, 2022 (the "Second Tranche").

On expiry of the vesting periods mentioned below, the phantom stock units will vest (subject to fulfilment of the performance conditions), entitling Paul Hudson to a cash bonus equal to the total number of phantom stock units multiplied by the value of Sanofi shares, computed as the average of the opening quoted market prices of Sanofi shares on Euronext Paris for the 20 trading days preceding each vesting date.

The phantom stock units are subject to the following performance conditions:

- attainment level for business net income (BNI), counting towards 50% of the final award;
- attainment level for free cash flow (FCF), counting towards 30% of the final award; and
- a performance criterion based on total shareholder return (TSR) as compared with a panel of our peers over each vesting period, counting towards 20% of the final award. In addition to Sanofi, the panel consists of ten companies: AstraZeneca plc, Bayer AG, Bristol-Myers-Squibb Inc., Eli Lilly and Company Inc., GlaxoSmithKline plc, Johnson & Johnson Inc., Merck Inc., Novartis AG, Pfizer Inc. and Roche Holding Ltd.

The reference periods for assessing the performance conditions relating to BNI and FCF are:

- January 1, 2020 through December 31, 2020, for the 25,000 phantom stock units with a vesting period ending March 30, 2021 (First Tranche); and
- January 1, 2020 through December 31, 2021, for the 25,000 phantom stock units with a vesting period ending March 30, 2022 (Second Tranche).

The reference periods for assessing the performance conditions relating to TSR are:

- the 2020 financial year versus 2019 financial year for the 25,000 phantom stock units with a vesting period ending March 30, 2021 (First Tranche); and
- the 2021 financial year versus 2019 financial year for the 25,000 phantom stock units with a vesting period ending March 30, 2022 (Second Tranche).

The global allocation rate is calculated using the rules set forth below:

(i) Attainment level for BNI

This performance criterion corresponds to the average actual-to-budget ratio of BNI attained over the entire vesting period. Budgeted BNI will be different from one financial year to the next, and will be approved by the Board of Directors at the beginning of each financial year.

For each financial year within the vesting period, a percentage will be calculated (at constant exchange rates) representing the ratio of actual BNI to budgeted BNI. That ratio is referred to as the “annual actual-to-budget BNI attainment level”.

At the end of the vesting period, the arithmetical average of the annual actual-to-budget BNI attainment levels for each financial year in that period (the actual-to-budget BNI attainment level, or “B”) will be calculated, and the Board will determine the BNI allocation rate corresponding to that attainment level as indicated below:

BNI actual-to-budget attainment level (“B”)	BNI allocation rate
If B is <95%	0%
If B = 95%	50%
If B is >95% but <98%	(50 + [(B - 95) x 16])%
If B is ≥98% but ≤105%	B%
If B is >105% but <110%	(105 + [(B - 105) x 3])%
If B is ≥110%	120%

(ii) Attainment level for free cash flow (FCF)

This performance criterion corresponds to the average actual-to-budget ratio of FCF attained over the entire vesting period.

Budgeted FCF will be different from one financial year to the next, and will be approved by the Board of Directors at the beginning of each financial year.

For each financial year within the vesting period, a percentage will be calculated (at constant exchange rates) representing the ratio of actual FCF to budgeted FCF. That ratio is referred to as the annual actual-to-budget FCF attainment level. At the end of the vesting period, the arithmetical average of the annual actual-to-budget FCF attainment levels for each financial year in that period (the actual-to-budget FCF attainment level, or “F”) will be calculated, and the Board will determine the FCF allocation rate corresponding to that attainment level as indicated below:

FCF actual-to-budget attainment level (“F”)	FCF allocation rate
If F is <40%	0%
If F is >40% but <80%	[(F - 40) x 1.625]%
If F = 80%	65%
If F is >80% but <100%	*(65 + [(F - 80) x 1.75])%*
If F = 100%	100%
If F is >100% but <120%	F%
If F is ≥120%	120%

(iii) Attainment level for TSR

For the vesting period, the total shareholder return (TSR) performance condition corresponds to the increase in the quoted market price of Sanofi shares plus dividends per share.

The TSR obtained will be compared with that of each of the companies in the panel of peers listed above, and Sanofi will be ranked against those companies. The TSR allocation rate will be assessed on the basis of Sanofi’s ranking within the panel, as described below:

TSR allocation rate calculation:

- if Sanofi's TSR is below M, the TSR allocation rate will be 0% – M being the median (i.e. performance of the company ranked sixth);
- if Sanofi's TSR is M, the TSR allocation rate will be 50%;
- if Sanofi's TSR is equal to the intermediate level, the TSR allocation rate will be 100%; the intermediate level equals M + [(H-M)/2];
- if Sanofi's TSR is ≥ H, the TSR allocation rate will be 150% - H being the highest position, i.e. the arithmetic average of the performance of companies in the panel ranked 1st and 2nd; and
- if Sanofi's TSR is above M but below H, the TSR allocation rate will be calculated using linear interpolation.

The number of phantom stock units actually vesting depends on the overall allocation rate, which for each vesting period is the weighted average of the business net income allocation rate (50%), the FCF allocation rate (30%) and the TSR allocation rate for the vesting period (20%).

The Board Meeting of March 3, 2021 determined the attainment applicable to the First Tranche of phantom stock units and decided to grant 25,000 phantom stock units to Paul Hudson. The amount of the cash bonus payable in this respect will be equal to the total number of Phantom Stock Units multiplied by the value of the Sanofi share with reference to the average opening price of the Sanofi share on Euronext Paris during the 20 trading days immediately preceding March 31, 2021 (vesting date). This amount will be disclosed on the Company's website under Investors / Corporate Governance / Compensations. Payment of that amount is contingent on Paul Hudson remaining in post as of March 30, 2021, and is subject to approval by the Ordinary General Meeting of the Chief Executive Officer's compensation package on the terms stipulated in Article L. 22-10-34 II of the French Commercial Code.

Equity-based compensation

Using the authorizations granted by our shareholders via the 20th resolution at the Annual General Meeting of April 30, 2019, and acting on the recommendations of the Compensation Committee, the Board of Directors meeting of April 28 2020 decided to award Paul Hudson 75,000 performance shares. The valuation of that award as of April 28, 2020, determined in accordance with IFRS and incorporating a market-related condition, was €5,708,250, equivalent to 4.39 times his fixed compensation.

The entire amount of the award is contingent upon both internal criteria based upon business net income (BNI) and free cash flow (FCF), and upon an external criterion based on total shareholder return (TSR) relative to a benchmark panel of twelve leading global pharmaceutical companies (plus Sanofi): Amgen, AstraZeneca plc, Bayer AG, Bristol-Myers-Squibb Inc., Eli Lilly and Company Inc., GlaxoSmithKline plc, Johnson & Johnson Inc., Merck Inc., Novartis AG, Novo Nordisk, Pfizer Inc., and Roche Holding Ltd.

To align equity-based compensation on our medium-term performance, a three-year period (2020-2022) is used to measure performance.

The above criteria were selected because they align medium-term equity-based compensation on the strategy adopted by Sanofi.

The arrangements relating to these awards are as follows:

- The performance criterion based on BNI accounts for 50% of the award. That criterion corresponds to the ratio, at constant exchange rates, of actual BNI to budgeted BNI. It represents the average actual-to-budget ratio attained over the entire period. Budgeted BNI is derived from the budget as approved by the Board of Directors at the beginning of each financial year. The BNI objective may not be lower than the bottom end of the full-year guidance range publicly announced by Sanofi at the beginning of each year. If the attainment level is less than 95%, the corresponding performance shares are forfeited.

BNI actual-to-budget attainment level ("B")	BNI allocation rate
If B <95%	0%
If B = 95%	50%
If B is >95% but <98%	(50 + [(B - 95) x 16])%
If B is ≥98% but ≤105%	B%
If B is >105% but <110%	(105 + [(B - 105) x 3])%
If B is ≥110%	120%

- The FCF criterion accounts for 30% of the award. This criterion was selected because it is aligned with Sanofi's current strategic objectives, and is transparent both within and outside the company. It has replaced the criterion based on return on assets (ROA) for awards made in or after 2019. In 2020, to take account of comments from certain institutional shareholders, we adjusted the free cash flow curve by raising the trigger point from 40% to 70% of budget.

The FCF criterion represents the average actual-to-budget FCF ratio attained over the entire period. The award is based on a target FCF, below which some or all of the performance shares are forfeited.

FCF actual-to-budget attainment level ("F")	FCF allocation rate
If F is ≤70%	0%
If F is >70% but <80%	[(F - 70) x 5]%
If F = 80%	50%
If F is >80% but <100%	(50 + [(F – 80) x 2.5])%
If F = 100%	100%
If F is >100% but <120%	F%
If F is ≥120%	120%

- The TSR criterion accounts for 20% of the award. Total shareholder return (TSR) reflects both the appreciation in the value of our shares (the increase in the share price, comparing the average opening quoted market prices from January 1, 2019 through December 31, 2019 and from January 1, 2022 through December 31, 2022) and the value distributed to our shareholders (dividends), i.e. the two sources of return on investment in Sanofi shares. Our TSR is compared with the benchmark panel of twelve companies listed above. The number of performance shares vesting depends upon our position relative to the TSR for the other companies in the panel. Below 70%, the corresponding performance shares are forfeited.

– Median TSR ("M") is the performance of the company ranked 7th in the panel.

– The upper bound ("H") is the arithmetical average of the performances of the panel companies ranked 1st, 2nd & 3rd.

– The intermediate level is calculated as M + [(H–M)/2].

The TSR allocation rate will be calculated as follows based on Sanofi's ranking within the panel:

– if Sanofi's TSR is below M, the TSR allocation rate will be 0%;

– if Sanofi's TSR is M, the TSR allocation rate will be 50%;

– if Sanofi's TSR is equal to the intermediate level, the TSR allocation rate will be 100%.

– if Sanofi's TSR is ≥ H, the TSR allocation rate will be 150%; and

– if Sanofi's TSR is above M but below H, the TSR allocation rate will be calculated using linear interpolation.

Paul Hudson is under an obligation to retain, until he ceases to hold office, a quantity of Sanofi shares equivalent to 50% of any gain (net of taxes and social contributions) arising on the vesting of his performance shares, calculated as of the date on which those shares vest.

In compliance with the AFEP-MEDEF Code and our Board Charter, Paul Hudson has undertaken to refrain from entering into speculative or hedging transactions, and so far as the Company is aware no hedging instruments have been contracted.

For confidentiality reasons, the amount of the quantitative measures for the internal criteria cannot be disclosed. However, they were determined on a precise basis, and attainment levels for the internal criteria will be disclosed at the end of the performance measurement period (see "— Item 6.E. – Share Ownership" below).

Performance shares awarded to Paul Hudson in 2020 (table No. 6 of the AFEP-MEDEF Code)

Source	Plan date	Valuation of performance shares (€)	Number of performance shares awarded during the period	Vesting date	Availability date[(a)]	Performance conditions
Sanofi	04/28/2020	5,708,250	75,000	05/02/2023	05/02/2023	Yes

(a) Under the terms of our Board Charter, Paul Hudson is required to retain a quantity of shares corresponding to 50% of the capital gain arising on the vesting of the shares, net of the associated taxes and social contributions.

Each performance share awarded on April 28, 2020, was valued at €76.11, valuing the total benefit at €5,708,250.

The Board of Directors has decided to limit the number of performance shares that can be awarded to executive officers to 5% of the total limit approved by the Shareholders' Annual General Meeting of April 30, 2019 (1.5% of the share capital). The number of shares awarded to Paul Hudson in 2020 represents 0.4% of the total limit approved by that Meeting and 0.006% of our share capital at the date of grant.

Performance shares awarded to Paul Hudson which became available in 2020 (table No. 7 of the AFEP-MEDEF Code)

Because Paul Hudson took office on September 1, 2019, he was not awarded any performance shares prior to the 2020 financial year. Consequently, no performance shares became available to him in 2020.

Source	Plan date	Valuation of performance shares (€)	Number of performance shares awarded during the period	Vesting date	Availability date	Performance conditions
Sanofi	—	—	None	—	—	–

Pension rights

Paul Hudson is entitled to benefits under the top-up defined-contribution pension plan introduced within Sanofi on January 1, 2020. Under the terms of the plan, the Chief Executive Officer receives (subject to attainment of a performance condition) an annual contribution of up to 25% of his reference compensation (annual fixed and variable compensation).

The performance condition for the vesting of pension rights is linked to the attainment of the performance criteria for 2020 variable compensation. The Board of Directors, at its meeting of March 3, 2021, ascertained whether that performance condition had been met, noting that the attainment level for the variable portion of Paul Hudson's compensation for the 2020 financial year was 113.5%, i.e. 170.3% of his fixed compensation.

The annual gross contribution is paid as follows:

- 50% as a gross insurance premium to the fund manager - the amount due to the fund manager with respect to 2020 is €439,156.25; and
- 50% to the Chief Executive Officer, to indemnify him for the social security and tax charges for which he will become immediately liable. The amount due to Paul Hudson with respect to 2020 was set by the Board of Directors at is meeting of March 3, 2021 at €439,156.25.

Payment of those amounts is contingent on approval of the Chief Executive Officer's compensation package by the shareholders in an Ordinary General Meeting, on the terms stipulated in Article L. 22-10-34 II of the French Commercial Code.

Social welfare and health insurance

Paul Hudson is subject to, benefits from and contributes to the same health cover, and death and disability plans as are applicable to other employees of Sanofi based in France. He also benefits from an unemployment insurance scheme.

Benefits in kind

The benefits in kind received by Paul Hudson in 2020 were valued at €168,842, and correspond to accommodation costs incurred during his acclimatization period (until August 2020).

Pay ratio between compensation of Executive Officers and average/median compensation of Sanofi employees - Changes in compensation of executive officers and employees relative to the performance of Sanofi

This information is disclosed in accordance with Article L. 22-10-9 6° of the French Commercial Code, further to the enactment of the "Pacte" law.

Explanations on calculation methods and on year-on-year changes in the executive pay ratio:

- The scope includes Sanofi SA (the parent company) and all of its direct and indirect subsidiaries located in France, and hence covers more than 80% of total payroll of permanent employees in France. No separate ratios are published for Sanofi SA (the parent company), as the low headcount at Sanofi SA means that such ratios would not be representative of our total headcount in France.
- The employee compensation used in the calculation is the full time equivalent (FTE) compensation of permanent employees with at least two financial years of uninterrupted employment.
- Compensation includes fixed compensation awarded during the reference year, and variable compensation related to the previous year and paid during the reference year. All compensation amounts are gross amounts.
- In order to maintain consistency, we have excluded from the numerator (i) compensation items not included in the denominator and (ii) non-recurring compensation items. This applies in particular to accommodation expenses related to the relocation to France of the Chief Executive Officer (Paul Hudson) in 2020, and to expenses related to unemployment insurance.
- Long term variable compensation: performance shares and stock options awarded during each reference year are valued at the date of grant in accordance with IFRS Rules. Valuation of the Performance Shares awarded in 2020 and including TSR indicator ("Total Shareholder Return") as vesting performance condition, includes market conditions. Those awards are subject to a continuing employment condition (three years minimum) and to performance conditions. Consequently, the valuation at the date of grant is not necessarily indicative of the value of stock options and performance shares at the end of the vesting period, especially if the performance conditions are not met.
- For plans that have expired since 2017, attainment levels were in the region of 81% for the Chief Executive Officer and 100% for the employee plans. For more information about attainment levels and allocation rates for our stock option plans and performance share plans, see "— Item 6.E. – Share Ownership" below.
- Since Olivier Brandicourt (our previous Chief Executive Officer) received the same number of stock options and performance shares each year from 2016 to 2019, fluctuations in the Sanofi share price had a significant impact on the pay ratio during this period.
- Business net income is a non-GAAP financial measure used by Sanofi and consolidated on a worldwide basis. The 2016 and 2017 business net income figures include the impacts of the first-time application of IFRS 15 on revenue recognition (see Note A.2.1.1. to our consolidated financial statements for the year ended December 31, 2018).
- 2018 and 2019 figures have been restated to exclude Sanofi's equity-accounted share of Regeneron's net profits (see note D-1 of our consolidated financial statements) and to include the effects of IFRS 16 for comparative purposes.
- Regular benchmarking reviews are conducted to ensure that the level of compensation awarded to our employees and CEO is competitive and consistent with pharmaceutical industry levels.

Comparison of compensation of Sanofi executive officers with employee compensation (parent company and all direct and indirect subsidiaries located in France)

Chief Executive Officer[a]	2016	2017	2018	2019	2020
Ratio versus average compensation	102.0	128.1	93.8	106.6	110.6
Change in %		25.6%	-26.8%	13.6%	3.8%
Ratio versus median compensation	131.2	165.0	120.3	135.4	142.8
Change in %		25.7%	-27.1%	12.5%	5.5%

Chairman of the Board (Serge Weinberg)	2016	2017	2018	2019	2020
Ratio versus average compensation	9.4	9.2	9.2	9.2	10.0
Change in %		-2.6%	0,7%	-0.1%	8.4%
Ratio versus median compensation	12.1	11.8	11.8	11.7	12.9
Change in %		-2.5%	0.3%	-1.1%	10.1%

(a) 2019: Olivier Brandicourt left office on August 31. Paul Hudson was appointed as CEO on September 1, 2019.
2020: The 2020 CEO compensation includes Paul Hudson's 2020 fixed compensation (€1.3 million), his 2019 variable compensation paid in 2020 and annualized (€1.95 million), and 75,000 performance shares awarded in 2020.

Based on full-time equivalent permanent employees of all Sanofi legal entities worldwide with at least two years of uninterrupted employment, the ratios for 2020 as follows:

CEO:

– ratio versus average compensation: 123.8

– ratio versus median compensation: 188.1

Chairman of the Board:

– ratio versus average compensation: 11.1

– ratio versus median compensation: 16.9

These ratios were calculated on the basis of annualized basic compensation, variable compensation in respect of the previous year and performance shares awarded during the year 2020, and using 2020 average exchange rates.

Annual change in compensation, company performance and average employee compensation (parent company and all direct and indirect subsidiaries located in France)

	FY 2015[a]	FY 2016 vs FY 2015	FY 2017 vs FY 2016	FY 2018 vs FY 2017	FY 2019 vs FY 2018[a]	FY 2020 vs 2019[b]
Chief Executive Officer (in € thousand)						
Compensation	9,931	7,693	9,916	7,213	8,200	8,958
Change in € thousand		(2,163)	2,720	(2,703)	0.987	0.758
Change in %		-23%	38%	-27%	14%	9.2%
Chairman of the Board (in € thousand)						
Compensation	708.22	708.35	708.35	708.36	708.19	807.72
Change in € thousand		0.13	0	0.01	0.17	99.52
Change in %		0.02%	0%	0%	(0.02%)	14.1%
Average employee compensation on FTE basis (in € thousand)						
Compensation	76.59	75.42	77.40	76.87	76.93	80.97
Change in € thousand		(1.17)	1.98	(0.53)	0.06	4.03
Change in %		-1.53%	2.62%	-0.69%	0.08%	5.2%
Business net income (in € thousand)						
Business net income	7,371,000	7,308,000	6,943,000	6,411,000	7,050,000	7,347,000
Change in € thousand		(63,000)	(365,000)	(532,000)	639,000	297,000
Change in %		-0.85%	-4.99%	-7.7%	10.0%	4.2%

(a) 2015 and 2016: Olivier Brandicourt was appointed as CEO on April 2, 2015. Christopher Viehbacher, his predecessor as CEO, left office on October 29, 2014. The Chairman of the Board, Serge Weinberg, served as interim CEO until the appointment of Olivier Brandicourt, but received no specific Christopher Viehbacher's 2014 compensation and Olivier Brandicourt's 2015 compensation have been annualized for the purpose of calculating the ratios. 2019: Olivier Brandicourt left office on August 31. Paul Hudson was appointed as CEO on September 1, 2019. His 2019 variable compensation, paid in 2020, has been annualized for the purpose of calculating the ratios.

(b) 2020: Paul Hudson took office on September 1, 2019. The 2020 CEO compensation includes Paul Hudson's 2020 fixed compensation (€1.3 million), his 2019 variable compensation paid in 2020 and annualized (€1,950 million), and 75,000 performance shares awarded in 2020.

Compensation and benefits of all kinds awarded to corporate officers in respect of 2021

Compensation and benefits of all kinds awarded to directors in respect of 2021

The amounts awarded to directors in respect of 2021 will be determined in accordance with the principles described above in “Compensation policy for directors”, within the section entitled “Compensation policy for corporate officers”.

Compensation and benefits of all kinds awarded in respect of 2021 to Serge Weinberg, Chairman of the Board of Directors

The components of the compensation awarded to the Chairman of the Board of Directors are described above in “Compensation policy for the Chairman of the Board of Directors”, within the section entitled “Compensation policy for corporate officers”.

Acting on a recommendation from the Compensation Committee, the Board of Directors meeting of March 3, 2021 determined the components of Serge Weinberg’s compensation. Serge Weinberg will receive annual fixed compensation of €800,000 for holding office as Chairman (the same as for the 2020 financial year; see explanations provided in the section entitled “Compensation policy for corporate officers” above).

Serge Weinberg does not receive any variable compensation, stock options or performance shares. In accordance with AMF recommendations, he does not receive any compensation (i) for serving as a director or (ii) from any company included in Sanofi’s scope of consolidation within the meaning of Article L. 233-16 of the French Commercial Code.

His benefits in kind for 2021 comprise a company car with a driver.

Compensation and benefits of all kinds awarded in respect of 2021 to Paul Hudson, Chief Executive Officer

Fixed and variable compensation

Acting on a recommendation from the Compensation Committee, the Board of Directors meeting of March 3, 2021 determined the components of Paul Hudson's compensation for the 2021 financial year.

Paul Hudson's annual compensation comprises (i) annual fixed gross compensation of €1,300,000 and (ii) annual variable compensation in a range from 0% to 250% of his annual fixed compensation, with a target of 150%, and subject to both quantitative and qualitative criteria.

Those objectives are 50% based on financial indicators (sales growth, business net income, free cash flow, BOI margin and growth of key new assets, each accounting for 10%), and 50% based on specific individual objectives. Those individual objectives, and comparatives for 2020, are shown below:

2021 individual objectives		2020 individual objectives	
Business transformation	15%	Growth of key new assets [(a)]	10%
Organization and people	7.5%	Business transformation	15%
Pipeline	12.5%	Organization and people	10%
CSR	15%	Pipeline	10%
		CSR	15%

(a) The"Growth of key new assets" objective is maintained for 2021 but is now included in the financial objectives.

Equity-based compensation

Acting on a recommendation from the Compensation Committee, the Board of Directors meeting of March 3, 2021 proposes to award 75,000 performance shares to Paul Hudson in respect of 2021. In accordance with the AFEP-MEDEF Code, the entire award will be subject to criteria that are both internal (based on our business net income and free cash flow) and external (based on total shareholder return as compared with 12 leading global pharmaceutical companies: Amgen, AstraZeneca plc, Bayer AG, Bristol-Myers-Squibb Inc., Eli Lilly and Company Inc., GlaxoSmithKline plc, Johnson & Johnson Inc., Merck Inc., Novartis AG, Novo Nordisk, Pfizer Inc., and Roche Holding Ltd.).

We will make details of the terms of the plan available to shareholders on the governance page of our corporate website (www.sanofi.com) in advance of the Annual General Meeting of April 30, 2021.

In accordance with the AFEP-MEDEF Code, Paul Hudson is bound by rules on insider trading that impose blackout periods, as contained in our Board Charter.

In accordance with the AFEP-MEDEF Code and with our Board Charter, Paul Hudson has undertaken not to engage in speculative or hedging transactions, and as far as the company as aware no hedging instruments have been contracted.

Transactions in shares by members of the Board of Directors and equivalent persons

As far as Sanofi is aware, transactions in our securities carried out during 2020 by (i) Board members, (ii) executives with the power to make management decisions affecting our future development and corporate strategy and (iii) persons with close personal ties to such individuals (as per Article L. 621-18-2 of the French Monetary and Financial Code), were as follows:

- on June 22, 2020, Gilles Schnepp (director) purchased 1,000 shares at a price of €95.15 per share;
- on November 12, 2020, Lise Kingo (director) purchased 1,000 shares at a price of €85.204 per share; and
- on November 18, 2020, Rachel Duan (director) purchased 1,000 shares at an average price of €85.594 per share.

Service contracts

Neither we nor our subsidiaries have entered into service contracts with members of our Board of Directors or executive officers providing for any benefits. Details of compensation and other arrangements for our executive officers are provided at " –B. Compensation – Compensation and arrangements for executive officers" above.

Compensation and arrangements for other Executive Committee members

Compensation

The compensation of Executive Committee members other than the Chief Executive Officer is reviewed by the Compensation Committee, taking into consideration the practices of leading global pharmaceutical companies.

In addition to fixed compensation, they receive variable compensation. Their target variable compensation depends on their position, and can represent up to 100% of their fixed compensation. The target amount of individual variable compensation is determined in line with market practice. It rewards the joint contribution of all Executive Committee members to Sanofi's performance.

For 2020, the variable component consisted of two elements:

- attainment of quantitative objectives (accounting for 50%) which are measured at consolidated level: sales growth 30%, ratio of business operating income to net sales ("BOI margin") 35%, research and development outcomes 20%, and free cash flow 15%; and
- attainment of quantitative and qualitative objectives both individually (30%) and collectively (20%) within the Executive Committee (together accounting for 50%).

The indicators used are intended to measure Sanofi's annual performance objectives, individual objectives, and the attainment of human capital objectives like gender parity in senior executive roles, individual career development plans, and talent and critical skills management.

In addition, Executive Committee members may be awarded performance shares.

For 2020, the total gross compensation paid and accrued in respect of members of the Executive Committee (excluding the Chief Executive Officer) was €23 million, including €7 million in fixed compensation.

On April 28, 2020 and October 28, 2020, a total of 230,478 performance shares were awarded to members of the Executive Committee (excluding the award to the Chief Executive Officer). No stock options were awarded in 2020 to members of the Executive Committee or the Chief Executive Officer.

In compliance with the AFEP-MEDEF Code, these entire awards are contingent upon two internal criteria, based on business net income (BNI)[1], free cash flow (FCF); and on an external criterion, based on total shareholder return (TSR). Those criteria were selected because they align medium-term equity-based compensation with the strategy adopted by Sanofi. The Board believes that the performance conditions applied are good indicators of shareholder value creation in terms of the quality of investment decision and the commitment to deliver exacting financial results in a difficult economic environment.

The arrangements relating to these awards are as follows:

- The BNI performance criterion accounts for 50% of the award. This criterion corresponds to the ratio, at constant exchange rates, of actual BNI to budgeted BNI. It represents the average actual-to-budget ratio attained over the entire period. Budgeted BNI is derived from the budget as approved by the Board of Directors at the beginning of each financial year. The BNI objective may not be lower than the bottom end of the full-year guidance range publicly announced by Sanofi at the beginning of each year. If the ratio is less than 95%, the corresponding performance shares are forfeited.

BNI actual-to-budget attainment level ("B")	BNI allocation rate
If B is <95%	0%
If B = 95%	50%
If B is >95% but <98%	(50 + [(B –95) x 16])%
If B is ≥98% but ≤105%	B%
If B is >105% but <110%	(105 + [(B –105) x 3])%
If B is ≥110%	120%

- The FCF criterion accounts for 30% of the award. It represents the average actual-to-budget ratio of free cash flow attained over the entire period. The award is based on a target FCF, below which some or all of or performance shares are forfeited.

FCF actual-to-budget attainment level ("F")	FCF allocation rate
If F is ≤70%	0%
If F is >70% but <80%	[(F – 70) x 5]%
If F = 80%	50%
If F is >80% but <100%	(50 + [(F – 80) x 2.5])%
If F = 100%	100%
If F is >100% but <120%	F%
If F is >120%	120%

- The TSR criterion accounts for 20% of the award.

For the vesting period, the TSR criterion corresponds to the increase in the quoted market price of Sanofi shares, determined by comparing the average of the opening quoted market prices from 1 January 1, 2019 through December 31, 2019 and the average of the opening quoted market prices from 1 January 1, 2022 to December 31, 2022, plus dividends per share.

The TSR obtained will be compared with that of each of the companies in a panel of peers to generate a ranking that includes Sanofi and the 12 companies in the panel: Amgen, AstraZeneca plc, Bayer AG, Bristol-Myers-Squibb Inc., Eli Lilly and Company Inc., GlaxoSmithKline plc, Johnson & Johnson Inc., Merck Inc., Novartis AG, Novo Nordisk, Pfizer Inc., and Roche Holding Ltd.

- Definitions:

– Median TSR ("M") is the performance of the company ranked 7th in the panel.

– The upper bound ("H") is the arithmetical average of the performances of the panel companies ranked 1st, 2nd & 3rd.

– The intermediate level is calculated as M + [(H–M)/2].

The TSR allocation rate will be calculated as follows based on Sanofi's ranking within the panel:

– if Sanofi's TSR is below M, the TSR allocation rate will be 0%;

– if Sanofi's TSR is M, the TSR allocation rate will be 50%;
– if Sanofi's TSR is equal to the intermediate level, the TSR allocation rate will be 100%.
– if Sanofi's TSR is ≥ H, the TSR allocation rate will be 150%; and
– if Sanofi's TSR is above M but below H, the TSR allocation rate will be calculated using linear interpolation.

- The number of performance shares actually vesting depends on the overall allocation rate, which for the vesting period is the weighted average of the BNI allocation rate (50%), the FCF allocation rate (30%) and the TSR allocation rate for the vesting period (20%).
- In order to align equity-based compensation with medium-term performance, performance is measured over three financial years.
- Vesting is subject to a non-compete clause.
- The entire award is forfeited in the event of resignation, or dismissal for gross or serious misconduct.
- In the event of individual dismissal other than for gross or serious misconduct or retirement before the age of 60, or if the beneficiary's employer ceases to be part of the Sanofi group, the overall allocation percentage is prorated to reflect the amount of time the person remained with the Sanofi group during the vesting period.
- If any of the following events occur, full rights to the award are retained: (i) dismissal as part of a collective redundancy plan or of an equivalent collective plan negotiated and approved by the Chief Executive Officer of Sanofi; (ii) retirement on or after reaching the statutory retirement age, or early retirement under a statutory or contractual early retirement plan implemented by the relevant Sanofi entity and duly approved by the Chief Executive Officer of Sanofi; (iii) disability classified in the second or third categories stipulated in Article L. 314-4 of the French Social Security Code; or (iv) death of the beneficiary.

For confidentiality reasons, the amount of the quantitative measures for the internal criteria cannot be disclosed. However, they were determined on a precise basis, and the level of attainment for the internal criteria will be disclosed at the end of the performance measurement period.

We publish in our Annual Report the level of attainment determined by the Board of Directors for performance conditions applicable to equity-based compensation plans awarded to the Chief Executive Officer and other members of the Executive Committee. The Board believes that disclosing the attainment level allows our shareholders to better understand the demanding nature of the performance conditions.

The attainment levels for the most recent equity-based compensation plans are as follows:

	Attainment level		Allocation rate
	Business net income	ROA	
May 4, 2016 plans	2016-2018: 102.5%	2016-2018: 1.2 percentage points above target	2016-2018: 101.5%[(a)]
May 10, 2017 plans	2017-2020: 101.3%	2017-2020: 0.29 of a percentage point above target	2017-2019: 100.8%[(a)]

(a) Effectively 100%: the maximum number of exercisable options or shares to be delivered cannot be more than the number of options initially granted or performance shares initially awarded.

In 2020, 55,510 stock options were exercised by individuals who were Executive Committee members at December 31, 2020.

All of the plans involved post-date the creation of the Executive Committee: Sanofi-Aventis plan of March 9, 2011, exercise price €50.48; Sanofi plan of March 5, 2012, exercise price €56.44 euros; and Sanofi plan of March 5, 2013, exercise price €72.19.

Pension arrangements

The total amount accrued as of December 31, 2020 in respect of corporate pension plans for (i) corporate officers with current or past executive responsibilities at Sanofi (or companies whose obligations have been assumed by Sanofi) and (ii) members of the Executive Committee was €28 million. That amount includes an expense of €2 million recognized in profit or loss during 2020.

C. Board Practices

Neither we nor our subsidiaries have entered into service contracts with members of our Board of Directors or corporate officers providing for benefits upon termination of employment. With respect to the Chief Executive Officer, see also "-B. Compensation - Compensation and arrangements for corporate officers" above.

Application of the AFEP-MEDEF Code

The AFEP-MEDEF Code requires us to report specifically on the application of its recommendations and if any of them have not been applied, explain why. Currently our departures from this Code are as follows:

Paragraph of the AFEP-MEDEF Code	Recommendation of the AFEP-MEDEF code	Application by Sanofi
10.2 Evaluation of the Board of Directors	The evaluation has three objectives: • […]; • measure the actual contribution of each director to the Board's work.	The evaluation of the Board conducted at the end of 2018 included an assessment of the actual contribution of each director to the Board's work. More generally, the issue of competence and individual contribution to the work of the Board and its Committees is addressed on a continuous basis, with a specific review when a director is up for reappointment as a Board or Committee member. Annual evaluations are conducted using a detailed questionnaire. The questionnaire deals specifically with the operating procedures of the Board and gives directors an opportunity to express freely their assessment of the individual contributions of other directors. These evaluations may be followed by individual meetings with the Secretary to the Board, at which the responses to the questionnaire are analyzed and discussed.
18.1 Membership of the Compensation Committee	It is recommended that one of its members be an employee director.	The Board intends to appoint a director representing employees to the Compensation Committee after an induction period that will give that director time to adapt to how the Company operates, understand its specific characteristics, familiarize himself or herself with the challenges and broad outlines of the Board's remit, and undertake any necessary training.
24.4 Non-competition agreement	In any event, no benefit can be paid over the age of 65.	Under the compensation policy for our Chief Executive Officer, he undertakes in the event he leaves the Company not to join a competitor of the Company as an employee or corporate officer, or to provide services to or cooperate with such a competitor. In return for this undertaking, he receives an indemnity corresponding to one year's total compensation based on his fixed compensation effective on the day he ceases to hold office and the last individual variable compensation received prior to that date. The indemnity is payable in 12 monthly installments. The Board of Directors, acting on a recommendation of the Compensation Committee, decided not to alter the compensation policy and non-compete undertaking of the Chief Executive Officer such that his indemnity would not be payable after he reaches the age of 65. Apart from the fact that the AFEP-MEDEF recommendation is contrary to the principle of the strict enforceability of legally constituted contractual arrangements, it is also out of line with the actual situation. In practice, many executive officers continue to work after they leave office, often in a consultancy role. Consequently, implementing the AFEP-MEDEF recommendation would put Sanofi at risk of having no legal protection if the Chief Executive Officer were to take up an activity in competition with the Company immediately after leaving office. However, the Board of Directors may decide at the time the Chief Executive Officer leaves office (regardless of his age) to release him from the non-compete undertaking for some or all of the 12-month period. In such a case, the non-compete indemnity would not be due for the period of time waived by the Company.

Activities of the Board of Directors in 2020

During 2020, the Board of Directors met 14 times (including the strategy seminar), with an overall attendance rate among Board members of 98%. This attendance rate includes participation by videoconference, which was the preferred method of participating in meetings during 2020 due to the COVID-19 crisis. Individual attendance rates varied between 71% and 100%.

The following persons attended meetings of the Board of Directors:

- the directors;
- the Secretary to the Board;
- frequently: members of the Executive Committee; and
- occasionally: the statutory auditors, managers of our global support functions, and other company employees.

The agenda for each meeting of the Board is prepared by the Secretary after consultation with the Chairman, taking account of the agendas for the meetings of the specialist Committees and the suggestions of the directors.

Approximately one week prior to each meeting of the Board of Directors, the directors each receive a file containing the agenda, the minutes of the previous meeting, and documentation relating to the agenda.

The minutes of each meeting are expressly approved at the next meeting of the Board of Directors.

In compliance with our Board Charter, certain issues are examined in advance by the various Committees according to their areas of competence to enable them to make a recommendation; those issues are then submitted for a decision by the Board of Directors.

Since 2016, acting on a recommendation from the Appointments, Governance and CSR Committee, the Board has held at least two executive sessions (i.e. meetings held without the Chief Executive Officer present) per year. If the Chairman of the Board so decides, such sessions may also be held without the directors representing employees (or any other Sanofi employee) being present. The primary purpose of such sessions is to evaluate the way the Board and its Committees operate, to discuss the performance of the Chief Executive Officer, and to debate succession planning. In light of the global pandemic and the fact that Paul Hudson has only recently taken office as CEO, only one executive session took place in 2020, on March 3.

In 2020, the main activities of the Board of Directors related to the following issues:

- Financial statements and financial matters:
  - review of the individual company and consolidated financial statements for the 2019 financial year and for the first half of 2020, review of the consolidated financial statements for the first three quarters of 2020, review of the draft press releases and presentations to analysts with respect to the publication of such financial statements, examination of documents relating to management forecasts;
  - delegation of authority to the Chief Executive Officer to issue bonds and guarantees, and renewal of the share repurchase program;
  - recording the amount of share capital, reducing the share capital through cancellation of treasury shares, and amending the Articles of Association accordingly; and
  - presentation of the 2021 budget, and 2021-2023 financial forecasts.
- Compensation matters:
  - determination of the 2019 variable compensation and top-up pension arrangements of Olivier Brandicourt, determination of the 2019 fixed compensation and the 2020 variable compensation objectives of Paul Hudson, determination of the 2020 compensation of the Chairman of the Board, plus an update on fixed and variable compensation of the Executive Committee for 2019 and 2020. During the presentation of the report of the Compensation Committee on the compensation of executive officers, the Board of Directors deliberates in executive session in their absence: the Board of Directors first discusses the compensation of the Chairman of the Board in his absence, and then the compensation of the Chief Executive Officer with the Chairman present but the Chief Executive Officer still absent;
  - allocation of the total amount of directors' compensation for 2019, determination of the total allocation to be summitted for approval by the Annual General Meeting on April 28, 2020, and changes to the allocation principles for 2020; and
  - adoption of the share performance plan for 2020, and determination of the fulfillment of performance conditions of previous equity-based compensation plans.
- Appointments and governance matters:
  - the composition of the Board and its Committees, proposed reappointment of directors and appointment of Rachel Duan and Lise Kingo as independent directors at the 2020 Annual General Meeting, and the co-opting of Gilles Schnepp as an independent director;
  - director independence;
  - reviews of the Board of Directors' Management Report, the report on corporate governance, and the reports of the statutory auditors;
  - arrangements for holding the Annual General Meeting of Shareholders and of Holders of Participating Shares (Series issued in 1983, 1984 and 1987) in light of the COVID-19 crisis, adoption of (i) the draft resolutions (ii) the report of the Board of Directors on the resolutions and (iii) the special reports on the awards of stock options and performance shares, and examination of questions submitted by shareholders in writing;
  - evaluation of the work of the Board and its Committees;

– objectives for gender balance in the Company's executive bodies, and the Company's diversity policy;
– presentation of a detailed report on the governance roadshows arranged for the main investors in Sanofi;
– revisions to the Board Charter; and
– review of previously-approved related party agreements.

- Review of Sanofi's risk profile.
- Various matters related to the COVID-19 pandemic.
- Update on progress in vaccine research.
- Update on Dupixent®.
- Status report on Depakine® litigation.
- Review and approval of Sanofi's new strategy on CSR issues.
- Update on strategy for China.
- Update on the Action 2020 employee share ownership plan.
- Scrutiny of strategic alliance proposals, in particular the Pluton project (i.e. the proposed creation of a new standalone company combing Sanofi's API commercial and development activities), and the alliance with Regeneron.
- Company policy on equal pay and equal opportunities.

In addition, a Strategy Seminar was held in October 2020, in which all members of the Executive Committee took part. The seminar gave directors an opportunity to address issues including:

- scrutiny of the "Play to Win" strategy for 2020-2025;
- changes to our R&D strategy;
- update on the situation in General Medicines;
- update on Vaccines;
- growth for Dupixent® and opportunities for Specialty Care;
- scrutiny of our Digital strategy; and
- the financial roadmap.

Activities of the Board Committees in 2020

Since 1999, our Board of Directors has been assisted in its deliberations and decisions by specialist Committees (for a description of the remit of each Committee, refer to our Board Charter, provided as Exhibit 1.2 to this Annual Report on Form 20-F). Chairs and members of these Committees are chosen by the Board from among its members, based on their experience.

The Committees are responsible for the preparation of certain items on the agenda of the Board of Directors. Decisions of the Committees are adopted by a simple majority with the Chair of the Committee having a casting vote. Minutes are drafted, and approved by the Committee members.

The Chair of each Committee reports to the Board on the work of that Committee, so that the Board is fully informed whenever it takes a decision.

During 2020:

- There were the following changes to the composition of the Audit Committee:

Audit Committee		
	Composition as of January 1, 2020	**Composition as of December 31, 2020**
Chair	Fabienne Lecorvaisier (independent director)	Fabienne Lecorvaisier (independent director)
Members	Diane Souza (independent director) Emmanuel Babeau (independent director)	Gilles Schnepp (independent director)[(a)] Diane Souza (independent director) Christophe Babule[(b)]
	Proportion of independent directors: 100% (3/3)	**Proportion of independent directors: 75% (3/4)**

(a) Appointed to the Audit Committee by the Board of Directors on May 22, 2020.
(b) Appointed to the Audit Committee by the Board of Directors on October 28, 2020.

- There were the following changes to the composition of the Appointments, Governance and CSR Committee and of the Compensation Committee:

Appointments, Governance and CSR Committee		
	Composition as of January 1, 2020	**Composition as of December 31, 2020**
Chair	Serge Weinberg (independent director)	Serge Weinberg (independent director)
Members	Claudie Haigneré[(a)] (independent director) Patrick Kron (independent director) Melanie Lee (independent director)	Patrick Kron (independent director) Melanie Lee (independent director)
	Proportion of independent directors: 100% (4/4)	**Proportion of independent directors: 100% (3/3)**

Compensation Committee		
	Composition as of January 1, 2020	**Composition as of December 31, 2020**
Chair	Patrick Kron (independent director)	Patrick Kron (independent director)
Members	Claudie Haigneré[(a)] (independent director) Carole Piwnica (independent director) Diane Souza (independent director)	Carole Piwnica (independent director) Diane Souza (independent director)
	Proportion of independent directors: 100% (4/4)	**Proportion of independent directors: 100% (3/3)**

(a) The term of office of Claudie Haigneré expired at the Annual General Meeting of April 28, 2020 and was not renewed.

Strategy Committee (no change in 2020)	
Chair	Serge Weinberg (independent director)
Members	Paul Hudson Laurent Attal Patrick Kron (independent director)
	Proportion of independent directors: 50% (2/4)

Scientific Committee (no change in 2020)	
Chair	Thomas Südhof (independent director)
Members	Laurent Attal Melanie Lee (independent director) Serge Weinberg (independent director)
	Proportion of independent directors: 75% (3/4)

Audit Committee

Three of the four members of the Audit Committee (Fabienne Lecorvaisier, Gilles Schnepp and Diane Souza) qualify as independent pursuant to the criteria adopted by the Board of Directors; they all have financial or accounting expertise as a consequence of their education and professional experience; and they are all deemed to be financial experts as defined by the Sarbanes-Oxley Act and by Article L. 823-19 of the French Commercial Code. See “Item 16A. Audit Committee Financial Expert”.

The Audit Committee met six times in 2020, including prior to the meetings of the Board of Directors during which the financial statements were approved. In addition to the statutory auditors, the principal financial officers, the Senior Vice President Group Internal Audit and other members of the senior management team attended meetings of the Audit Committee, in particular when risk exposure and off-balance-sheet commitments were discussed.

The Committee members had a good attendance record, with an overall attendance rate of 93% and individual attendance rates ranging from 67% to 100%.

The statutory auditors attend all meetings of the Audit Committee; they presented their opinions on the annual and half-year financial statements at the Committee meetings of February 3 and July 27, 2020, respectively.

In 2020, the main activities of the Audit Committee related to:

- preliminary review of the individual company and consolidated financial statements for the 2020 financial year, review of the individual company and consolidated financial statements for the first half of 2020, review of the consolidated financial statements for the first three quarters of 2020, review of the draft press releases and analyst presentations relating to the publication of such financial statements;
- Sanofi’s financial position, indebtedness and liquidity;
- review of the work of the Internal Control function and evaluation of that work for 2019 as certified by the statutory auditors pursuant to Section 404 of the Sarbanes-Oxley Act, and examination of the 2019 Annual Report on Form 20-F;
- reporting on guarantees;
- the principal risks (risk management and risk profiles) facing Sanofi including a report of the Risk Committee, impairment testing of goodwill, a review of whistleblowing and material compliance investigations, a review of tax risks and deferred tax assets and changes in tax legislation, a review of material litigation, and an update on actuarial assumptions;
- conclusions of Sanofi senior management on internal control procedures, the Board of Directors’ Report on Corporate Governance and Management Report, and the description of risk factors contained in the French-language *Document d'enregistrement universel* and the Annual Report on form 20-F for 2019;

- the internal audit plan;
- assessment of fulfilment of the performance conditions of the 2017 equity-based compensation plans;
- update on restructuring and similar costs, and on non-GAAP financial measures
- update on cyber-security;
- update on intellectual property strategy;
- internal audit report for 2020, and audit program for 2021;
- update on the data protection compliance program;
- update on supply chain continuity;
- update on pension plans and actuarial assumptions;
- presentation on ethics and business integrity;
- presentation of the 2021 budget; and
- statutory audit engagement and audit fees, budget for non-audit services (audit-related services, tax, and other services), and update on the renewal of statutory auditor appointments.

The Committee did not use external consultants in 2020.

Compensation Committee

All three members of the Compensation Committee are deemed to be independent.

The Compensation Committee met three times in 2020, with all members having an attendance rate of 100%.

When the Committee discusses the compensation policy for members of senior management who are not corporate officers, i.e. the members of the Executive Committee, the Committee invites the Chief Executive Officer to attend.

In 2020, the main activities of the Compensation Committee related to:

- components of the compensation of executive officers (Chief Executive Officer and Chairman of the Board), in particular variable compensation for 2019 and the top-up pension arrangements for Olivier Brandicourt;
- review of the performance criteria applicable to annual variable compensation (inclusion of two new financial criteria from 2020 onwards);
- monitoring of the 2019 and 2020 fixed and variable compensation of Executive Committee members;
- allocating the amount of directors' compensation for 2019, and consideration of the maximum amount of directors' compensation and of the principles for allocating such compensation between the directors from 2020 onwards;
- review of the disclosures about compensation contained in the corporate governance section of the 2019 French-language *Document d'enregistrement universel* and the Annual Report on form 20-F, and of equal pay ratios;
- review of the equity-based compensation policy (consisting of performance share awards), including a consideration of the free cash flow (FCF) criterion that led to the trigger point for that criterion being increased;
- implementation of equity-based compensation plans awarded in previous years (determining the attainment levels for performance conditions in the 2017 plans);
- review of arrangements for applying the new "say on pay" requirements, including draft resolutions submitted to the shareholders at the Annual General Meeting of April 28, 2020 and an analysis of votes cast at that meeting, in particular the rejection of Resolution 19 relating to the ex post vote on the components of Olivier Brandicourt's 2019 compensation;
- consideration of the next employee share ownership plan, and implementation of the "Action 2020" plan; and
- the governance roadshow campaign targeted at the main investors in Sanofi, and an analysis of the policies adopted by proxy advisors;

The Committee used external consultants in 2020.

Appointments, Governance and CSR Committee

All three members of the Committee are deemed to be independent.

The Committee met five times in 2020, with all members having an attendance rate of 100%.

In 2020, the main activities of the Appointments, Governance and CSR Committee related to:

- succession planning for the Chairman and the Chief Executive Officer, and changes to the Executive Committee in line with the new strategy implemented by the Chief Executive Officer;
- summary of the 2019 Board evaluation (conducted under the direction of the Committee), and implementation of the 2020 evaluation of the work of the Board and its Committees;
- review of the Board of Directors' Management Report, and the corporate governance section of the 2019 French-language *Document d'enregistrement universel* and the Annual Report on Form 20-F;

- changes in the composition of the Board and its Committees, director independence, proposed reappointments of directors, and recruitment of three new directors;
- issues relating to trends in the gender balance on Sanofi's executive bodies;
- review of the CSR policies of Sanofi and its principal competitors, and consideration of new orientations and specifically the commitment to showing leadership in health care;
- revisions to the Board Charter; and
- the governance roadshow campaign targeted at the main investors in Sanofi, and an analysis of the policies adopted by proxy advisors.

The Committee used external consultants in 2020.

Strategy Committee

Two of the four members of the Strategy Committee are deemed to be independent: Serge Weinberg and Patrick Kron.

The Strategy Committee met six times in 2020.

The Committee members had an exemplary attendance record, with all members having an attendance rate of 100%.

The main activities of the Strategy Committee related to:

- update on digital matters;
- divestment and acquisition proposals, business development priorities;
- Delivery on the Play to Win strategy;
- Sanofi's ambitions in France; and
- opportunities for alliances.

The Committee did not use external consultants in 2020.

Scientific Committee

The Scientific Committee has four members, and its main roles are:

- to assist the Board in scrutinizing the strategic orientation and investments proposed by senior management from a scientific standpoint;
- to identify and discuss emerging trends and new challenges in science and technology, and ensure that Sanofi is as well prepared as possible to meet those challenges;
- to ensure that processes are in place to enable optimal decision-making on investments in R&D, consistent with the strategy determined by the Board; and
- to review and evaluate the quality of Sanofi's scientific expertise, and advise the Board accordingly.

The Committee met five times in 2020. All of its members attended along with the Chief Executive Officer, global support function managers and other Sanofi employees. The Committee members had an exemplary attendance record, with all members having an attendance rate of 100%.

The main activities of the Committee in 2020 related to:

- update on rare diseases
- the proposed acquisition of Principia Biopharma, Inc.;
- our gene therapy strategy;
- preparation of the R&D presentation for investors on June 23, 2020;
- our oncology strategy;
- update on COVID-19 vaccine candidates;
- immuno-inflammatory diseases; and
- our R&D pipeline.

The Committee did not use external consultants in 2020.

Attendance rate of Board members

Director	Attendance rate at Board meetings	Attendance rate at Committee meetings	Overall attendance rate
Serge Weinberg, Chairman of the Board	100%	100%	100%
Paul Hudson, Chief Executive Officer	100%	100%	100%
Laurent Attal	100%	100%	100%
Emmanuel Babeau[(c)]	100%	100%	100%
Christophe Babule	93%	100%[(a)]	80%
Bernard Charlès	100%	—	100%
Claudie Haigneré[(c)]	100%	100%	100%
Rachel Duan	100%	—	100%
Lise Kingo	89%	—	89%
Patrick Kron	100%	100%	100%
Fabienne Lecorvaisier	100%	100%	100%
Melanie Lee	100%	100%	100%
Suet-Fern Lee[(c)]	100%	—	100%
Marion Palme	71%	—	71%
Carole Piwnica	100%	100%	100%
Christian Senectaire	100%	—	100%
Gilles Schnepp	100%	67%[(b)]	84%
Diane Souza	100%	100%	100%
Thomas Südhof	100%	100%	100%

Average attendance rate at Board and Committee meetings	Average attendance rate at Board meetings	Average attendance rate at Committee meetings
98%	98%	97%

(a) Christophe Babule joined the Audit Committee in October 2020 and attended two meetings during 2020.
(b) Gilles Schnepp joined the Audit Committee in May 2020 and attended two of the three meetings held after his appointment.
(c) Emmanuel Babeau, Claudie Haigneré and Suet-Fern Lee all left the Board during 2020.

Directors who were absent from some meetings provided clear and substantiated explanations for their absence, which related mainly to personal matters or to unscheduled meetings called at short notice (especially where sudden developments on an ongoing project necessitated a Board meeting). The Board pays particular attention to the availability of directors, and makes sure that their other professional commitments do not prevent them from fully discharging their remit with respect to the Company.

D. Employees

Number of Employees

In 2020, Sanofi employed 99,412 people worldwide, 997 fewer than in 2019. The tables below give a breakdown of employees by geographic area and function as of December 31, 2020, 2019 and 2018.

Employees by Geographical Area

	As of December 31,					
	2020	%	2019	%	2018	%
Europe	46,761	47.0 %	46,236	46,0 %	46,256	44.4 %
United States	12,972	13.0 %	12,592	12.5 %	13,434	12.9 %
Rest of the World	39,679	39,9 %	41,581	41,4 %	44.536	42.7 %
Total	**99,412**	**100.0 %**	**100,409**	**100.0 %**	**104,226**	**100.0 %**

Employees by Function

	As of December 31,			
	2020	2019	2018	2017
Sales Force	25,203	26,178	28,914	30,284
Research and Development	15,446	15,538	15,140	14,764
Production	37,935	37,873	38,790	40,417
Marketing and Support Functions	20,828	20,820	21,382	21,101
Total	**99,412**	**100,409**	**104,226**	**106,566**

Industrial Relations

In all countries where we operate, we seek to strike a balance between our economic interests and those of our employees, which we regard as inseparable.

Our responsibility towards our employees is based on the basic principles of our Social Charter, which outlines the rights and duties of all Sanofi employees. The Social Charter addresses our key commitments towards our workforce: equal opportunity for all people without discrimination, the right to health and safety, respect for privacy, the right to information and professional training, social protection for employees and their families, freedom of association and the right to collective bargaining, and respect for the principles contained in the Global Compact on labor relations and ILO treaties governing the physical and emotional well-being and safety of children.

Our labor relations are based on respect and dialogue. In this spirit, management and employee representatives meet regularly to exchange views, negotiate, sign agreements and ensure that agreements are being implemented.

Employee dialogue takes place in different ways from country to country, as dictated by specific local circumstances. Depending on the circumstances, employee dialogue relating to information, consultation and negotiation processes may take place at national, regional or company level. It may be organized on an interprofessional or sectorial basis, or both. Employee dialogue may be informal or implemented through a specific formal body, or a combination of both methods. Whatever the situation, Sanofi encourages employees to voice their opinions, help create a stimulating work environment and take part in decisions aiming to improve the way we work. These efforts reflect one of the principles of the Social Charter, whereby improving working conditions and the necessary adaptation to our business environment go hand-in-hand.

Profit-sharing Schemes, Employee Savings Schemes and Employee Share Ownership

Profit-sharing Schemes

All employees of our French companies belong to voluntary and statutory profit-sharing schemes.

Voluntary Schemes

Voluntary schemes (*intéressement des salariés*) are collective schemes that are optional for the employer and contingent upon performance. The aim is to give employees an interest in the growth of the business and improvements in its performance.

The amount distributed by our French companies during 2020 in respect of voluntary profit-sharing for the year ended December 31, 2019 represented 4.67% of total payroll.

In April 2020, we entered into a new fixed-term statutory profit-sharing agreement for the 2020, 2021 and 2022 financial years, which applies to all employees of our French companies. Under the agreement, Sanofi pays collective variable compensation determined on the basis of the more favorable of (i) growth in consolidated net sales (at constant exchange rates and on a constant structure basis) or (ii) the ratio of our business operating income to net sales, expressed as a percentage (BOI margin). For each of those criteria, a matrix determines what percentage of total payroll is to be allocated to the scheme. An additional sum may be distributed, based on a CSR-related performance condition reflecting progress in environmental matters (reduction in greenhouse gas emissions) and capped at 0.5% of total payroll.

This overall allocation is reduced by the amount required by law to be transferred to a special profit-sharing reserve. The balance is then distributed between the employees unless the transfer to the reserve equals or exceeds the maximum amount determined under the specified criteria, in which case no profit share is paid to the employees.

Statutory Scheme

The statutory scheme (p*articipation des salaries aux résultats de l'entreprise*) is a French legal obligation for companies with more than 50 employees that made a profit in the previous financial year.

The amount distributed by our French companies during 2020 in respect of the statutory scheme for the year ended December 31, 2019 represented 4.92% of total payroll.

Distribution Formula

In order to favor lower-paid employees, the voluntary and statutory profit-sharing agreements entered into since 2005 split the benefit between those entitled as follows:

- 60% prorated on the basis of time spent in the Company's employment in the year; and
- 40% prorated on the basis of gross annual salary received during the year, subject to a lower limit equal to the social security ceiling and an upper limit of three times the social security ceiling.

Employee Savings Schemes and Collective Retirement Savings Plan

The employee savings arrangements operated by Sanofi are based on a collective savings scheme (*Plan d'Épargne Groupe*) and a collective retirement savings scheme (*Plan d'Épargne pour la Retraite Collectif*). Those schemes reinvest the sums derived from the statutory and voluntary profit-sharing schemes, plus voluntary contributions from employees.

In June 2020, 93.46% of the employees who benefited from the profit-sharing schemes opted to invest in the collective savings scheme, and nearly 83% opted to invest in the collective retirement savings scheme.

Sanofi supplements the amount invested by employees in these schemes by making a top-up contribution.

In 2020, €123 million and €61.1 million were invested in the collective savings scheme and the collective retirement savings scheme respectively through the voluntary and statutory schemes for 2019, and through top-up contributions.

Employee Share Ownership

As of December 31, 2020, shares held under the collective savings scheme by employees of Sanofi, employees of related companies and former employees amounted to 1.81% of our share capital.

For more information about our most recent employee share ownership plan, refer to “Item 10. Additional Information — Changes in Share Capital — Increases in Share Capital”.

E. Share Ownership

Senior Management

Members of the Executive Committee hold shares of our Company amounting in the aggregate to less than 1% of our share capital.

In 2020, 55,510 stock options were exercised by individuals who were Executive Committee members at the time of exercise.

All of the plans involved post-date the creation of the Executive Committee: Sanofi-Aventis plan of March 9, 2011, exercise price €50.48; Sanofi plan of March 5, 2012, exercise price €56.44; and Sanofi plan of March 5, 2013, exercise price €72.19.

Existing Option Plans as of December 31, 2020

In 2019, the Board of Directors reviewed Sanofi’s compensation policy and decided that stock options would no longer be awarded in or after 2020. That decision was taken to standardize the terms of equity-based compensation awards within Sanofi, and in response to feedback from some shareholders and proxy advisors who have concerns about stock options given their dilutive effect and potential unintended consequences.

Share Purchase Option Plans

As of December 31, 2020 there were no stock purchase option plans outstanding.

Share Subscription Option Plans

Source	Date of shareholder authorization	Date of grant	Total number of options granted	to corporate officers[a]	to the 10 employees awarded the most options[b]	Start date of exercise period	Expiry date	Exercise price (€)	Number of shares subscribed as of 12/31/2020	Number of options canceled as of 12/31/2020[c]	Number of options outstanding
Sanofi-aventis	04/17/2009	03/01/2010	7,316,355	—	665,000	03/03/2014	02/28/2020	54.12	6,346,325	970,030	—
Sanofi-aventis	04/17/2009	03/01/2010	805,000	275,000	805,000	03/03/2014	02/28/2020	54.12	755,000	50,000	—
Sanofi-aventis	04/17/2009	03/09/2011	574,500	—	395,000	03/10/2015	03/09/2021	50.48	506,598	35,454	32,448
Sanofi-aventis	04/17/2009	03/09/2011	300,000	300,000	—	03/10/2015	03/09/2021	50.48	292,200	7,800	—
Sanofi	05/06/2011	03/05/2012	574,050	—	274,500	03/06/2016	03/05/2022	56.44	304,240	95,943	173,867
Sanofi	05/06/2011	03/05/2012	240,000	240,000	—	03/06/2016	03/05/2022	56.44	204,720	35,280	—
Sanofi	05/06/2011	03/05/2013	548,725	—	261,000	03/06/2017	03/05/2023	72.19	235,324	109,065	204,336
Sanofi	05/06/2011	03/05/2013	240,000	240,000	—	03/06/2017	03/05/2023	72.19	—	64,080	175,920
Sanofi	05/03/2013	03/05/2014	769,250	—	364,500	03/06/2018	03/05/2024	73.48	225,800	102,625	440,825
Sanofi	05/03/2013	03/05/2014	240,000	240,000	—	03/06/2018	03/05/2024	73.48	—	46,560	193,440
Sanofi	05/03/2013	06/24/2015	12,500	—	12,500	06/25/2019	06/24/2025	89.38	—	8,500	4,000
Sanofi	05/03/2013	06/24/2015	202,500	—	202,500	06/25/2019	06/24/2025	89.38	45,000	—	157,500
Sanofi	05/03/2013	06/24/2015	220,000	220,000	—	06/25/2019	06/24/2025	89.38	—	41,536	178,464
Sanofi	05/04/2016	05/04/2016	17,750	—	17,750	05/05/2020	05/04/2026	75.90	—	9,750	8,000
Sanofi	05/04/2016	05/04/2016	165,000	—	165,000	05/05/2020	05/04/2026	75.90	67,500	—	97,500
Sanofi	05/04/2016	05/04/2016	220,000	220,000	—	05/05/2020	05/04/2026	75.90	—	41,250	178,750
Sanofi	05/10/2017	05/10/2017	158,040	—	157,140	05/11/2021	05/10/2027	88.97	—	41,250	116,790
Sanofi	05/10/2017	05/10/2017	220,000	220,000	—	05/11/2021	05/10/2027	88.97	—	42,570	177,430
Sanofi	05/02/2018	05/02/2018	220,000	220,000	—	05/03/2022	05/03/2028	65.84	—	—	220,000
Sanofi	04/30/2019	04/30/2019	220,000	220,000	—	05/01/2023	04/30/2029	76.71	—	—	220,000

(a) Comprises the Chief Executive Officer, and any Deputy Chief Executive Officers or members of the Management Board in office at the date of grant.
(b) In office at the date of grant.
(c) Includes 338,996 options cancelled due to partial non-fulfilment of performance conditions.

As of December 31, 2020, a total of 2,579,270 stock subscription options remained outstanding. As of the same date, 1,845,050 options were immediately exercisable.

The main characteristics of our stock options are also described in Note D.15.8. to our consolidated financial statements, included in Item 18. of this annual report.

Existing Performance Share Plans as of December 31, 2020

The Board of Directors awards shares to certain employees in order to give them a direct stake in our future and performances via trends in the share price, as a partial substitute for the granting of stock options.

Shares are awarded to employees by the Board of Directors on the basis of a list submitted to the Compensation Committee. The Board of Directors sets terms of the awards, including continuing employment conditions and performance conditions (measured over three financial years).

The employee plans have a three-year vesting period, with no lock-up period.

At its meeting of April 28, 2020, the Board of Directors awarded a share performance plan, cascaded down into five sub-plans:

- a France plan under which 91 beneficiaries classified as “Senior Executives” were awarded a total of 328,113 shares;
- a France plan under which 2,224 beneficiaries not classified as “Senior Executives” were awarded a total of 753,720 shares;
- an International plan under which 97 beneficiaries classified as “Senior Executives” were awarded a total of 400,495 shares;
- an International plan under which 4,774 beneficiaries classified as “Senior Executives” were awarded a total of 1,783,173 shares; and
- a plan under which 75,000 performance shares were awarded to the Chief Executive Officer.

Of the 7,187 beneficiaries, 46% were women.

At its meeting of October 28, 2020, the Board of Directors awarded a share performance plan under which 10 beneficiaries classified as “Senior Executives” were awarded a total of 73,027 shares.

Of the 10 beneficiaries, 30% were women.

The entirety of those awards is contingent upon criteria based on business net income (BNI) and free cash flow (FCF); in the case of employees classified as “Senior Executives”, an additional criterion based on total shareholder return (TSR) is added, accounting for 20% of the total. Vesting is subject to a non-compete clause.

The number of shares awarded to the Chief Executive Officer in 2020 represents 0.4% of the total limit approved by our shareholders at the Annual General Meeting of April 30, 2019 (1.5% of our share capital); 0.006% of our share capital at the date of grant; and 2.20% of the total amount awarded to all beneficiaries.

The 2020 awards represent a dilution of approximately 0.27% of our undiluted share capital as of December 31, 2020.

Not all of our employees were awarded performance shares, but a new voluntary profit-sharing agreement was signed in April 2020 which gives all of our employees an interest in Sanofi’s performance (for more details refer to “- Profit-Sharing Schemes, Employee Savings Schemes and Employee Share Ownership”, above).

Performance Share Plans

Source	Date of shareholder authorization	Date of award	Total number of shares awarded	to corporate officers[a]	to the 10 employees awarded the most shares[b]	Start date of vesting period[c]	Vesting date	End of lock-up period	Number of shares vested as of 12/31/2020	Number of rights canceled as of 12/31/2020[d]	Number of shares not yet vested
Sanofi	05/04/16	05/10/17	1,174,270	—	150,363	05/10/17	05/11/20	05/11/20	1,092,734	81,536	—
Sanofi	05/04/16	05/10/17	2,363,195	—	155,203	05/10/17	05/11/20	05/11/20	1,944,013	419,192	—
Sanofi	05/04/16	05/10/17	50,000	50,000	—	05/10/17	05/11/20	05/11/20	40,325	9,675	—
Sanofi	05/04/16	05/02/18	1,513,074	—	144,372	05/02/18	05/03/21	05/03/21	350	66,162	1,446,562
Sanofi	05/04/16	05/02/18	2,827,142	—	272,447	05/02/18	05/03/21	05/03/21	1,899	534,175	2 291 068
Sanofi	05/04/16	05/02/18	50,000	50,000	—	05/02/18	05/03/21	05/03/21	—	—	50,000
Sanofi	05/04/16	07/30/18	141,669	—	39,874	07/30/18	07/31/21	07/31/21	—	42,962	98,707
Sanofi	04/30/19	04/30/19	50,000	50,000	—	04/30/19	05/01/22	05/02/22	—	—	50,000
Sanofi	04/30/19	04/30/19	1,243,434	—	142,541	04/30/19	05/01/22	05/02/22	326	18 514	1,224,594
Sanofi	04/30/19	04/30/19	2,504,148	—	219,990	04/30/19	05/01/22	05/02/22	—	403,025	2,101,123
Sanofi	04/30/19	04/28/20	75,000	75,000	—	04/28/20	05/01/23	05/02/23	—	—	75,000
Sanofi	04/30/19	04/28/20	328,113	—	120,951	04/28/20	05/01/23	05/02/23	—	1,485	326,628
Sanofi	04/30/19	04/28/20	400,495	—	151,761	04/28/20	05/01/23	05/02/23	—	36,950	363,545
Sanofi	04/30/19	04/28/20	753,720	—	19,027	04/28/20	05/01/23	05/02/23	—	5,772	747,948
Sanofi	04/30/19	04/28/20	1,783,173	—	26,542	04/28/20	05/01/23	05/02/23	—	84,763	1,698,410
Sanofi	04/30/19	10/28/20	73,027	—	73,027	10/28/20	10/29/23	10/30/23	—	—	73,027

(a) Comprises the Chairman & Chief Executive Officer, the Chief Executive Officer, and any Deputy Chief Executive Officers or members of the Management Board in office at the date of grant.

(b) In office at the date of grant.

(c) Subject to the conditions set.

(d) Includes 702,543 rights cancelled due to partial non-fulfilment of performance conditions.

As of December 31, 2020, 10,546,612 shares had not yet vested pending fulfilment of performance conditions.

The attainment levels and allocation rates for the most recent equity-based compensation plans are as follows:

	Attainment level			Allocation rate
	BNI	ROA	TSR	
May 4, 2016 plans	2016-2018: 102.5%	2016-2018: 1.2 percentage points above target	2016-2018: 0% (10th of 11)	2016-2018: 81.25% i.e. 178,750 stock options and 40,625 performance shares
May 10, 2017 plans	2017-2019: 101.3%	2017-2019: 0.29 of a percentage point above target	2017-2019: 0% (9th of 11)	2017-2019: 80.65% i.e. 177,430 stock options and 40,325 performance shares
May 2, 2018 plans	2018-2020: 100.7%	2018-2020: 0.25 of a percentage point below target	2018-2020: 0% (8th of 11)	2018-2020: 76.72% i.e. 168,784 stock options and 38,360 performance shares

During the year ended December 31, 2020, the ten employees (other than corporate officers) awarded the most shares were collectively awarded a total of 203,920 shares.

Shares Owned by Members of the Board of Directors

As of December 31, 2020, members of our Board of Directors held in the aggregate 19,298 shares, or under 1% of the share capital and of the voting rights, excluding the beneficial ownership of 118,227,307 shares held by L'Oréal as of such date which may be attributed to Laurent Attal or Christophe Babule (who disclaim beneficial ownership of such shares).

Transactions in Shares by Members of the Board of Directors and Equivalent Persons in 2020

As far as Sanofi is aware, transactions in our securities carried out during 2020 by (i) Board members, (ii) executives with the power to make management decisions affecting our future development and corporate strategy and (iii) persons with close personal ties to such individuals (as per Article L. 621-18-2 of the French Monetary and Financial Code), were as follows:

- on June 22, 2020, Gilles Schnepp (director) purchased 1,000 shares at a price of €95.15 per share;
- on November 12, 2020, Lise Kingo (director) purchased 1,000 shares at a price of €85.204 per share; and
- on November 18, 2020, Rachel Duan (director) purchased 1,000 shares at an average price of €85.594 per share.

Item 7. Major Shareholders and Related Party Transactions

A. Major Shareholders

The table below shows the ownership of our shares as of January 31, 2021, indicating the beneficial owners of our shares. To the best of our knowledge and on the basis of the notifications received as disclosed below, except for L'Oréal and BlackRock, Inc., no other shareholder currently holds more than 5% of our share capital or voting rights.

	Total number of issued shares		Number of actual voting rights (excluding treasury shares)[(d)]		Theoretical number of voting rights (including treasury shares)[(e)]	
	Number	%	Number	%	Number	%
L'Oréal	118,227,307	9.39	236,454,614	16.85	236,454,614	16.73
BlackRock[(a)]	87,594,110	6.96	87,594,110	6.24	87,594,110	6.20
Employees[(b)]	22,686,564	1.80	42,007,079	2.99	42,007,079	2.97
Public	1,020,424,003	81.05	1,037,628,540	73.92	1,037,628,540	73.39
Treasury shares[(c)]	10,039,754	0.80	—	—	10,039,754	0.71
Total	**1,258,971,738**	**100**	**1,403,684,343**	**100**	**1,413,724,097**	**100**

(a) Based on BlackRock's declaration dated January 26, 2021.
(b) Shares held via the Sanofi Group Employee Savings Plan.
(c) Number of shares repurchased as of January 31, 2021 under the share repurchase program in force.
(d) Based on the total number of voting rights as of January 31, 2021.
(e) Based on the total number of voting rights as of January 31, 2021 as published in accordance with article 223-11 and seq. of the General Regulations of the Autorité des marchés financiers (i.e. including treasury shares, the voting rights of which are suspended).

Our Articles of Association provide for double voting rights for shares held in registered form for at least two years. All of our shareholders may benefit from double voting rights if these conditions are met, and no shareholder benefits from specific voting rights. For more information relating to our shares, see "Item 10. Additional Information — B. Memorandum and Articles of Association."

Neither L'Oréal nor BlackRock holds different voting rights from those of our other shareholders.

To the best of our knowledge, no other shareholder currently holds, directly or indirectly and acting alone or in concert, more than 5% of our share capital or voting rights. Furthermore, we believe that we are not directly or indirectly owned or controlled by another corporation or government, or by any other natural or legal persons. To our knowledge, there are no arrangements that may result in a change of control.

During the year ended December 31, 2020 we received several share ownership declarations informing us that a legal threshold had been passed, as required under Article L. 233-7 of the French Commercial Code.

La Caisse des dépôts et consignations ("CDC"), acting on its own behalf as well as on behalf of its affiliates, declared during 2020 that it had successively passed above and below the 5% threshold in terms of voting rights, and according to the last available data holds 1.99% of the share capital and 1.78% of the voting rights (October 6, 2020 declaration).

In addition to the statutory requirement to inform the Company and the *Autorité des marchés financiers* (AMF, the French Financial Markets Regulator) that they hold a number of shares (or of securities equivalent to shares or of voting rights pursuant to Article L. 233-9 of the French Commercial Code) representing more than one-twentieth (5%), one-tenth (10%), three-twentieths (15%), one-fifth (20%), one-quarter (25%), three-tenths (30%), one-third (1/3), one-half (50%), two-thirds (2/3), nine-tenths (90%) or nineteen-twentieths (95%) of the share capital or theoretical voting rights within four trading days after crossing any such ownership threshold (Article L. 233-7 of the French Commercial Code), any natural or legal person who directly or indirectly comes to hold a percentage of the share capital, voting rights or securities giving future access to the Company's capital that is equal to or greater than 1% or any multiple of that percentage, is obliged to inform the Company thereof by registered mail, return receipt requested, indicating the number of securities held, within five trading days following the date on which each of the thresholds was crossed.

If such declaration is not made, the shares in excess of the fraction that should have been declared will be stripped of voting rights at shareholders' meetings, if on the occasion of such meeting, the failure to declare has been formally noted and one or more shareholders collectively holding at least 5% of the Company's share capital or voting rights so request at that meeting.

Any natural or legal person is also required to inform the Company, in the forms and within the time limits stipulated above for passing above a specified threshold, if their direct or indirect holding passes below any of the aforementioned thresholds.

Since January 1, 2021 Sanofi has only received share ownership declarations of statutory threshold.

As of December 31, 2020, individual shareholders (including employees of Sanofi and its subsidiaries, as well as retired employees holding shares via the Sanofi Group Employee Savings Plan) held approximately 6.6% of our share capital. Institutional shareholders (excluding L'Oréal) held approximately 78% of our share capital. Such shareholders are primarily American (29.34%), French (15.10%) and British (13%). German institutions held 4.24% of our share capital, Swiss institutions held 2.10%, institutions from other European countries held 2.32% and Canadian institutions held 1.30% of our share capital. Other international institutional investors (excluding those from Europe and North America) held approximately 1.26% of our share capital. In France, our home country, we have

10,149 identified shareholders of record. In the United States, our host country, we have 54 identified shareholders of record and 17,146 identified ADS holders of record.

(Source: a survey conducted by Euroclear France as of December 31, 2020, and internal information).

Shareholders' Agreement

We are unaware of any shareholders' agreement currently in force.

B. Related Party Transactions

See Note D.33. to our consolidated financial statements included at Item 18. of this annual report.

C. Interests of Experts and Counsel

N/A

Item 8. Financial Information

A. Consolidated Financial Statements and Other Financial Information

Our consolidated financial statements as of and for the years ended December 31, 2020, 2019 and 2018 are included in this annual report at "Item 18. Financial Statements."

Dividends on Ordinary Shares

We paid annual dividends for the years ended December 31, 2016, 2017, 2018 and 2019 and our shareholders will be asked to approve the payment of an annual dividend of 3.20 per share for the 2020 fiscal year at our next annual shareholders' meeting. If approved, this dividend will be paid on May 7, 2021.

We expect that we will continue to pay regular dividends based on our financial condition and results of operations. The proposed 2020 dividend equates to a distribution of 54.6% of our business net income. For information on the non-GAAP financial measure "business earnings per share" see "Item 5. Operating and Financial Review and Prospects — Business Net Income."

The following table sets forth information with respect to the dividends paid by our Company in respect of the 2016, 2017, 2018 and 2019 fiscal years and the dividend that will be proposed for approval by our shareholders in respect of the 2020 fiscal year at our April 28, 2021 shareholders' meeting.

	2020 [(a)]	2019	2018	2017	2016
Dividend per Share (€)	3.20	3.15	3.07	3.03	2.96
Dividend per Share ($)[(b)]	3.91	3.53	3.52	3.63	3.12

(a) Proposal, subject to shareholder approval.
(b) Based on the relevant year-end exchange rate.

The declaration, amount and payment of any future dividends will be determined by majority vote of the holders of our shares at an ordinary general meeting, following the recommendation of our Board of Directors. Any declaration will depend on our results of operations, financial condition, cash requirements, future prospects and other factors deemed relevant by our shareholders. Accordingly, we cannot assure you that we will pay dividends in the future on a continuous and regular basis. Under French law, we are required to pay dividends approved by an ordinary general meeting of shareholders within nine months following the meeting at which they are approved.

Disclosure pursuant to Section 13(r) of the United States Exchange Act of 1934

Sanofi engages in limited business activities with Iran related to human health products – namely, sales of bulk and branded pharmaceuticals and vaccines . These activities, which are disclosed pursuant to Section 13(r) of the United States Exchange Act of 1934, as amended, are not financially material to Sanofi and contributed well under 1% of Sanofi's consolidated net sales in 2020.

Sanofi's US affiliates and non-US affiliates owned or controlled by Sanofi's US affiliates either do not engage in Iran-related activities or act under licenses issued by the US Department of the Treasury's Office of Foreign Assets Control (OFAC).

Sanofi and certain non-US Sanofi affiliates engage in limited business activities that neither are expressly authorized by OFAC nor require such authorization.

In 2016, Sanofi and the Iran Food and Drug Administration (IFDA), an entity affiliated with the Iranian Ministry of Health and Medical Education, signed a Memorandum of Cooperation (MOC) regarding: (i) potential future projects to reinforce current partnerships with reputable Iranian manufacturers (in particular, to enhance industrial quality standards); (ii) collaborating with the Ministry of Health and Medical Education on programs for the prevention and control of certain chronic and non-communicable diseases (in particular, diabetes); and (iii) potential future collaboration on epidemiological studies. In 2020, activities conducted under the MOC did not generate any revenue or net profits.

Certain non-US Sanofi affiliates engage in limited business with Iranian counterparties associated with the Iranian Ministry of Health, such as public hospitals or distributors. In 2020, those business activities generated approximately €12 million in gross revenue and contributed no more than €2.2 million in net profits.

In 2020, Sanofi learned that certain non-government-affiliated Iranian distributors with which a non-US affiliate was doing business have engaged in downstream sales or other dealings with entities (a wholesaler and a subcontractor) owned or controlled by persons whose property and interests in property are blocked pursuant to relevant US executive orders. Neither Sanofi nor its non-US affiliate had a direct financial relationship with their distributors' wholesaler or subcontractor, and, to Sanofi's knowledge, the downstream sales did not involve US-controlled products. At Sanofi's instruction, the distributors have ceased all dealings with the wholesaler and the contract with the subcontractor has been terminated.

Finally, a representative office in Tehran incurs incidental expenses from state-owned utilities.

Sanofi has determined that it and its affiliates' activities are compliant with applicable law, and in light of the nature of the activities concerned, Sanofi and its affiliates intend to continue their ongoing activities in Iran.

Information on Legal or Arbitration Proceedings

This Item 8. incorporates by reference the disclosures found in Note D.22. to the consolidated financial statements at Item 18. of this annual report; material updates thereto as of the date of this annual report are found below under the heading "- B. Significant Changes — Updates to Note D.22.".

Sanofi and its subsidiaries are involved in litigation, arbitration and other legal proceedings. These proceedings typically are related to product liability claims, intellectual property rights (particularly claims against generic companies seeking to limit the patent protection of Sanofi products), competition law and trade practices, commercial claims, employment and wrongful discharge claims, tax assessment claims, waste disposal and pollution claims, and claims under warranties or indemnification arrangements relating to business divestitures. As a result, we may become subject to substantial liabilities that may not be covered by insurance and could affect our business and reputation. While we do not currently believe that any of these legal proceedings will have a material adverse effect on our financial position, litigation is inherently unpredictable. As a consequence, we may in the future incur judgments or enter into settlements of claims that could have a material adverse effect on results of operations, cash flows and/or our reputation.

Patents

Lantus® Mylan Patent Litigation (United States)

In June 2017, Mylan Pharmaceuticals, Inc. filed petitions for *Inter Partes* Review (IPR) for US Patent Nos. 7,476,652 and 7,713,930 regarding Lantus® with the United States Patent Office Patent Trial and Appeal Board (PTAB). In these petitions, Mylan attacks the validity of all claims of these patents. In December 2017, the PTAB decided to move forward with Mylan's IPRs for these two patents. In December 2018, the PTAB issued a decision invalidating the claims of the two formulation patents. In November 2019, a panel of three judges of the United States Court of Appeals for the Federal Circuit issued a divided public ruling affirming the December 2018 PTAB decisions invalidating the Lantus® formulation patents. On January 28, 2020, our petition for rehearing by the full Federal Circuit was denied. In October 2020, the Supreme Court declined review of the November 2019 Federal Circuit ruling. In November 2020, the District of New Jersey entered final judgment of invalidity on these formulation patents. The proceedings concerning the formulation patents are now closed.

In October 2017, several Sanofi entities filed a patent infringement suit against Mylan N.V., Mylan GmbH, Mylan Inc., and Mylan Pharmaceuticals Inc. (collectively, "Mylan") in the United States District Courts for the District of New Jersey and Northern District of West Virginia. In its suits, Sanofi alleges infringement of several patents. The suits were triggered by a notification received from Mylan in mid-September 2017, in which Mylan stated that it had filed an 505(b)(2) NDA with the FDA for insulin glargine drug pen and vial products. Mylan also stated that its NDA included a paragraph IV certification challenging all of the Sanofi patents then listed in the FDA Orange Book for Sanofi's Lantus® and Lantus® SoloSTAR® products. These suits resulted in a 30-month stay during which the FDA could not approve Mylan's NDA. The 30-month stay is no longer in place for either Mylan's pen or vial products. In February 2018, the West Virginia case was dismissed and the parties proceeded only with the New Jersey lawsuit. Biocon Ltd., Biocon Research Ltd., Biocon SDN.BHD., and Biocon S.A., were added to the New Jersey lawsuit in July 2018. In December 2019, trial took place in the New Jersey District Court concerning the infringement of US Patent No. 9,526,844 by Mylan's pen product, as well as this patent's validity. On March 10, 2020, the New Jersey District Court ruled in Mylan's favor, finding the asserted claims of US Patent No. 9,526,844 invalid and not infringed by Mylan's pen product. Sanofi has appealed to the US Court of Appeals for the Federal Circuit, and the appeal is underway. Mylan received FDA approval in June 2020 and launched its non-interchangeable pen and vial products in August 2020.

In September 2018, Mylan filed 10 petitions asking the PTAB to commence IPR proceedings of US Patent Nos. 8,603,044, 8,679,069, 8,992,486, 9,526,844, and 9,604,008, challenging the validity of certain claims of these Sanofi patents. The PTAB decided to move forward with nine of the 10 IPR proceedings concerning these five patents. Pfizer Inc. joined eight of these nine IPRs, and filed a separate IPR concerning US Patent No. 8,679,069. Administrative rulings on the validity of these patents were issued by the PTAB in April, May and August of 2020. The PTAB ruled that two claims of US 9,604,008 are valid and that the rest of the challenged claims are invalid. Sanofi has appealed the adverse PTAB decisions to the Federal Circuit, and Mylan and Pfizer have cross-appealed the decision that was adverse to them. On January 11, 2021, Sanofi settled with Pfizer concerning its involvement in these matters. The appeals with Mylan are underway.

In October 2019, Mylan filed two petitions asking the PTAB to commence IPR proceedings of US Patent No. RE47,614, challenging the validity of the claims of this Sanofi patent. The PTAB decided to move forward and examine the validity of the claims of this patent in one of these two IPRs in April 2020. A written decision on the validity of this patent is expected in April 2021.

Cerdelga® Patent Litigation (United States)

Cerdelga® is covered by six Orange Book listed patents US 6,916,802, US 7,196,205, US 7,253,185, US 7,615,573, US 10,888,544 and US 10,888,547. In the fourth quarter of 2018, six different generic manufacturers each separately notified Sanofi-Genzyme that they had filed ANDA applications for Cerdelga® with Paragraph IV certifications challenging the US '802, '205, '185 and/or '573 patents. Sanofi-Genzyme filed suit against each ANDA filer within 45 days of receipt of each notification in the US District Court for the District of Delaware. The associated 30-month stay of FDA approval on each ANDA is expected to expire on the earlier of (i) February 19, 2022 or (ii) a court decision in favor of the generic manufacturer(s). Sanofi-Genzyme has settled with four of the defendants (Cipla Limited; Zenara Pharma Private Limited; Teva Pharmaceuticals USA, Inc.; Dr. Reddy's Laboratories, Ltd.). A trial is scheduled to begin in March 2021.

Government Investigations and Related Litigation

From time to time, subsidiaries of Sanofi are subject to governmental investigations and information requests from regulatory authorities inquiring as to the practices of Sanofi with respect to the sales, marketing, and promotion of its products.

In December 2013, Genzyme entered into a settlement agreement to resolve civil claims arising out of the investigation into promotional practices of Seprafilm® and paid in that respect approximately $23 million. As part of this settlement, and as part of the settlement entered into by Sanofi US in December 2012 relating to civil claims arising out of an investigation into sampling of its former product Hyalgan® for which Sanofi US paid $109 million, the companies entered into a Corporate Integrity Agreement ("CIA") with the Office of the Inspector General of the United States Department of Health and Human Services in September 2015; the CIA expired in September 2020.

In January 2018, Sanofi US received a subpoena from the US Attorney's Office for the District of Massachusetts requesting documents and information relating to Sanofi US's relationship with non-profit organizations that provide assistance to patients taking Sanofi drugs and Sanofi US's patient assistance programs as well as documents and information relating to the sale and marketing of Aubagio® and Lemtrada®. On February 28, 2020, Sanofi US entered into a Civil Settlement with the United States Department of Justice, without admitting any wrongdoing, and agreed to pay approximately $11.85 million to resolve allegations regarding certain charitable donations Sanofi US made to an independent patient assistance foundation that assisted patients being treated for multiple sclerosis. In connection

with this settlement, Sanofi US also entered into a Corporate Integrity Agreement ("CIA") with the Office of the Inspector General for the United States Department of Health and Human Services effective the same day which will require the Company to continue certain compliance requirements in the US through 2025. This settlement concludes the US Government investigation initiated in 2018.

In June 2016, the United States declined to intervene in a False Claims Act action filed in Federal Court in New Jersey regarding the sale and marketing of and variability of response to Plavix®. The relator appealed the dismissal of the complaint. The Third Circuit Court of Appeals reversed the dismissal in September 2020 and remanded to the trial court in New Jersey for further proceedings. Sanofi US is also defending a State Attorney General action in New Mexico concerning the sale and marketing of Plavix®. The trial court's denial of Sanofi's motion to dismiss was affirmed by the New Mexico Supreme Court. Sanofi filed a petition for a writ of certiorari with the US Supreme Court. This petition was denied in January 2021, and this case is now proceeding in the state courts of New Mexico.

In April 2018, after federal and state governments declined to intervene, a lawsuit was unsealed in the US District Court for the Southern District of New York, alleging violations of the False Claims Act and 29 state-law analogs by Sanofi US and other manufacturers and pharmacy benefit managers (or PBM) defendants. The Court dismissed the case in July 2019, and the relator filed a notice of appeal in September 2019. On December 1, 2020, the Second Circuit issued a summary order affirming the District Court's dismissal of the complaint, and the relator has until April 30, 2021 to file a writ of certiorari at the Supreme Court.

From 2017 through 2020, several government agencies have issued Civil Investigative Demands (CIDs) or other discovery requests calling for the production of documents and information relating to Sanofi's trade and pricing practices for its insulin products and/or Lantus®-related litigation. Sanofi US is cooperating with each of the following investigations, none of which has been closed:

- Washington State Attorney General's office (CID issued in March 2017, covering the period from 2005 to the present);
- California State Attorney General's office (issued first set of interrogatories in April 2018 covering the period from 2009 to the present; document requests in February 2020, covering the period from 2014 to the present; investigative examination subpoena in June 2020, covering the period 2014 to the present; and second set of interrogatories in September 2020, covering the period from 2014 to the present);
- New York State Attorney General's office (document subpoena issued in July 2019, covering the period from 2013 to the present);
- Colorado State Attorney General's office (CID issued in December 2019, covering the period from 2010 to the present);
- Vermont State Attorney General's office (CID issued in December 2020, covering the period from 2011 to the present); and
- Mississippi State Attorney General's office (document subpoena issued in December 2020).

In September 2019, Sanofi US received a CID from the US Department of Justice concerning Dupixent®, Kevzara®, Praluent® and Zaltrap®. The CID requests documents and information relating to Sanofi US's payments made to healthcare providers. Sanofi US is cooperating with this investigation.

In February 2020, Genzyme Corporation received a CID from the US Department of Justice. The CID requests documents and information relating to Genzyme Corporation's payments made to vendors or developers of electronic health record technology. Genzyme Corporation is cooperating with this investigation.

Following the September 2018 civil settlement with the US SEC fully resolving the SEC's investigation into possible violation of the US FCPA, Sanofi agreed to a two-year period of self-reporting on the effectiveness of its enhanced internal controls which ended in January 2021.

Sanofi is currently involved in a number of matters relating to the 340B Drug Pricing Program in the United States. In two of those matters, one filed in October 2020 in the United States District Court for the District of Columbia, and one in December 2020 in the US District Court for the Northern District of California, certain 340B Covered Entities and advocacy groups filed lawsuits against the US Department of Health and Human Services ("HHS"), its Secretary, its agency the Health Resources and Services Administration ("HRSA"), and HRSA's administrator alleging that the 340B statute requires drug manufactures, like Sanofi, to supply Contract Pharmacies with drugs discounted under the 340B Program and prohibits manufacturers from imposing conditions on the provision of such drugs to Contract Pharmacies. Plaintiffs seek, in these actions, to have the defendant agencies and their officials enforce plaintiffs' interpretation of the 340B statute. Sanofi, along with certain other drug manufacturers, have filed a motion to intervene in these lawsuits. The lawsuit pending in the District of Columbia is currently stayed and the lawsuit pending in the Northern District of California was recently dismissed without prejudice. An advocacy group, on behalf of a number of Covered Entities, has also filed an Administrative Dispute Resolution (ADR) proceeding before HRSA against Sanofi and two other drug manufacturers seeking to require the named manufacturers to supply Contract Pharmacies with drugs discounted under the 340B Program without imposing conditions. In February 2021, the Vermont Attorney General issued a Civil Investigative Subpoena seeking certain information about Sanofi's 340B program participation.

In addition to these matters, in January 2021, Sanofi filed a lawsuit against HHS, its Secretary, its General Counsel, HRSA, and HRSA's administrator in the US District Court for the District of New Jersey. Sanofi's lawsuit challenges: (i) under the Administrative Procedure Act, an Advisory Opinion issued by the HHS Office of General Counsel on December 30, 2020, which concludes that drug manufacturers are legally obligated to provide drugs discounted under the 340B program to Contract Pharmacies and that drug manufacturers may not impose conditions on the provision of such drugs to Contract Pharmacies; and (ii) under the United States Constitution and the Administrative Procedure Act, an ADR Rule, issued by HHS on December 10, 2020, which establishes certain procedures for disputes between Covered Entities and drug manufacturers participating in the 340B Program. Sanofi is seeking a preliminary injunction in this matter in connection with its constitutional claims to enjoin defendants from implementing, enforcing, or otherwise giving effect to the ADR Rules in any administrative proceeding.

Insulin Related Litigation

In December 2016 and January 2017, two putative class actions were filed against Sanofi US and Sanofi GmbH in the US Federal Court in Massachusetts on behalf of direct purchasers of Lantus® alleging certain antitrust violations. In January 2018, the Court dismissed Plaintiffs' complaint against Sanofi. Plaintiffs appealed that order to the Court of Appeals for the First Circuit, which issued its decision on February 13, 2020 reversing and remanding to the district court. Discovery is underway.

There are several litigation matters pending in the United States that have been filed against Sanofi US (and other insulin manufacturers) regarding, as concerns Sanofi US, the pricing of Lantus®, Apidra®, and Toujeo®. The suits allege some combination of: violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO Act"); violations of various state unfair/deceptive trade practices statutes, violations of federal antitrust laws, unjust enrichment, common-law fraud, and civil conspiracy. The status of these matters is as follows:

- *In re Insulin Pricing* (Federal District Court of New Jersey, filed in 2017 on behalf of a putative class of diabetes patients):
  - the parties commenced discovery in September 2019;
- *MSP Recovery Claims, Series LLC* (Federal District Court of New Jersey, filed in 2018 on behalf of Medicare Secondary Payors):
  - the parties commenced discovery in November 2020;
- *State of Minnesota vs. Sanofi US et al* (Federal District Court of New Jersey, filed in 2018):
  - defendants' partial Motion to Dismiss the Second Amended Complaint is pending; the parties commenced discovery in July 2020;
- *In re Direct Purchaser Insulin Pricing Litigation* (Federal District Court of New Jersey, filed in 2020 by FWK Holdings, LLC and Professional Drug Company):
  - named defendants are insulin manufacturers as well as the top three Pharmacy Benefit Managers (PBMs) and related entities,
  - defendants' Motions to Dismiss will be fully briefed and awaiting resolution by May 2021;
- *Commonwealth of Kentucky vs. Sanofi US et al* (Kentucky State Court, filed in 2019):
  - in January 2020, the Court denied the Defendants' motion to dismiss. Discovery has yet to commence;
- *Harris County, Texas vs. Sanofi US et al* (Federal Southern District Court of Texas, filed in 2019):
  - named defendants are insulin manufacturers as well as the top three Pharmacy Benefit Managers (PBMs) and related entities,
  - defendants' partial Motion to Dismiss the Second Amended Complaint is pending.

B. Significant Changes

Updates to Note D.22.

Plavix® (clopidogrel) – Attorney General Action in Hawaii

In February 2021, the Court issued its decision, imposing penalties in the total amount of $834,012,000 against both Sanofi and BMS, with $417,006,000 being apportioned to each company. Sanofi and BMS are appealing the decision.

Praluent® (alirocumab)-related Amgen Patent Litigation in the US

In February 2021, the Court of Appeals for the Federal Circuit affirmed the District Court's ruling invalidating the remaining Amgen asserted patent claims. Amgen has until mid-March 2021 to seek further review by the Federal Circuit and until mid-July 2021 to seek US Supreme Court review.

Other Changes

On January 11, 2021, Sanofi and Kymab, a clinical-stage biopharmaceutical company developing fully human monoclonal antibodies with a focus on immune-mediated diseases and immuno-oncology therapeutics, announced that they had entered into an agreement under which Sanofi will acquire Kymab for an upfront payment of approximately $1.1 billion and up to $350 million upon achievement of certain milestones. The transaction will result in Sanofi having full global rights to KY1005, a fully human monoclonal antibody that has a novel mechanism of action. KY1005 binds to OX40-Ligand and has the potential to treat a wide variety of immune-mediated diseases and inflammatory disorders. Sanofi plans to finance the transaction with cash on hand. The closing of the transaction is subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 and other customary closing conditions. Sanofi expects to complete the acquisition in the first half of 2021.

On January 12, 2021, Sanofi unveiled EUROAPI as the name of the new industry-leading European company dedicated to the development, production and marketing of active pharmaceutical ingredients (API). Sanofi also announced the appointment of Karl Rotthier as the future Chief Executive Officer of EUROAPI effective January 18, 2020. Karl Rotthier, aged 53, is a seasoned leader with strong API business experience. He was most recently Chief Executive Officer of Centrient Pharmaceuticals. During a 29-year international career in the Netherlands, Germany, Austria, Belgium and Singapore, he has successfully driven a number of operational carve-outs and spin-offs. Karl will lead the creation of EUROAPI, working with the new company's management team to help EUROAPI deliver on its goals. An IPO on Euronext Paris is envisaged by 2022, subject to market conditions.

On January 27, 2021, Sanofi and BioNTech entered into an agreement under which Sanofi will support manufacturing and supply of BioNTech's COVID-19 vaccine, which is being co-developed with Pfizer. Sanofi will provide BioNTech access to its established infrastructure and expertise to produce over 125 million doses of COVID-19 vaccine in Europe. Initial supplies will originate from Sanofi's production facilities in Frankfurt from summer of 2021.

On February 5, 2021, at the Capital Markets Day, Sanofi announced that the development of venglustat in Parkinson's Disease had been halted following the MOVES-PD Phase II study readout. The study did not meet the primary or secondary efficacy endpoints.

On February 9, 2021, the US Food and Drug Administration (FDA) approved the PD-1 inhibitor Libtayo® (cemiplimab-rwlc) as the first immunotherapy indicated for patients with advanced basal cell carcinoma (BCC) previously treated with a hedgehog pathway inhibitor

(HHI) or for whom an HHI is not appropriate. Full approval was granted for patients with locally advanced BCC and accelerated approval was granted for patients with metastatic BCC.

On February 12, 2021, Sanofi announced an all-cash offer to all holders of Kiadis shares, to acquire their shares at an offer price of €5.45 (cum dividend) in cash. The Acceptance Period commenced on February 15, 2021, and unless extended will expire on April 12, 2021. Completion of the offer is currently expected in the second quarter of 2021.

On February 12, 2021, The Lancet published Libtayo® (cemiplimab) data showing extended overall survival in patients with first-line advanced non-small cell lung cancer with PD-L1 expression of ≥50%

On February 22, 2021, Sanofi and GSK announced the initiation of a new Phase II study with 720 volunteers aged 18 and over to select the most appropriate antigen dosage for Phase III evaluation of their adjuvanted recombinant protein COVID-19 vaccine candidate. In parallel to the new Phase II study and recognizing the global emergence of new SARS-CoV-2 variants and their potential impact on vaccine efficacy, Sanofi has commenced development work against new variants, which will be used to inform next stages of the Sanofi/GSK development program.

On February 22, 2021, the US FDA approved the PD-1 inhibitor Libtayo® (cemiplimab-rwlc) for the first-line treatment of patients with advanced non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression (tumor proportion score ≥50%), as determined by an FDA-approved test.

At its meeting on March 3, 2021, the Board of Directors decided to ask the forthcoming Annual General Meeting of shareholders, to be held on April 30, 2021, to approve the appointment of two new Directors, Christian Brandts and Barbara Lavernos; to ratify the co-opting of Gilles Schnepp as a director; and to renew the terms of office of Fabienne Lecorvaisier and Melanie Lee as directors. Bernard Charlès, whose term of office expires at the end of the forthcoming Annual General Meeting, is not seeking reappointment as a director in order to avoid potential conflicts of interest that might arise from the development of the partnership between Sanofi and Dassault Systèmes, of which he is an executive officer. Laurent Attal, after serving on the Sanofi Board of Directors for nine years, has declared his intention to retire and hence to resign from office as a director in advance of the Annual General Meeting.

Christian Brandts is currently Director at the University Cancer Center Frankfurt. In addition to his duties, Christian Brandts is pursuing his research activities, focused mainly on translational cancer research and personalized oncology. He is part of several national and international networks of oncology experts and is a member of the Board of the Organisation of European Cancer Institutes (OECI). Christian Brandts graduated from the Medical School of the Free University of Berlin, and then specialized in Internal Medicine and Hematology/Oncology at the Charité University Hospital in Berlin and the University Hospital in Münster.

Barbara Lavernos took over in February 2021 as President Research, Innovation and Technologies of the L'Oréal Group, having spent her entire career at L'Oréal, which she joined in 1991. In 2004, she was appointed Global Chief Procurement Officer at L'Oréal, and in 2012 as General Manager of Travel Retail. In 2014, she was appointed Chief Operating Officer and became a member of the L'Oréal group Executive Committee. Since the end of 2018, she has headed up the group's IT teams, with a mission to lead the tech transformation of L'Oréal. Barbara Lavernos is a graduate of the *Ecole des Hautes Etudes d'Ingénieur en génie chimique* (School of Advanced Studies in Chemical Engineering – HEI) in Lille, France.

On March 4, 2021, the US FDA accepted for review the supplemental Biologics License Application (sBLA) for Dupixent® (dupilumab) as an add-on treatment for children aged 6 to 11 years with uncontrolled moderate-to-severe asthma. Dupixent® is currently approved as an add-on treatment for patients with uncontrolled moderate-to-severe asthma aged 12 and older with elevated eosinophils or oral corticosteroid dependent asthma. The target action date for the FDA decision is October 21, 2021 and the EU regulatory submission for children aged 6 to 11 years with asthma is planned for the first quarter of 2021.

Item 9. The Offer and Listing

A. Offer and Listing Details

We have one class of shares. Each American Depositary Share, or ADS, represents one-half of one share. The ADSs are evidenced by American Depositary Receipts, or ADRs, which are issued by JPMorgan Chase Bank, N.A.

Our shares trade on Compartment A of the regulated market of Euronext Paris, and our ADSs trade on the Nasdaq Global Select Market, or Nasdaq.

B. Plan of Distribution

N/A

C. Markets

Shares and ADSs

Our shares are listed on Euronext Paris under the symbol “SAN” and our ADSs are listed on the Nasdaq under the symbol “SNY”.

As of the date of this annual report, our shares are included in a large number of indices, including the “CAC 40 Index”, the principal French index published by Euronext Paris. This index contains 40 stocks selected among the top 100 companies based on free-float capitalization and the most active stocks listed on the Euronext Paris market. The CAC 40 Index indicates trends in the French stock market as a whole and is one of the most widely followed stock price indices in France. Our shares are also included in the S&P Global 100 Index, the Dow Jones Euro STOXX 50, the Dow Jones STOXX 50, the FTS Eurofirst 100, the FTS Eurofirst 80 and the MSCI Pan-Euro Index, among other indices.

Trading by Sanofi in our own Shares

Under French law, a company may not issue shares to itself, but it may purchase its own shares in the limited cases described at “Item 10. Additional Information — B. Memorandum and Articles of Association — Trading in Our Own Shares.”

D. Selling Shareholders

N/A

E. Dilution

N/A

F. Expenses of the Issue

N/A

Item 10. Additional Information

A. Share Capital

N/A

B. Memorandum and Articles of Association

General

Our Company is a *société anonyme*, a form of limited liability company, organized under the laws of France. The LEI number of the Company is 549300E9PC51EN656011.

In this section, we summarize material information concerning our share capital, together with material provisions of applicable French law and our Articles of Association (*statuts*), an English translation of which has been filed as an exhibit to this annual report. For a description of certain provisions of our Articles of Association relating to our Board of Directors and statutory auditors, see "Item 6. Directors, Senior Management and Employees." You may obtain copies of our Articles of Association in French from the *greffe* (Clerk) of the *Registre du Commerce et des Sociétés de Paris* (Registry of Commerce and Companies of Paris, France, registration number: 395 030 844). Please refer to that full document for additional details.

Our Articles of Association specify that our corporate affairs are governed by:

- applicable laws and regulations (in particular, Title II of the French Commercial Code); and
- the Articles of Association themselves.

Article 3 of our Articles of Association specifies that the Company's corporate purpose, in France and abroad, is:

- acquiring interests and holdings, in any form whatsoever, in any company or enterprise, in existence or to be created, connected directly or indirectly with the health and fine chemistry sectors, human and animal therapeutics, nutrition and bio-industry;

in the following areas:

- purchase and sale of all raw materials and products necessary for these activities;
- research, study and development of new products, techniques and processes;
- manufacture and sale of all chemical, biological, dietary and hygienic products;
- obtaining or acquiring all intellectual property rights related to results obtained and, in particular, filing all patents, trademarks and models, processes or inventions;
- operating directly or indirectly, purchasing, and transferring – for free or for consideration – pledging or securing all intellectual property rights, particularly all patents, trademarks and models, processes or inventions;
- obtaining, operating, holding and granting all licenses;
- within the framework of a group-wide policy and subject to compliance with the relevant legislation, participating in treasury management transactions, whether as lead company or otherwise, in the form of centralized currency risk management or intra-group netting, or any other form permitted under the relevant laws and regulations;

and, more generally:

- all commercial, industrial, real or personal property, financial or other transactions, connected directly or indirectly, totally or partially, with the activities described above and with all similar or related activities and even with any other purposes likely to encourage or develop the Company's activities.

Directors

Transactions in which directors are materially interested

Under French law, any agreement entered into (directly or through an intermediary) between our Company and any one of the members of the Board of Directors that is not entered into (i) in the ordinary course of our business and (ii) under normal conditions, is subject to the prior authorization of the disinterested members of the Board of Directors. The same provision applies to agreements between our Company and another company if one of the members of the Board of Directors is the owner, general partner, manager, director, general manager or member of the executive or supervisory board of the other company, as well as to agreements in which one of the members of the Board of Directors has an indirect interest.

The Board of Directors must also authorize any undertaking taken by our Company for the benefit of our Chairman, Chief Executive Officer (*directeur général*) or his delegates (*directeurs généraux délégués*) pursuant to which such persons will or may be granted compensation, benefits or any other advantages as a result of the termination of or a change in their offices or following such termination or change.

In addition, except with respect to any non-compete indemnity or certain pension benefits, any such termination package: (i) must be authorized by our shareholders through the adoption of a separate general shareholders meeting resolution for each such beneficiary, which authorization must be renewed at each renewal of such beneficiary's mandate, and (ii) cannot be paid to such beneficiary unless (a) the Board of Directors decides that such beneficiary has satisfied certain conditions, linked to such beneficiary's performance measured by our Company's performance, that must have been defined by the Board of Directors when granting such package, and (b) such decision is publicly disclosed.

Directors' compensation

The aggregate amount of attendance fees (*jetons de présence*) of the Board of Directors is determined at the Shareholders' Ordinary General Meeting. The Board of Directors then divides this aggregate amount among its members by a simple majority vote. In addition, the Board of Directors may grant exceptional compensation (*rémunérations exceptionnelles*) to individual directors on a case-by-case basis for special assignments following the procedures described above at "- Transactions in which directors are materially Interested." The Board of Directors may also authorize the reimbursement of travel and accommodation expenses, as well as other expenses incurred by Directors in the corporate interest. See also "Item 6. Directors, Senior Management and Employees."

Board of Directors' borrowing powers

All loans or borrowings on behalf of the Company may be decided by the Board of Directors within the limits, if any, imposed by the Shareholders' Extraordinary General Meeting. There are currently no limits imposed on the amounts of loans or borrowings that the Board of Directors may approve.

Directors' age limits

For a description of the provisions of our Articles of Association relating to age limits applicable to our Directors, see "Item 6. Directors, Senior Management and Employees."

Directors' share ownership requirements

Pursuant to the Board Charter, our Directors must within no more than two years from their appointment hold at least 1,000 Sanofi shares in their own name, which must be retained until they cease to hold office.

Share Capital

As of December 31, 2020, our share capital amounted to €2,517,943,476, divided into 1,258,971,738 outstanding shares with a par value of €2 per share. All of our outstanding shares are of the same class and are fully paid. Of these shares, we or entities controlled by us held 8,281,185 shares (or 0.66% of our outstanding share capital), as treasury shares as of such date. As of December 31, 2020, the carrying amount of such shares was €694 million.

At a combined general meeting held on April 30, 2019, our shareholders authorized our Board of Directors to increase our share capital, through the issuance of shares or other securities giving access to the share capital with or without preemptive rights, by an aggregate maximum nominal amount of €997 million. See "- Changes in Share Capital — Increases in Share Capital," below.

The maximum total number of authorized but unissued shares as of December 31, 2020 was 133.13 million, reflecting the unused part of the April 30, 2019 shareholder authorizations to issue shares without preemptive rights, outstanding options to subscribe for shares, and awards of shares.

Stock Options

Types of stock options

We have two types of stock options outstanding: options to subscribe for shares (*options de souscription d'actions*) and options to purchase shares (*options d'achat d'actions*). Upon exercise of an option to subscribe for shares, we issue new shares, whereas upon exercise of an option to purchase shares, the option holder receives existing shares. We purchase our shares on the market prior to the vesting of the options to purchase in order to provide the option holder with shares upon exercise.

Because the exercise of options to purchase shares will be satisfied with existing shares repurchased on the market or held in treasury, the exercise of options to purchase shares has no impact on the amount of our share capital.

Stock option plans

Our combined general meeting held on April 30, 2019 authorized our Board of Directors for a period of 38 months to grant, on one or more occasions, options to subscribe for shares and options to purchase shares in favor of persons to be chosen by the Board of Directors from among the salaried employees and corporate officers of our Company or of companies or groupings of economic interest of the Group in accordance with Article L. 225-180 of the French Commercial Code.

The aggregate number of options to subscribe for shares and options to purchase shares that may be granted under this authorization may not give entitlement to a total number of shares exceeding 0.5% of the share capital as of the date of the decision by the Board of Directors to grant such options.

The Board of Directors sets the exercise price of options to subscribe for shares and options to purchase shares. However, the exercise price never incorporates a discount and must be at least equal (i) in the case of a grant of options to subscribe for shares, to the average of the quoted market prices of Sanofi's shares on the 20 trading sessions preceding the date of grant by the Board of Directors and (ii) in the case of a grant of options to purchase shares, either (a) the price indicated in (i) or (b) the average purchase price of shares held by Sanofi under Articles L. 225-208 and L. 225-209 of the French Commercial Code.

Stock option plans generally provide for a lock-up period of four years and have a duration of ten years.

Under such authorization the shareholders expressly waive, in favor of the grantees of options to subscribe for shares, their preemptive rights in respect of shares that are to be issued as and when options are exercised.

The Board of Directors is granted full power to implement this authorization and to set the terms and conditions on which options are granted and the arrangements with respect to the dividend entitlement of the shares.

See "Item 6. Directors, Senior Management and Employees — E. Share Ownership" for a description of our option plans currently in force.

Awards of Shares

Our combined general meeting held on April 30, 2019 authorized our Board of Directors for a period of 38 months to allot, on one or more occasions, existing or new restricted shares in favor of persons to be chosen by the Board of Directors from among the salaried employees and corporate officers of our Company or of companies or economic interest groupings of the Group in accordance with Articles L. 225-197-1 et seq. of the French Commercial Code.

The existing or new shares allotted under this authorization may not represent more than 1.5% of our share capital as of the date of the decision by the Board of Directors to allot such shares.

The authorization provides that allotment of shares to the allottees will become irrevocable at the end of a minimum vesting period of three years.

In the case of newly issued shares, the authorization entails the express waiver by the shareholders, in favor of the allottees of restricted shares, of their preemptive rights in respect of shares that are to be issued as and when restricted shares vest.

The Board of Directors sets the terms on which restricted shares are granted and the arrangements with respect to the dividend entitlement of the shares.

See “Item 6. Directors, Senior Management and Employees — E. Share Ownership” for a description of our restricted shares plans currently in force.

Changes in Share Capital in 2020

See Note D.15.1. to our consolidated financial statements included at Item 18 of this annual report.

Voting Rights

In general, each shareholder is entitled to one vote per share at any shareholders’ general meeting. Our Articles of Association do not provide for cumulative voting rights. However, our Articles of Association provide that any fully paid-up shares that have been held in registered form under the name of the same shareholder for at least two years acquire double voting rights. The double voting rights cease automatically for any share converted into bearer form or transferred from one owner to another, subject to certain exceptions permitted by law.

As of December 31, 2020, there were 154,766,438 shares that were entitled to double voting rights, representing 12.3% of our total share capital, and approximately 22.02% of the voting rights which can be cast at our shareholders’ general meeting as of that date.

Double voting rights are not taken into account in determining whether a quorum exists.

Under the French Commercial Code, treasury shares or shares held by entities controlled by that company are not entitled to voting rights and do not count for quorum purposes.

Our Articles of Association allow us to obtain from Euroclear France the name, nationality, address and number of shares held by holders of our securities that have, or may in the future have, voting rights. If we have reason to believe that a person on any list provided by Euroclear France holds securities on behalf of another person, our Articles of Association allow us to request information regarding beneficial ownership directly from such person. See “- B. Memorandum and Articles of Association — Form, Holding and Transfer of Shares,” below.

Our Articles of Association provide that Board members are elected on a rolling basis for a maximum tenure of four years.

Shareholders’ Agreement

We are not aware of any shareholder’s agreement currently in force concerning our shares.

Shareholders’ Meetings

General

In accordance with the provisions of the French Commercial Code, there are three types of shareholders’ meetings: ordinary, extraordinary and special.

Ordinary general meetings of shareholders are required for matters such as:

- electing, replacing and removing Directors;
- appointing independent auditors;
- approving the annual financial statements;
- declaring dividends or authorizing dividends to be paid in shares, provided the Articles of Association contain a provision to that effect; and
- approving share repurchase programs.

Extraordinary general meetings of shareholders are required for approval of matters such as amendments to our Articles of Association, including any amendment required in connection with extraordinary corporate actions. Extraordinary corporate actions include:

- changing our Company’s name or corporate purpose;
- increasing or decreasing our share capital;
- creating a new class of equity securities;
- authorizing the issuance of:

– shares giving access to our share capital or giving the right to receive debt instruments, or

– other securities giving access to our share capital;

- establishing any other rights to equity securities;
- selling or transferring substantially all of our assets; and
- the voluntary liquidation of our Company.

Special meetings of shareholders of a certain category of shares or shares with certain specific rights (such as shares with double voting rights) are required for any modification of the rights derived from that category of shares. The resolutions of the shareholders' general meeting affecting these rights are effective only after approval by the relevant special meeting.

Annual ordinary meetings

The French Commercial Code requires the Board of Directors to convene an annual ordinary general shareholders' meeting to approve the annual financial statements. This meeting must be held within six months of the end of each fiscal year. This period may be extended by an order of the President of the Commercial Court. -Article 4 of Order No. 2020-321 of March 25, 2020, Adapting the Rules for Meetings and Deliberations of the Meetings and Governing Bodies of French Legal Entities and Entities without Legal Personality under Private Law due to the COVID-19 Epidemic, as amended by Article 2 of Order No. 2020-1497 of December 2, 2020, provides that the Shareholders' Meeting may exceptionally be held ''behind closed doors'' without the shareholders and other persons entitled to attend being physically present. These provisions are applicable until April 1, 2021.

The Board of Directors may also convene an ordinary or extraordinary general shareholders' meeting upon proper notice at any time during the year. If the Board of Directors fails to convene a shareholders' meeting, our independent auditors may call the meeting. In case of bankruptcy, the liquidator or court-appointed agent may also call a shareholders' meeting in some instances. In addition, any of the following may request the court to appoint an agent for the purpose of calling a shareholders' meeting:

- one or several shareholders holding at least 5% of our share capital;
- duly qualified associations of shareholders who have held their shares in registered form for at least two years and who together hold at least 1% of our voting rights;
- the works council in cases of urgency; or
- any interested party in cases of urgency.

Notice of shareholders' meetings

All prior notice periods provided for below are minimum periods required by French law and cannot be shortened, except in case of a public tender offer for our shares.

We must announce general meetings at least thirty-five days in advance by means of a preliminary notice (*avis de réunion*), which is published in the *Bulletin des Annonces Légales Obligatoires*, or *BALO*. The preliminary notice must first be sent to the French Financial markets authority (*Autorité des marchés financiers*, the "AMF"), with an indication of the date on which it will be published in the *BALO*. It must be published on our website at least twenty-one days prior to the general meeting. The preliminary notice must contain, among other things, the agenda, a draft of the resolutions to be submitted to the shareholders for consideration at the general meeting and a detailed description of the voting procedures (proxy voting, electronic voting or voting by mail), the procedures permitting shareholders to submit additional resolutions or items to the agenda and to ask written questions to the Board of Directors. The AMF also recommends that, prior to or simultaneously with the publication of the preliminary notice, we publish a summary of the notice indicating the date, time and place of the meeting in a newspaper of national circulation in France and on our website.

At least fifteen days prior to the date set for a first convening, and at least ten days prior to any second convening, we must send a final notice (*avis de convocation*) containing the final agenda, the date, time and place of the meeting and other information related to the meeting. Such final notice must be sent by mail to all registered shareholders who have held shares in registered form for more than one month prior to the date of the final notice and by registered mail, if shareholders have asked for it and paid the corresponding charges. The final notice must also be published in a newspaper authorized to publish legal announcements in the local administrative department (*département*) in which our Company is registered as well as in the *BALO*, with prior notice having been given to the AMF for informational purposes. Even if there are no proposals for new resolutions or items to be submitted to the shareholders at the meeting, we must publish a final notice in a newspaper authorized to publish legal announcements in the local administrative department (*département*) in which our Company is registered as well as in the *BALO*.

Other issues

In general, shareholders can only take action at shareholders' meetings on matters listed on the agenda. As an exception to this rule, shareholders may take action with respect to the appointment and dismissal of directors even if this action has not been included on the agenda.

Additional resolutions to be submitted for approval by the shareholders at the shareholders' meeting may be proposed to the Board of Directors, for recommendation to the shareholders at any time from the publication of the preliminary notice in the *BALO* until twenty-five days prior to the general meeting and in any case no later than twenty days following the publication of the preliminary notice in the *BALO* by:

- one or several shareholders together holding a specified percentage of shares;
- a duly qualified association of shareholders who have held their shares in registered form for at least two years and who together hold at least 1% of our voting rights; or
- the works council.

Within the same period, the shareholders may also propose additional items (*points*) to be submitted and discussed during the shareholders' meeting, without a shareholders' vote. The shareholders must substantiate the reasons for their proposals of additional items.

The resolutions and the list of items added to the agenda of the shareholders' meeting must be promptly published on our website.

The Board of Directors must submit the resolutions to a vote of the shareholders after having made a recommendation thereon. The Board of Directors may also comment on the items that are submitted to the shareholders' meeting.

Following the date on which documents must be made available to the shareholders (including documents to be submitted to the shareholders' meeting and resolutions proposed by the Board of Directors, which must be published on our website at least twenty-one days prior to the general meeting), shareholders may submit written questions to the Board of Directors relating to the agenda for the meeting until the fourth business day prior to the general meeting. The Board of Directors must respond to these questions during the meeting or may refer to a Q&A section located on our website in which the question submitted by a shareholder has already been answered.

Attendance at Shareholders' Meetings; Proxies and Votes by Mail

In general, all shareholders may participate in general meetings either in person or by proxy. Shareholders may vote in person, by proxy or by mail.

The right of shareholders to participate in general meetings is subject to the recording (*inscription en compte*) of their shares on the second business day, zero hour (Paris time), preceding the general meeting:

- for holders of registered shares: in the registered shareholder account held by the Company or on its behalf by an agent appointed by it; and
- for holders of bearer shares: in the bearer shareholder account held by the accredited financial intermediary with whom such holders have deposited their shares; such financial intermediaries shall deliver to holders of bearer shares a shareholding certificate (*attestation de participation*) enabling them to participate in the general meeting.

Attendance in person

Any shareholder may attend ordinary general meetings and extraordinary general meetings and exercise its voting rights subject to the conditions specified in the French Commercial Code and our Articles of Association.

Proxies and votes by mail

Proxies are sent to any shareholder upon a request received between the publication of the final notice of meeting and six days before the general meeting and must be made available on our website at least twenty-one days before the general meeting. In order to be counted, such proxies must be received at our registered office, or at any other address indicated on the notice of the meeting or by any electronic mail indicated on the notice of the meeting, prior to the date of the meeting (in practice, we request that shareholders return proxies at least three business days prior to the meeting; electronic proxies must be returned before 3 p.m. Paris time, on the day prior to the general meeting). A shareholder may grant proxies to any natural person or legal entity. The agent may be required to disclose certain information to the shareholder or to the public.

Alternatively, the shareholder may send us a blank proxy without nominating any representative. In this case, the chairman of the meeting will vote the blank proxies in favor of all resolutions proposed or approved by the Board of Directors and against all others.

With respect to votes by mail, we must send shareholders a voting form upon request or must make available a voting form on our website at least twenty-one days before the general meeting. The completed form must be returned to us at least three days prior to the date of the shareholders' meeting. For holders of registered shares, in addition to traditional voting by mail, instructions may also be given via the internet.

Quorum

The French Commercial Code requires that shareholders holding in the aggregate at least 20% of the shares entitled to vote must be present in person, or vote by mail or by proxy, in order to fulfill the quorum requirement for:

- an ordinary general meeting; and
- an extraordinary general meeting where the only resolutions pertain to either (a) a proposed increase in our share capital through incorporation of reserves, profits or share premium, or (b) the potential issuance of free share warrants in the event of a public tender offer for our shares (Article L. 233-32 of the French Commercial Code).

For any other extraordinary general meeting the quorum requirement is at least 25% of the shares entitled to vote, held by shareholders present in person, voting by mail or by proxy.

For a special meeting of holders of a certain category of shares, the quorum requirement is one third of the shares entitled to vote in that category, held by shareholders present in person, voting by mail or by proxy.

If a quorum is not present at a meeting, the meeting is adjourned. However, only questions that were on the agenda of the adjourned meeting may be discussed and voted upon once the meeting resumes.

When an adjourned meeting is resumed, there is no quorum requirement for meetings cited in the first paragraph of this "Quorum" section. In the case of any other reconvened extraordinary general meeting or special meeting, the quorum requirement is 20% of the shares entitled to vote (or voting shares belonging to the relevant category for special meetings of holders of shares of such specific category), held by shareholders present in person or voting by mail or by proxy. If a quorum is not met, the reconvened meeting may be adjourned for a maximum of two months with the same quorum requirement. No deliberation or action by the shareholders may take place without a quorum.

Votes Required for Shareholder Action

The affirmative vote of a simple majority of the votes cast may pass a resolution at either an ordinary general meeting or an extraordinary general meeting where the only resolution(s) pertain(s) to either (a) a proposed increase in our share capital through incorporation of reserves, profits or share premium, or (b) the potential issuance of free share warrants in the event of a public tender offer for our shares (Article L. 233-32 of the French Commercial Code). At any other extraordinary general shareholders' meeting and at any special meeting of holders of a specific category of shares, the affirmative vote of two-thirds of the votes cast by those present or those represented by proxy or voting by mail is required.

As a result of a recent change in French law, as of the Annual General Meeting of April 28, 2020, abstention from voting, blank votes and null votes by those present or those represented by proxy or voting by mail are no longer counted as votes against the resolution submitted to a shareholder vote at any of the three types of meetings.

Changes to Shareholders' Rights

Under French law, the affirmative vote of two-thirds of the votes cast at an extraordinary shareholders' meeting is required to change our Articles of Association, which set out the rights attached to our shares, except for capital increases through incorporation of reserves, profits or share premium, or through the issuance of free share warrants in the event of a public tender offer for our shares (Article L. 233-32 of the French Commercial Code).

The rights of a class of shareholders can be amended only after a special meeting of the class of shareholders affected has taken place. The voting requirements applicable to this type of special meeting are the same as those applicable to an extraordinary general shareholders' meeting. The quorum requirements for a special meeting are one-third of the voting shares, or 20% upon resumption of an adjourned meeting.

A unanimous shareholders' vote is required to increase the liabilities of shareholders.

Financial Statements and Other Communications with Shareholders

In connection with any shareholders' meeting, we must provide a set of documents which includes our annual report.

We must also provide on our website at least twenty-one days before a shareholders' meeting certain information and a set of documents that includes the preliminary notice, the proxies and voting forms, the resolutions proposed by the Board of Directors, and the documents to be submitted to the shareholders' meeting pursuant to Articles L. 225-115 and R. 225-83 of the French Commercial Code, etc. The resolutions and the list of items added to the agenda of the shareholders' meeting must be promptly published on our website.

Dividends

We may only distribute dividends out of our "distributable profits," plus any amounts held in our reserves that the shareholders decide to make available for distribution, other than those reserves that are specifically required by law or our Articles of Association. "Distributable profits" consist of our unconsolidated net profit in each fiscal year, as increased or reduced by any profit or loss carried forward from prior years, less any contributions to the reserve accounts pursuant to law or our Articles of Association.

Legal reserve

The French Commercial Code requires us to allocate 5% of our unconsolidated net profit for each year to our legal reserve fund before dividends may be paid with respect to that year. Funds must be allocated until the amount in the legal reserve is equal to 10% of the aggregate par value of the issued and outstanding share capital. This restriction on the payment of dividends also applies to each of our French subsidiaries on an unconsolidated basis. At December 31, 2020, our legal reserve amounted to €282,280,863.40, representing 11.21% of the aggregate par value of our issued and outstanding share capital as of that date. The legal reserve of any company subject to this requirement may serve to allocate losses that may not be allocated to other reserves, or may be distributed to shareholders upon liquidation of the company.

Approval of dividends

According to the French Commercial Code, our Board of Directors may propose a dividend for approval by shareholders at the annual general shareholders' meeting. If we have earned distributable profits since the end of the preceding fiscal year, as reflected in an interim income statement certified by our independent auditors, our Board of Directors may distribute interim dividends to the extent of the distributable profits for the period covered by the interim income statement. Our Board of Directors exercises this authority subject to French law and regulations and may do so without obtaining shareholder approval.

Distribution of dividends

Dividends are distributed to shareholders pro rata according to their respective holdings of shares. In the case of interim dividends, distributions are made to shareholders on the date set by our Board of Directors during the meeting in which the distribution of interim dividends is approved. The actual dividend payment date is decided by the shareholders at an ordinary general shareholders' meeting or by our Board of Directors in the absence of such a decision by the shareholders. Shareholders that own shares on the actual payment date are entitled to the dividend.

Dividends may be paid in cash or, if the shareholders' meeting so decides, in kind, provided that all shareholders receive a whole number of assets of the same nature paid in lieu of cash. Our Articles of Association provide that, subject to a decision of the shareholders' meeting taken by ordinary resolution, each shareholder may be given the choice to receive his dividend in cash or in shares.

Timing of payment

According to the French Commercial Code, we must pay any existing dividends within nine months of the end of our fiscal year, unless otherwise authorized by court order. Dividends on shares that are not claimed within five years of the date of declared payment revert to the French State.

Changes in Share Capital

Increases in Share Capital

As provided for by the French Commercial Code, our share capital may be increased only with shareholders' approval at an extraordinary general shareholders' meeting following the recommendation of our Board of Directors. The shareholders may delegate to our Board of Directors either the authority *(délégation de compétence)* or the power *(délégation de pouvoir)* to carry out any increase in share capital. Our Board of Directors may further delegate this power to our Chief Executive Officer or, subject to our Chief Executive Officer's approval, to his delegates *(directeurs généraux délégués)*.

Increases in our share capital may be effected by:

- issuing additional shares;
- increasing the par value of existing shares;
- creating a new class of equity securities; or
- exercising the rights attached to securities giving access to the share capital.

Increases in share capital by issuing additional securities may be effected through one or a combination of the following:

- in consideration for cash;
- in consideration for assets contributed in kind;
- through an exchange offer;
- by conversion of previously issued debt instruments;
- by capitalization of profits, reserves or share premium; or
- subject to various conditions, in satisfaction of debt incurred by our Company.

Decisions to increase the share capital through the capitalization of reserves, profits and/or share premium or through the issuance of free share warrants in the event of a public tender offer for our shares (Article L. 233-32 of the French Commercial Code) require shareholders' approval at an extraordinary general shareholders' meeting, acting under the quorum and majority requirements applicable to ordinary shareholders' meetings. Increases effected by an increase in the par value of shares require unanimous approval of the shareholders, unless effected by capitalization of reserves, profits or share premium. All other capital increases require shareholders' approval at an extraordinary general shareholders' meeting acting under the regular quorum and majority requirements for such meetings. See "- Quorum" and "- Votes Required for Shareholder Action" above.

On April 30, 2019, our shareholders approved various resolutions delegating to the Board of Directors the authority to increase our share capital through the issuance of shares or securities giving access to the share capital, subject to an overall cap set at €997 million. This cap applies to all the resolutions whereby the extraordinary shareholders' meeting delegated to the Board of Directors the authority to increase the share capital, it being also specified that:

- the maximum aggregate par value of capital increases that may be carried out with preemptive rights maintained was set at €997 million;
- the maximum aggregate par value of capital increases that may be carried out by public offering without preemptive rights was set at €240 million;
- the maximum aggregate par value of capital increases that may be carried out by private placement without preemptive rights was set at €240 million;
- capital increases resulting in the issuance of securities to members of employee savings plans are limited to 1% of the share capital as computed on the date of the Board of Directors' decision to issue such securities, and such issuances may be made at a discount of 30% (or 40%) if certain French law restrictions on resales were to apply, i.e. a lock up period of five years (or 10 years).

As of December 31, 2020, the shares held by the company's employees or by employees of affiliated companies, as well as former employees in the Group savings programs represented 1.81% of the share capital.

At its February 2020 meeting , our Board of Directors decided to delegate to the Chief Executive Officer the powers necessary to carry out a capital increase reserved for members of the Group savings program. Every employee subscribing for at least five shares received one additional new share as an employer's top-up contribution. Beyond the first twenty shares there was no entitlement to any further shares by way of employer's top-up contribution (every employee subscribing for twenty shares received four additional shares as an employer's top-up contribution). The subscription period was open during June 2020.

33,524 employees from nearly 70 countries subscribed for a total of 2,467,101 shares. Of these, 1,158,840 shares were subscribed via FCPE Actions Sanofi, the dedicated employee share ownership fund for employees of our French subsidiaries; 566,104 shares via FCPE Sanofi Shares, the dedicated employee share ownership fund for employees of our foreign subsidiaries; and 742,157 shares directly by employees who were eligible for the employee share ownership plan but were in countries where local regulations did not allow the use of a dedicated employee share ownership fund.

A total of 123 615 shares were issued by way of employer's top-up contribution. Of these, 49,859 were issued to FCPE Actions Sanofi; 35,941 to FCPE Sanofi Shares; and 37,815 directly to employees who were eligible for the employee share ownership plan but were in countries where local regulations did not allow the use of a dedicated employee share ownership fund.

Voting rights attached to shares held by FCPE Actions Sanofi are exercised individually by the employees who hold units in the fund; fractional rights are exercised by the fund's supervisory board.

Voting rights attached to shares held by FCPE Sanofi Shares are also exercised individually by the employees who hold units in the fund; any rights not exercised by them are exercised by the fund's supervisory board.

In each case, the supervisory board includes an equal number of representatives of employees and of Sanofi management.

On April 30, 2019, our shareholders approved resolutions delegating to the Board of Directors the authority to increase the share capital by granting options to our employees and/or corporate officers, subject to the overall cap mentioned above and under the following terms and conditions:

- the authorization is valid for a period of 38 months, and any options granted may not give entitlement to a total number of shares exceeding 0.5% of the share capital as computed on the date of the decision of the Board of Directors to grant such options; see "- Stock Options" above;

On April 30, 2019, our shareholders also approved resolutions delegating to the Board of Directors the authority to increase the share capital by granting existing or new restricted shares to our employees and/or corporate officers, subject to the overall cap mentioned above and under the following terms and conditions:

- the authorization is valid for a period of 38 months, and is subject to a limit of 1.5% of the share capital as computed on the date of the decision of the Board of Directors to allot such shares; see "- Awards of Shares" above.

See also "Item 6. Directors, Senior Management and Employees - E. Share Ownership".

Decreases in share capital

In accordance with the provisions of the French Commercial Code, any decrease in our share capital requires approval by the shareholders entitled to vote at an extraordinary general meeting. The share capital may be reduced either by decreasing the par value of the outstanding shares or by reducing the number of outstanding shares. The number of outstanding shares may be reduced either by an exchange of shares or by the repurchase and cancellation of shares. Holders of each class of shares must be treated equally unless each affected shareholder agrees otherwise.

In addition, specific rules exist to permit the cancellation of treasury shares, by which the shareholders' meeting may authorize the cancellation of up to a maximum of 10% of a company's share capital within any 24-month period. On April 30, 2019, our shareholders delegated to our Board of Directors for 26 months (i.e. until June 30, 2021) the right to reduce our share capital by canceling our own shares.

Preemptive Rights

According to the French Commercial Code, if we issue additional securities to be paid in cash, current shareholders will have preemptive rights to these securities on a pro rata basis. These preemptive rights require us to give priority treatment to current shareholders. The rights entitle the individual or entity that holds them to subscribe to the issuance of any securities that may increase the share capital of our Company by means of a cash payment or a set-off of cash debts. Preemptive rights are transferable during the subscription period relating to a particular offering. These rights may also be listed on Euronext Paris Stock Exchange.

Preemptive rights with respect to any particular offering may be waived by the affirmative vote of shareholders holding two-thirds of the shares entitled to vote at an extraordinary general meeting. Our Board of Directors and our independent auditors are required by French law to present reports that specifically address any proposal to waive preemptive rights. In the event of a waiver, the issuance of securities must be completed within the period prescribed by law. Shareholders may also notify us that they wish to waive their own preemptive rights with respect to any particular offering if they so choose.

The shareholders may decide at extraordinary general meetings to give the existing shareholders a non-transferable priority right to subscribe to the new securities, for a limited period of time.

In the event of a capital increase without preemptive rights to existing shareholders, French law requires that the capital increase be made at a price equal to or exceeding the weighted average market prices of the shares for the last three trading days on Euronext Paris Stock Exchange prior to the beginning of the public offering less 10%.

Form, Holding and Transfer of Shares

Form of shares

Our Articles of Association provide that the shares may be held in either bearer form or registered form at the option of the holder.

Holding of shares

In accordance with French law relating to the dematerialization of securities, shareholders' ownership rights are represented by book entries instead of share certificates. We maintain a share account with Euroclear France (a French clearing system, which holds securities for its participants) for all shares in registered form, which is administered by BNP Paribas Securities Services. In addition, we maintain separate accounts in the name of each shareholder either directly or, at a shareholder's request, through the shareholder's accredited intermediary. Each shareholder account shows the name of the holder and the number of shares held. BNP Paribas Securities Services issues confirmations (*attestations d'inscription en compte*) to each registered shareholder as to shares registered in the shareholder's account, but these confirmations are not documents of title.

Shares of a listed company may also be issued in bearer form. Shares held in bearer form are held and registered on the shareholder's behalf in an account maintained by an accredited financial intermediary and are credited to an account at Euroclear France maintained by such intermediary. Each accredited financial intermediary maintains a record of shares held through it and provides the account holder with a securities account statement. Transfers of shares held in bearer form may only be made through accredited financial intermediaries and Euroclear France.

Shares held by persons who are not domiciled in France may be registered in the name of intermediaries who act on behalf of one or more investors. When shares are so held, we are entitled to request from such intermediaries the names of the investors. Also, we may request

any legal entity (*personne morale*) which holds more than 2.5% of our shares or voting rights to disclose the name of any person who owns, directly or indirectly, more than one-third of its share capital or of its voting rights. A person not providing the complete requested information in time, or who provides incomplete or false information, will be deprived of its voting rights at shareholders' meetings and will have its payment of dividends withheld until it has provided the requested information in strict compliance with French law. If such person acted willfully, the person may be deprived by a French court of either its voting rights or its dividends or both for a period of up to five years.

Transfer of shares

Our Articles of Association do not contain any restrictions relating to the transfer of shares.

Registered shares must be converted into bearer form before being transferred on the Euronext Paris Stock Exchange on the shareholders' behalf and, accordingly, must be registered in an account maintained by an accredited financial intermediary on the shareholders' behalf. A shareholder may initiate a transfer by giving instructions to the relevant accredited financial intermediary.

A fee or commission is payable to the broker involved in the transaction, regardless of whether the transaction occurs within or outside France. Registration duty is currently payable in France if a written deed of sale and purchase (*acte*) is executed in France or outside France with respect to the shares of the Company.

Redemption of Shares

Under French law, our Board of Directors is entitled to redeem a set number of shares as authorized by the extraordinary shareholders' meeting. In the case of such an authorization, the shares redeemed must be cancelled within one month after the end of the offer to purchase such shares from shareholders. However, shares redeemed on the open market do not need to be cancelled if the company redeeming the shares grants options on or awards those shares to its employees within one year following the acquisition. See also "- Trading in Our Own Shares" below.

Sinking Fund Provisions

Our Articles of Association do not provide for any sinking fund provisions.

Liability to Further Capital Calls

Shareholders are liable for corporate liabilities only up to the par value of the shares they hold; they are not liable to further capital calls.

Liquidation Rights

If we are liquidated, any assets remaining after payment of our debts, liquidation expenses and all of our remaining obligations will first be distributed to repay in full the par value of our shares. Any surplus will be distributed pro rata among shareholders in proportion to the par value of their shareholdings.

Requirements for Holdings Exceeding Certain Percentages

The French Commercial Code provides that any individual or entity, acting alone or in concert with others, that becomes the owner, directly or indirectly, of more than 5%, 10%, 15%, 20%, 25%, 30%, $33^{1}/_{3}$%, 50%, $66^{2}/_{3}$%, 90% or 95% of the outstanding shares or voting rights of a listed company in France, such as our Company, or that increases or decreases its shareholding or voting rights above or below any of those percentages, must notify the company, before the end of the fourth trading day following the date it crosses the threshold, of the number of shares it holds and their voting rights. The individual or entity must also notify the AMF before the end of the fourth trading day following the date it crosses any such threshold. The AMF makes the notice public.

Pursuant to the French Commercial Code and the AMF General Regulation, the participation thresholds shall be calculated on the basis of the shares and voting rights owned, and shall take into account the shares and voting rights which are deemed to be shares and voting rights owned, even if the individual or entity does not itself hold shares or voting rights. In accordance with this deemed ownership principle, the individual or entity must take into account specific situations where shares and voting rights are deemed to be shares and voting rights owned when calculating the number of shares owned to be disclosed in the notifications to the Company and to the AMF. It includes among others situations where an individual or entity is entitled to acquire issued shares at its own initiative, immediately or at the end of a maturity period, under an agreement or a financial instrument, without set-off against the number of shares that this individual or entity is entitled to sell under another agreement or financial instrument. The individual or entity required to make such notification shall also take into account issued shares covered by an agreement or cash-settled financial instrument and having an economic effect for said individual or entity that is equivalent to owning such shares. In the cases of deemed ownership described above, the notification shall mention the type of deemed ownership and include a description of the main characteristics of the financial instrument or agreement with specific details required by the AMF General Regulation.

The AMF General Regulation provides that shares and voting rights subject to multiple cases of deemed ownership shall only be counted once.

When an individual or entity modifies the allocation between the shares it owns and its financial instruments or agreements deemed to be owned shares, it must disclose that change in a new notification. However, the change must only be disclosed if the acquisition of owned shares due to the settlement of the financial instruments or agreements causes the investor to cross a threshold.

Subject to certain limited exceptions, French law and AMF regulations impose additional reporting requirements on persons who acquire more than 10%, 15%, 20%, or 25% of the outstanding shares or voting rights of a company listed in France. These persons must file a report with the company and the AMF before the end of the fifth trading day following the date they cross any such threshold.

In the report, the acquirer will have to specify its intentions for the following six months including:

- whether it acts alone or in concert with others;
- the means of financing of the acquisition (the notifier shall indicate in particular whether the acquisition is being financed with equity or debt, the main features of that debt, and, where applicable, the main guarantees given or received by the notifier. The notifier shall also indicate what portion of its holding, if any, it obtained through securities loans);
- whether or not it intends to continue its purchases;
- whether or not it intends to acquire control of the company in question;
- the strategy it contemplates *vis-à-vis* the issuer;
- the way it intends to implement its strategy, including: (i) any plans for a merger, reorganization, liquidation, or partial transfer of a substantial part of the assets of the issuer or of any other entity it controls within the meaning of Article L. 233-3 of the French Commercial Code, (ii) any plans to modify the business of the issuer, (iii) any plans to modify articles of association of the issuer, (iv) any plans to delist a category of the issuer's financial instruments, and (v) any plans to issue the issuer's financial instruments;
- any agreement for the temporary transfer of shares or voting rights of the issuer;
- the way it intends to settle its agreements or instruments on the shares or voting rights of the issuer mentioned in Article L. 233- 9,4° and 4° bis of the French Commercial Code; and
- whether it seeks representation on the Board of Directors.

The AMF makes the report public. Upon any change of intention within the six-month period following the filing of the report, it will have to file a new report for the following six-month period.

In order to enable shareholders to give the required notice, we must each month publish on our website and send the AMF a written notice setting forth the total number of our shares and voting rights (including treasury shares) whenever they vary from the figures previously published.

If any shareholder fails to comply with an applicable legal notification requirement, the shares in excess of the relevant threshold will be deprived of voting rights for all shareholders' meetings until the end of a two-year period following the date on which the owner complies with the notification requirements. In addition, any shareholder who fails to comply with these requirements may have all or part of its voting rights suspended for up to five years by the Commercial Court at the request of our Chairman, any shareholder or the AMF, and may be subject to criminal fines.

Under AMF regulations, and subject to limited exemptions granted by the AMF, any person or entity, acting alone or in concert, that crosses the threshold of 30% of the share capital or voting rights of a French listed company must initiate a public tender offer for the balance of the shares and securities giving access to the share capital or voting rights of such company. Cash-settled derivative instruments or agreements mentioned in Article L. 233-9, 4° bis of the French Commercial Code are not included in the calculation of the number of shares related to the mandatory public tender offer.

In addition, our Articles of Association provide that any person or entity, acting alone or in concert with others, who becomes the owner of 1%, or any multiple of 1% of our share capital or our voting rights, even beyond the minimum declaration limits permitted by the legal and regulatory provisions, must notify us by certified mail, return receipt requested, within five trading days, of the total number of shares and securities giving access to our share capital and voting rights that such person then owns. The same provisions of our Articles of Association apply whenever such owner increases or decreases its ownership of our share capital or our voting rights to such extent that it goes above or below one of the thresholds described in the preceding sentence. Any person or entity that fails to comply with such notification requirement will, upon the request of one or more shareholders holding at least 5% of our share capital or of our voting rights made at the general shareholders' meeting, be deprived of voting rights with respect to the shares in excess of the relevant threshold for all shareholders' meetings until the end of a two-year period following the date on which such person or entity complies with the notification requirements.

Change in Control/Anti-Takeover

There are no provisions in our Articles of Association that would have the effect of delaying, deferring or preventing a change in control of our Company or that would operate only with respect to a merger, acquisition or corporate restructuring involving our Company or any of our subsidiaries. Further, there are no provisions in our Articles of Association that allow the issuance of preferred stock upon the occurrence of a takeover attempt or the addition of other "anti-takeover" measures without a shareholder vote.

Our Articles of Association do not include any provisions discriminating against any existing or prospective holder of our securities as a result of such shareholder owning a substantial number of shares.

See below additional information in relation to foreign direct investments under "- Ownership of Shares by Non-French Persons."

Trading in our Own Shares

Under French law, Sanofi may not issue shares to itself. However, we may, either directly or through a financial intermediary acting on our behalf, acquire up to 10% of our issued share capital within a maximum period of 18 months, provided our shares are listed on a regulated market. Prior to acquiring our shares, we must publish a description of the share repurchase program (*descriptif du programme de rachat d'actions*).

We may not cancel more than 10% of our issued share capital over any 24-month period. Our repurchase of shares must not result in our Company holding, directly or through a person acting on our behalf, more than 10% of our issued share capital. We must hold any shares that we repurchase in registered form. These shares must be fully paid up. Shares repurchased by us continue to be deemed "issued" under French law but are not entitled to dividends or voting rights so long as we hold them directly or indirectly, and we may not exercise the preemptive rights attached to them.

The shareholders, at an extraordinary general shareholders meeting, may decide not to take these shares into account in determining the preemptive rights attached to the other shares. However, if the shareholders decide to take them into account, we must either sell the rights attached to the shares we hold on the market before the end of the subscription period or distribute them to the other shareholders on a pro rata basis.

On April 28, 2020, our shareholders approved a resolution authorizing us to repurchase up to 10% of our shares over an 18-month period. Under this authorization, the purchase price for each Sanofi ordinary share may not be greater than €150.00 and the maximum amount that Sanofi may pay for the repurchases is €18,807,691,650. This authorization was granted for a period of 18 months from April 28, 2020 and cancelled and replaced the authorization granted to the Board of Directors by the combined general meeting held on April 30, 2019. A description of this share repurchase program as adopted by the ordinary general meeting held on April 28, 2020 (*descriptif du programme de rachat d'actions*) was published on March 5, 2020.

Purposes of Share Repurchase Programs

Under the European regulation 596/2014, dated April 16, 2014 on market abuse and its delegated regulation 2016/1052 on repurchase programs and stabilization measures, dated March 8, 2016 (which we refer to in this section as the "Regulation"), an issuer will benefit from a safe harbor for share transactions that comply with certain conditions relating in particular to the pricing, volume and timing of transactions (see below) and that are made in connection with a share repurchase program authorized by the shareholders the purpose of which is:

- to reduce the share capital through the cancellation of treasury shares;
- to meet obligations arising from debt financial instruments that are exchangeable into equity instruments; and/or
- to meet obligations arising from share option programs or other allocations of shares to employees or to members of the administrative, management or supervisory bodies of the issuer or of an associate company.

Safe harbor transactions will by definition not be considered market abuses under the Regulation. Transactions that are carried out for other purposes than those mentioned above do not qualify for the safe harbor.

However, as permitted by the Regulation, which provides for a presumption of legitimacy for existing market practices that do not constitute market manipulation and that conform with certain criteria, the AMF has established as a French accepted market practice, which therefore benefits from a presumption of legitimacy, the use of liquidity agreements for share purchases that are entered into with a financial services intermediary and that comply with the criteria set out by the AMF.

The AMF confirmed that all transactions directed at maintaining the liquidity of an issuer's shares must be conducted pursuant to a liquidity agreement with a financial services intermediary acting independently.

As of July 3, 2016, the purchase of shares that are subsequently used as acquisition currency in a business combination transaction, which the AMF previously permitted as an accepted market practice, is no longer considered as such, although such practice, while not benefiting from the presumption of legitimacy, is not prohibited under the Regulation.

Pricing, Volume and Other Restrictions

In order to qualify for the safe harbor described above, the issuer must generally comply with the following pricing and volume restrictions:

- a share purchase must not be made at a price higher than the higher of the price of the last independent trade and the highest current independent bid on the trading venues where the purchase is carried out; and
- subject to certain exceptions for illiquid securities, the issuer must not purchase on any trading day more than 25% of the average daily volume of the shares on the regulated market on which the purchase is carried out. The average daily volume figure must be based on the average daily volume traded in the month preceding the month of public disclosure of the share repurchase program and fixed on that basis for the authorized period of that program. If the program does not make reference to this volume, the average daily volume figure must be based on the average daily volume traded in the 20 trading days preceding the date of purchase.

In addition, unless the issuer has in place a time-scheduled repurchase program or the repurchase program is lead-managed by an investment firm or a credit institution which makes its trading decisions concerning the timing of the purchase of the issuer's shares independently of the issuer, the issuer must not, for the duration of the repurchase program, engage in the following activities:

- selling its own shares;
- effecting any transaction during a closed period imposed by the applicable law of the Member State in which the transaction occurs (i.e. under French law, during the period between the date on which the company has knowledge of insider information and the date on which such information is made public and during the 30 calendar day period before the announcement of an interim financial report or a year-end report which the issuer is obliged to make public); or
- effecting any transaction in securities with respect to which the issuer has decided to delay the public disclosure of inside information, in accordance with applicable rules.

Use of Share Repurchase Programs

Pursuant to the AMF rules, issuers must immediately allocate the repurchased shares to one of the purposes provided for in the Regulation and must not subsequently use the shares for a different purpose. As an exception to the foregoing, shares repurchased with a view to covering stock option plans may, if no longer needed for this purpose, be re-allocated for cancellation or sold in compliance with AMF requirements relating in particular to blackout periods. Shares repurchased in connection with one of the market practices authorized by the AMF (see above) may also be re-allocated to one of the purposes contemplated by the Regulation or sold in compliance with AMF requirements. Shares repurchased with a view to their cancellation must be cancelled within 24 months following their acquisition.

During the year ended December 31, 2020, we used the authority delegated by our shareholders to repurchase our shares on the stock market.

Pursuant to our share repurchase programs authorized by our shareholders on April 30, 2019 and on April 28, 2020, we repurchased 9,668,365 of our shares for a weighted average price of €84.81, i.e. a total cost of €820 million. Brokerage fees, financial transaction taxes and the AMF contribution (net of income taxes) amounted to €2.10 million. Our Company did not resort to derivatives to repurchase our own shares.

During 2020, we did not proceed to any cancellations of treasury shares.

During 2020, we did not use a liquidity contract.

During 2020, we did not allocate any shares to stock purchase option plans outstanding at December 31, 2020.

In 2020, in addition to the 19,481 shares allocated to performance share plans outstanding at December 31, 2019, Sanofi:

- purchased 9,668,365 of its shares at an average weighted price of €84.81 for a total amount of €819,999,839;
- transferred 1,407,499 of its shares to beneficiaries of performance shares at an average weighted price of €90.20 for a total amount of €126,956,155.

As of December 31, 2020, the 8,280,347 treasury shares held under our share repurchase program were allocated to covering performance share plans. As of the same date, 838 shares initially issued in connection with the Action 2020 employee share ownership plan (but not ultimately allocated to employees under that plan) were allocated to a sales objective. Consequently, no treasury shares were held as of that date (i) to cover stock option plans or (ii) for liquidity purposes or (iii) with a view to cancellation.

As of December 31, 2020, we directly owned 8,281,185 Sanofi shares with a par value of €2 representing around 0.66% of our share capital and with an estimated value of €694 million, based on the share price at the time of purchase.

Reporting Obligations

Pursuant to the Regulation, the AMF Regulation and the French Commercial Code, issuers trading in their own shares are subject to the following reporting obligations:

- issuers must report all transactions in their own shares to the competent authority of each trading venue on which the shares are admitted to trading or are traded within seven trading days of the transaction in a prescribed format, unless such transactions are carried out pursuant to a liquidity agreement that complies with the ethical code approved by the AMF;
- issuers must declare to the AMF on a monthly basis all transactions completed under the share repurchase program unless they provide the same information on a weekly basis; and
- post on its website the transactions disclosed and keep that information available to the public for at least a 5-year period from the date of public disclosure.

Ownership of Shares by Non-French Persons

The French Commercial Code and our Articles of Association currently do not limit the right of non-residents of France or non-French persons to own or, where applicable, to vote our securities. However, non-residents of France must file an administrative notice with the French authorities in connection with certain direct and indirect investments in us, including the acquisition of a controlling interest in our Company. Under existing administrative rulings, ownership of $33^{1}/_{3}$% or more of our share capital or voting rights is regarded as a controlling interest, but a lower percentage might be held to be a controlling interest in certain circumstances depending upon factors such as:

- the acquiring party's intentions;
- the acquiring party's ability to elect directors; or
- financial reliance by the company on the acquiring party.

Moreover, certain foreign investments in companies incorporated under French law are subject to prior authorization from the French Minister of the Economy, where all or part of the target's business and activity relate to a strategic sector, such as energy, transportation, public health, telecommunications, etc.

In addition, pursuant to the provisions of the French Monetary and Financial Code (CMF), any investment by any non-French citizen, any French citizen not residing in France, any non-French entity or any French entity controlled such persons or entities that will result in the relevant investor (a) acquiring control of an entity registered in France, (b) acquiring all or part of a business line of an entity registered in France, or (c) for non-EU or non-EEA investors crossing, directly or indirectly, alone or in concert, a 25% threshold of voting rights in an entity registered in France, in each case, conducting activities in certain strategic industries, including activities essential to protecting public health, as well as biotechnology-related research and development activities, is subject to the prior authorization of the French Ministry of Economy, which may be conditional on certain undertakings. In the context of the ongoing COVID-19 pandemic, a decree, as modified added a new 10% threshold, in addition to the abovementioned 25% threshold, in force through December 31, 2021.

The CMF provides for statistical reporting requirements. Transactions by which non-French residents acquire at least 10% of the share capital or voting rights, or cross the 10% threshold, of a French resident company, are considered as foreign direct investments in France and are subject to statistical reporting requirements (Articles R. 152-1; R. 152-3 and R. 152-11 of the CMF). When the investment exceeds €15,000,000, companies must declare foreign transactions directly to the Banque de France within 20 business days following the date of certain direct foreign investments in us, including any purchase of ADSs. Failure to comply with such statistical reporting requirement may be sanctioned by five years' imprisonment and a fine of a maximum amount equal to twice the amount which should have been reported, in accordance with Article L. 165-1 of the CMF. This amount may be increased fivefold if the violation is made by a legal entity.

Enforceability of Civil Liabilities

We are a limited liability company (*société anonyme*) organized under the laws of France, and most of our officers and directors reside outside the United States. In addition, a substantial portion of our assets is located outside of the United States.

As a result, it may be difficult for investors:

- to obtain jurisdiction over us or our non-US resident officers and directors in US courts, or obtain evidence in France or from French citizen or any individual being resident in France or any officer, representative, agent or employee of a legal person having its registered office or an establishment in a territory of France, in connection with those actions in actions predicated on the civil liability provisions of the US federal securities laws;
- to enforce in US courts judgments obtained in such actions against us or our non-US resident officers and directors;
- to bring an original action in a French court to enforce liabilities based upon the US federal securities laws against us or our non-US resident officers or directors; and
- to enforce in US courts against us or our directors in non-US courts, including French courts, judgments of US courts predicated upon the civil liability provisions of the US federal securities laws.

Nevertheless, a final judgment for the payment of money rendered by any federal or state court in the United States based on civil liability, whether or not predicated solely upon the US federal securities laws, would be recognized and enforced in France provided that a French judge considers that this judgment meets the French legal requirement concerning the recognition and the enforcement of foreign judgments and is capable of being immediately enforced in the United States. A French court is therefore likely to grant the enforcement of a foreign judgment without a review of the merits of the underlying claim, only if (1) that judgment resulted from legal proceedings compatible with French standards of due process, (2) the judgment does not contravene international public order and public policy of France and (3) the jurisdiction of the US federal or state court has been based on principles of French private international law. The French court would also require that the US judgment is not tainted with fraud and is not incompatible with a judgment rendered by a French court in the same matter, or with an earlier judgment rendered by a foreign court in the same matter.

In addition, French law guarantees full compensation for the harm suffered but is limited to the actual damages, so the the victim does not suffer or benefit from the situation. Such system excludes damages such as, but not limited to, punitive and exemplary damages.

As a result, the enforcement, by US investors, of any judgments obtained in US courts in civil and commercial matters, including judgments under the US federal securities law against us or members of our Board of Directors, officers or certain experts named herein who are residents of France or countries other than the United States would be subject to the above conditions.

Finally, there may be doubt as to whether a French court would impose civil liability on us, the members of our Board of Directors, our officers or certain experts named herein in an original action predicated solely upon the US federal securities laws brought in a court of competent jurisdiction in France against us or such members, officers or experts, respectively.

C. Material Contracts

In connection with its acquisition of Genzyme Corporation, now a wholly-owned subsidiary of Sanofi, Sanofi issued one CVR per Genzyme share. On March 30, 2011, Sanofi and American Stock Transfer & Trust Company, LLC (“AST”), as trustee, entered into a Contingent Value Rights Agreement (the “CVR Agreement”) governing the terms of the CVRs. On May 13, 2016, AST tendered its resignation as trustee under the CVR Agreement to Sanofi and UMB Bank, National Association replaced AST and became the successor trustee under the CVR Agreement. A copy of the form of CVR Agreement was filed with the SEC as Annex B to Amendment No. 2 to the Registration Statement on Form F-4 on March 24, 2011. Reference is also made to Sanofi’s Form 6-K submitted to the SEC on October 31, 2019, in which Sanofi disclosed an agreement to settle litigation involving claims against Sanofi for breach of the CVR Agreement. Among other things, the settlement agreement provided that the CVRs would be delisted from the NASDAQ and extinguished, and the CVR Agreement terminated, which occurred in March 2020.

D. Exchange Controls

French exchange control regulations currently do not limit the amount of payments that we may remit to non-residents of France. Laws and regulations concerning foreign exchange controls do require, however, that all payments or transfers of funds made by a French resident to a non-resident be handled by an accredited intermediary.

E. Taxation

General

The following generally summarizes the material French and US federal income tax consequences to US holders (as defined below) of purchasing, owning and disposing of our ADSs and ordinary shares (collectively the “Securities”). This discussion is intended only as a descriptive summary and does not purport to be a complete analysis or listing of all potential tax effects of the purchase, ownership or disposition of our Securities. All of the following is subject to change. Such changes could apply retroactively and could affect the consequences described below.

This summary does not constitute a legal opinion or tax advice. Holders are urged to consult their own tax advisers regarding the tax consequences of the purchase, ownership and disposition of Securities in light of their particular circumstances, including the effect of any US federal, state, local or other national tax laws.

A set of tax rules is applicable to French assets that are held by or in foreign trusts. These rules provide inter alia for the inclusion of trust assets in the settlor’s net assets for purpose of applying the French real estate wealth tax, for the application of French gift and death duties to French assets held in trust, for a specific tax on capital on the French assets of foreign trusts not already subject to the French real estate wealth tax and for a number of French tax reporting and disclosure obligations. The following discussion does not address the French tax consequences applicable to Securities held in trusts. *If Securities are held in trust, the grantor, trustee and beneficiary are urged to consult their own tax adviser regarding the specific tax consequences of acquiring, owning and disposing of Securities.*

The description of the French and US federal income tax consequences set forth below is based on the laws (including, for US federal income tax purposes, the Internal Revenue Code of 1986, as amended (the "Code"), final, temporary and proposed US Treasury Regulations promulgated thereunder and administrative and judicial interpretations thereof) in force as of the date of this annual report, the Convention Between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income and Capital of August 31, 1994 (the "Treaty"), which entered into force on December 30, 1995 (as amended by any subsequent protocols, including the protocol of January 13, 2009), and the tax regulations issued by the French tax authorities within the *Bulletin Officiel des Finances Publiques-Impôts* (the "Regulations") in force as of the date of this report. *US holders are advised to consult their own tax advisers regarding their eligibility for Treaty benefits, especially with regard to the "Limitations on Benefits" provision, in light of their own particular circumstances.*

No advance ruling has been obtained with respect to the tax consequences of the acquisition, ownership or disposition of the Securities from either the French or US tax authorities. Thus, there can no assurances that either or both of such authorities will not take a position concerning said tax consequences different from that set out herein or that such a position would not be sustained by a court.

For the purposes of this discussion, a US holder is a beneficial owner of Securities that is (i) an individual who is a US citizen or resident for US federal income tax purposes, (ii) a US domestic corporation or certain other entities created or organized in or under the laws of the United States or any state thereof, including the District of Columbia, or (iii) otherwise subject to US federal income taxation on a net income basis in respect of Securities. A non-US holder is a person other than a US holder.

If a partnership holds Securities, the tax treatment of a partner generally will depend upon the status of the partner and the activities of the partnership. *If a US holder is a partner in a partnership that holds Securities, the holder is urged to consult its own tax adviser regarding the specific tax consequences of acquiring, owning and disposing of Securities.*

This discussion is intended only as a general summary and does not purport to be a complete analysis or listing of all potential tax effects of the acquisition, ownership or disposition of the Securities to any particular investor, and does not discuss tax considerations that arise from rules of general application or that are generally assumed to be known by investors. The discussion applies only to investors that hold our Securities as capital assets that have the US dollar as their functional currency, that are entitled to Treaty benefits under the "Limitation on Benefits" provision contained in the Treaty, and whose ownership of the Securities is not effectively connected to a permanent establishment or a fixed base in France. Certain holders (including, but not limited to, US expatriates, partnerships or other entities classified as partnerships for US federal income tax purposes, banks, insurance companies, regulated investment companies, tax-exempt organizations, financial institutions, persons subject to the alternative minimum tax, persons who acquired the Securities pursuant to the exercise of employee stock options or otherwise as compensation, persons that own (directly, indirectly or by attribution) 5% or more of our voting stock or 5% or more of our outstanding share capital, dealers in securities or currencies, persons that elect to mark their securities to market for US federal income tax purposes, persons that acquire ADSs in "pre-release" transactions (i.e. prior to deposit of the relevant ordinary shares, although our depositary has indicated that such transactions have been halted) and persons holding Securities as a position in a synthetic security, straddle or conversion transaction) may be subject to special rules not discussed below. *Holders of Securities are advised to consult their own tax advisers with regard to the application of French tax law and US federal tax law to their particular situations, as well as any tax consequences arising under the laws of any state, local or other foreign jurisdiction.*

French Taxes

Estate and gift taxes and transfer taxes

In general, a transfer of Securities by gift or by reason of death of a US holder that would otherwise be subject to French gift or inheritance tax, respectively, will not be subject to such French tax by reason of the Convention between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Estates, Inheritances and Gifts, dated November 24, 1978, unless the donor or the transferor is domiciled in France at the time of making the gift or at the time of his or her death, or the Securities were used in, or held for use in, the conduct of a business through a permanent establishment or a fixed base in France.

Pursuant to Article 235 ter ZD of the French General Tax Code, purchases of Securities are subject to a 0.3% French tax on financial transactions (the "FTFF") provided that Sanofi's market capitalization exceeds 1 billion euros as of December 1 of the year preceding the taxation year. A list of companies whose market capitalization exceeds 1 billion euros as of December 1 of the year preceding the taxation year used to be published annually by the French Ministry of Economy. It is now published by the French tax authorities, and could be amended at any time. Pursuant to Regulations BOI-ANNX-000467-23/12/2020 issued on December 23, 2020, purchases of Sanofi's Securities in 2020 should be subject to the FTFF as the market capitalization of Sanofi exceeded 1 billion euros as of December 1, 2020. In accordance with Article 726-II-d of the French General Tax Code, purchases which are subject to the FTFF should however not be subject to transfer taxes (*droits d'enregistrement*) in France.

Wealth Tax

The French wealth tax (*impôt de solidarité sur la fortune*) has been replaced with a French real estate wealth tax (*impôt sur la fortune immobilière*) with effect from January 1, 2018. French real estate wealth tax applies only to individuals and does not generally apply to the Securities if the holder is a US resident, as defined pursuant to the provisions of the Treaty, provided that the individual does not own directly or indirectly a shareholding exceeding 10% of the financial rights and voting rights.

US Taxes

Ownership of the securities

Deposits and withdrawals by a US holder of ordinary shares in exchange for ADSs, will not be taxable events for US federal income tax purposes. For US tax purposes, holders of ADSs will be treated as owners of the ordinary shares represented by such ADSs. Accordingly, the discussion that follows regarding the US federal income tax consequences of acquiring, owning and disposing of ordinary shares is equally applicable to ADSs.

Information reporting and backup withholding tax

Distributions made to holders and proceeds paid from the sale, exchange, redemption or disposal of Securities may be subject to information reporting to the Internal Revenue Service. Such payments may be subject to backup withholding taxes unless the holder (i) is a corporation or other exempt recipient or (ii) provides a taxpayer identification number and certifies that no loss of exemption from backup withholding has occurred. Holders that are not US persons generally are not subject to information reporting or backup withholding. However, such a holder may be required to provide a certification of its non-US status in connection with payments received within the United States or through a US-related financial intermediary to establish that it is an exempt recipient. Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a holder's US federal income tax liability. A holder may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the Internal Revenue Service and furnishing any required information.

Foreign asset reporting

In addition, a US holder that is an individual (and, to the extent provided in future regulations, an entity), may be subject to recently-enacted reporting obligations with respect to ordinary shares and ADSs if the aggregate value of these and certain other "specified foreign financial assets" exceeds $50,000. If required, this disclosure is made by filing Form 8938 with the US Internal Revenue Service. Significant penalties can apply if holders are required to make this disclosure and fail to do so. In addition, a US holder should consider the possible obligation to file online a FinCEN Form 114 – Foreign Bank and Financial Accounts Report as a result of holding ordinary shares or ADSs. Holders are encouraged to consult their US tax advisors with respect to these and other reporting requirements that may apply to their acquisition of ordinary shares and ADSs.

State and local taxes

In addition to US federal income tax, US holders of Securities may be subject to US state and local taxes with respect to such Securities. *Holders of Securities are advised to consult their own tax advisers with regard to the application of US state and local income tax law to their particular situation.*

ADSs-Ordinary Shares

French Taxes

Taxation of dividends

Under French law, dividends paid by a French corporation, such as Sanofi, to non-residents of France are generally subject to French withholding tax at a rate of 26.5% (12.8% for distributions made to individuals, and 15% for distributions made to not-for-profit organizations with a head office in a Member State of the European Economic Area which would be subject to the tax regime set forth under article 206 paragraph 2 of the French General Tax Code if its head office were located in France and which meet the criteria set forth in the Regulations BOI-RPPM-RCM-30-30-10-70-24/12/2019, No. 130). Dividends paid by a French corporation, such as Sanofi, towards non-cooperative States or territories, as defined in Article 238-0 A of the French General Tax Code, will generally be subject to French withholding tax at a rate of 75%, irrespective of the tax residence of the beneficiary of the dividends if the dividends are received in such States or territories; however, eligible US holders entitled to Treaty benefits under the "Limitation on Benefits" provision contained in the Treaty who are US residents, as defined pursuant to the provisions of the Treaty and who receive dividends in non-cooperative States or territories, will not be subject to this 75% withholding tax rate.

Under the Treaty, the rate of French withholding tax on dividends paid to an eligible US holder who is a US resident as defined pursuant to the provisions of the Treaty and whose ownership of the ordinary shares or ADSs is not effectively connected with a permanent establishment or fixed base that such US holder has in France, is reduced to 15%, or to 5% if such US holder is a corporation and owns directly or indirectly at least 10% of the share capital of the issuing company; such US holder may claim a refund from the French tax authorities of the amount withheld in excess of the Treaty rates of 15% or 5%, if any. For US holders that are not individuals but are US residents, as defined pursuant to the provisions of the Treaty, the requirements for eligibility for Treaty benefits, including the reduced 5% or 15% withholding tax rates contained in the "Limitation on Benefits" provision of the Treaty, are complicated, and certain technical changes were made to these requirements by the protocol of January 13, 2009. US holders are advised to consult their own tax advisers regarding their eligibility for Treaty benefits in light of their own particular circumstances.

Dividends paid to an eligible US holder may immediately be subject to the reduced rates of 5% or 15% provided that such holder establishes before the date of payment that it is a US resident under the Treaty by completing and providing the depositary with a treaty form (Form 5000). Dividends paid to a US holder that has not filed the Form 5000 before the dividend payment date will be subject to French withholding tax at the rate of 26.5% and then reduced at a later date to 5% or 15%, provided that such holder duly completes and provides the French tax authorities with the treaty forms Form 5000 and Form 5001 before December 31 of the second calendar year following the year during which the dividend is paid. Pension funds and certain other tax-exempt entities are subject to the same general filing requirements as other US holders except that they may have to supply additional documentation evidencing their entitlement to these benefits.

The depositary agrees to use reasonable efforts to follow the procedures established, or that may be established, by the French tax authorities (i) to enable eligible US holders to qualify for the reduced withholding tax rate provided by the Treaty, if available at the time the dividends are paid, or (ii) to recover any excess French withholding taxes initially withheld or deducted with respect to dividends and other distributions to which such US holders may be eligible from the French tax authorities and (iii) to recover any other available tax credits. In particular, associated forms (including Form 5000 and Form 5001, together with their instructions), will be made available by the depositary to all US holders registered with the depositary, and are also generally available from the US Internal Revenue Service.

The withholding tax refund, if any, ordinarily is paid within 12 months of filing the applicable French Treasury Form, but not before January 15 of the year following the calendar year in which the related dividend is paid.

Tax on sale or other disposition

In general, under the Treaty, a US holder who is a US resident for purposes of the Treaty will not be subject to French tax on any capital gain from the redemption (other than redemption proceeds characterized as dividends under French domestic law), sale or exchange of ordinary shares or ADSs unless the ordinary shares or the ADSs form part of the business property of a permanent establishment or fixed base that the US holder has in France. Special rules apply to holders who are residents of more than one country.

US Taxes

Taxation of dividends

For US federal income tax purposes, the gross amount of any distribution paid to US holders (that is, the net distribution received plus any tax withheld therefrom) will be treated as ordinary dividend income to the extent paid or deemed paid out of the current or accumulated earnings and profits of Sanofi (as determined under US federal income tax principles). Dividends paid by Sanofi will not be eligible for the dividends-received deduction generally allowed to corporate US holders.

Subject to certain exceptions for short-term and hedged positions, the US dollar amount of dividends received by an individual US holder with respect to the ADSs or our ordinary shares is currently subject to taxation at a maximum rate of 20% if the dividends are "qualified dividends". Dividends paid on the ordinary shares or ADSs will be treated as qualified dividends if (i) the issuer is eligible for the benefits of a comprehensive income tax treaty with the United States that the Internal Revenue Service has approved for the purposes of the qualified dividend rules and (ii) the issuer was not, in the year prior to the year in which the dividend was paid, and is not, in the year in which the dividend is paid, a passive foreign investment company ("PFIC"). The Treaty has been approved for the purposes of the qualified dividend rules. Based on our financial statements and relevant market and shareholder data, we believe Sanofi was not a PFIC for US federal income tax purposes with respect to its 2020 taxable year. In addition, based on its current expectations regarding the value and nature of its assets, the sources and nature of its income, and relevant market and shareholder data, we do not anticipate that Sanofi will become a PFIC for its 2021 taxable year. *Holders of ordinary shares and ADSs should consult their own tax advisers regarding the availability of the reduced dividend tax rate in light of their own particular circumstances.*

If you are a US holder, dividend income received by you with respect to ADSs or ordinary shares generally will be treated as foreign source income for foreign tax credit purposes. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. Distributions out of earnings and profits with respect to the ADSs or ordinary shares generally will be treated as "passive category" income (or, in the case of certain US holders, "general category" income). Subject to certain limitations, French income tax withheld in connection with any distribution with respect to the ADSs or ordinary shares may be claimed as a credit against the US federal income tax liability of a US holder if such US holder elects for that year to credit all foreign income taxes. Alternatively, such French withholding tax may be taken as a deduction against taxable income. Foreign tax credits will not be allowed for withholding taxes imposed in respect of certain short-term or hedged positions in Securities and may not be allowed in respect of certain arrangements in which a US holder's expected economic profit is insubstantial. *The US federal income tax rules governing the availability and computation of foreign tax credits are complex. US holders should consult their own tax advisers concerning the implications of these rules in light of their particular circumstances.*

To the extent that an amount received by a US holder exceeds the allocable share of our current and accumulated earnings and profits, such excess will be applied first to reduce such US holder's tax basis in its ordinary shares or ADSs and then, to the extent it exceeds the US holder's tax basis, it will constitute capital gain from a deemed sale or exchange of such ordinary shares or ADSs (see "- Tax on Sale or Other Disposition", below).

The amount of any distribution paid in euros will be equal to the US dollar value of the euro amount distributed, calculated by reference to the exchange rate in effect on the date the dividend is received by a US holder of ordinary shares (or by the depositary, in the case of ADSs) regardless of whether the payment is in fact converted into US dollars on such date. *US holders should consult their own tax advisers regarding the treatment of foreign currency gain or loss, if any, on any euros received by a US holder that are converted into US dollars on a date subsequent to receipt.*

Distributions to holders of additional ordinary shares (or ADSs) with respect to their ordinary shares (or ADSs) that are made as part of a pro rata distribution to all ordinary shareholders generally will not be subject to US federal income tax. However, if a US holder has the option to receive a distribution in shares (or ADSs) or to receive cash in lieu of such shares (or ADSs), the distribution of shares (or ADSs) will be taxable as if the holder had received an amount equal to the fair market value of the distributed shares (or ADSs), and such holder's tax basis in the distributed shares (or ADSs) will be equal to such amount.

Tax on sale or other disposition

In general, for US federal income tax purposes, a US holder that sells, exchanges or otherwise disposes of its ordinary shares or ADSs will recognize capital gain or loss in an amount equal to the US dollar value of the difference between the amount realized for the ordinary shares or ADSs and the US holder's adjusted tax basis (determined in US dollars and under US federal income tax rules) in the ordinary shares or ADSs. Such gain or loss generally will be US-source gain or loss, and will be treated as long-term capital gain or loss if the US holder's holding period in the ordinary shares or ADSs exceeds one year at the time of disposition. If the US holder is an individual, any capital gain generally will be subject to US federal income tax at preferential rates (currently a maximum of 20%) if specified minimum holding periods are met. The deductibility of capital losses is subject to significant limitations.

Medicare tax

Certain US holders who are individuals, estates or trusts are required to pay a Medicare tax of 3.8% (in addition to taxes they would otherwise be subject to) on their "net investment income" which would include, among other things, dividends and capital gains from the ordinary shares and ADSs.

F. Dividends and Paying Agents

N/A

G. Statement by Experts

N/A

H. Documents on Display

We are subject to the information requirements of the US Securities Exchange Act of 1934, as amended, or Exchange Act, and, in accordance therewith, we are required to file reports, including this annual report on Form 20-F, and other information with the US Securities and Exchange Commission, or Commission, by electronic means.

You may review a copy of our filings with the Commission, as well as other information furnished to the Commission, including exhibits and schedules filed with it, at the Commission's public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information. In addition, the Commission maintains an Internet site at http://www.sec.gov that contains reports and other information regarding issuers that file electronically with the Commission (these documents are not incorporated by reference in this annual report).

I. Subsidiary Information

N/A

Item 11. Quantitative and Qualitative Disclosures about Market Risk[1]

General policy

Liquidity risk, foreign exchange risk and interest rate risk, as well as related counterparty risks, are managed centrally by our dedicated treasury team within the Group Finance Department. Where it is not possible to manage those risks centrally – in particular due to regulatory restrictions (such as foreign exchange controls) or local tax restrictions – credit facilities and/or currency lines, guaranteed whenever necessary by the parent company, are contracted by our subsidiaries locally with banks, under the supervision of the central treasury team.

Our financing and investment strategies, and our interest rate and currency hedging strategies, are reviewed monthly by the Group Finance Department.

Our policy prohibits the use of derivatives for speculative purposes.

Counterparty risk

Our financing and investing transactions, and our currency and interest rate hedges, are contracted with leading counterparties. We set limits for investment and derivative transactions with individual financial institutions, depending on the rating of each institution. Compliance with these limits, which are based on the notional amounts of the investments and the fair value of the hedging instruments, is monitored on a daily basis.

The table below shows our total exposure as of December 31, 2020 by rating and in terms of our percentage exposure to the dominant counterparty.

(€ million)	Cash and cash equivalents (excluding mutual funds) [a]	Notional amounts of currency hedges [b]	Fair value of currency hedges	Notional amounts of interest rate hedges [b]	Fair value of interest rate hedges	General corporate purpose credit facilities
AA	26	1,576	(12)	250	1	500
AA-	1,458	6,217	(75)	850	8	1,500
A+	1,073	5,038	(64)	650	6	3,500
A	1,378	4,979	(47)	949 [c]	4	1,000
A-	—	—	—	—	—	500
BBB+	148	1,644	(11)	—	—	1,000
Unallocated	123	—	—	—	—	—
Total	**4,206**	**19,454**	**(209)**	**2,699**	**20**	**8,000**
% / rating of dominant counterparty	17% / AA-	11% / AA-		**11**% / AA-		6% / BBB+

(a) Cash equivalents include mutual fund investments of €8,703 million.

(b) The notional amounts are translated into euros at the relevant closing exchange rate as of December 31, 2020.

(c) Includes interest rate swaps hedging fixed-rate bonds of €99 million held in a Professional Specialized Investment Fund dedicated to Sanofi, recognized in "Long-term loans, advances and other non-current receivables" (see Note D.7. to our consolidated financial statements).

As of December 31, 2020, we held investments in euro and US dollar denominated money-market mutual funds. Those instruments have low volatility, low sensitivity to interest rate risk, and a very low probability of loss of principal. The depositary banks of the mutual funds, and of Sanofi itself, have a long-term rating of at least A. Realization of counterparty risk could impact our liquidity in certain circumstances.

Foreign exchange risk

A. Operating foreign exchange risk

A substantial portion of our net sales is generated in countries where the euro, which is our reporting currency, is not the functional currency. In 2020, for example, 37.4% of our net sales were generated in the United States; 25.4% in Europe; and 37.2% in the Rest of the World region (see the definition in “Item 5. Operating and Financial Review and Prospects — A/ Operating results), including countries that are, or may in the future become, subject to exchange controls, of which 6.8% was generated in China and 4.8% in Japan. Although we also incur expenses in those countries, the impact of those expenses is not enough wholly to offset the impact of exchange rates on our net sales. Consequently, our operating income may be materially affected by fluctuations in exchange rates between the euro and other currencies. Sanofi operates a foreign exchange risk hedging policy to reduce the exposure of operating income to exchange rate movements. That policy involves regular assessments of Sanofi’s worldwide foreign currency exposure, based on foreign currency transactions carried out by the parent company and its subsidiaries. Those transactions mainly comprise sales, purchases, research costs, co-marketing and co-promotion expenses, and royalties. To reduce the exposure of those transactions to exchange rate movements, Sanofi contracts hedges using liquid derivative instruments, mainly forward currency purchases and sales, and also foreign exchange swaps.

[1] The disclosures in this section supplement those provide in Note B.8.7. to the consolidated financial statements as regards the disclosure requirements of IFRS 7, and are covered by the independent registered public accounting firms' opinion on the consolidated financial statements.

The table below shows operating currency hedging instruments in place as of December 31, 2020, with the notional amount translated into euros at the relevant closing exchange rate (see Note D.20. to the consolidated financial statements for the accounting classification of those instruments as of December 31, 2020).

Operating foreign exchange derivatives as of December 31, 2020:

(€ million)	Notional amount	Fair value
Forward currency sales	**3,477**	**7**
of which US dollar	1,367	10
of which Chinese yuan renminbi	521	2
of which Singapore dollar	287	(1)
of which Japanese yen	143	1
of which Mexican peso	121	—
Forward currency purchases	**1,932**	**—**
of which US dollar	580	(1)
of which Singapore dollar	571	(1)
of which Chinese yuan renminbi	286	1
of which Russian rouble	61	—
of which Japanese yen	55	—
Total	**5,409**	**7**

The above positions mainly hedge future material foreign-currency cash flows arising after the end of the reporting period in relation to transactions carried out during the year ended December 31, 2020 and recognized in the balance sheet at that date. Gains and losses on hedging instruments (forward contracts) are calculated and recognized in parallel with the recognition of gains and losses on the hedged items. Due to this hedging relationship, the commercial foreign exchange profit or loss on these items (hedging instruments and hedged transactions) will be immaterial in 2021.

B. Financial foreign exchange risk

The cash pooling arrangements for foreign subsidiaries outside the euro zone, and some of Sanofi's financing activities, expose certain Sanofi entities to financial foreign exchange risk (i.e. the risk of changes in the value of borrowings and loans denominated in a currency other than the functional currency of the borrower or lender). That foreign exchange exposure is hedged using derivative instruments (foreign exchange swaps, forward contracts or currency swaps) that alter the currency split of Sanofi's net debt once those instruments are taken into account.

The table below shows financial currency hedging instruments in place as of December 31, 2020, with the notional amounts translated into euros at the relevant closing exchange rate (see also Note D.20. to the consolidated financial statements for the accounting classification of these instruments as of December 31, 2020).

Financial foreign exchange derivatives as of December 31, 2020:

(€ million)	Notional amount	Fair value	Expiry
Forward currency sales	**5,064**	**10**	
of which US dollar	*3,721* (a)	*20*	*2021*
of which Japanese yen	*283*	*—*	*2021*
of which Pound sterling	*257*	*(6)*	*2021*
Forward currency purchases	**9,004**	**(226)**	
of which US dollar	*6,068* (b) (c)	*(200)*	*2022*
of which Singapore dollar	*2,250* (d)	*(27)*	*2021*
of which Chinese yuan renminbi	*195*	*1*	*2021*
Total	**14,068**	**(216)**	

(a) Includes forward sales with a notional amount of $3,615 million expiring in 2021, designated as a hedge of Sanofi's net investment in Bioverativ. As of December 31, 2020, the fair value of these forward contracts represented an asset of €13 million; the opposite entry was recognized in Other comprehensive income, with the impact on financial income and expense being immaterial.

(b) Includes forward purchases with a notional amount of $3,000 million expiring in 2021 and 2022, designated as a fair value hedge of the exposure of $3,000 million of bond issues to fluctuations in the EUR/USD spot rate. As of December 31, 2020, the fair value of the contracts was a liability of €109 million.

(c) Includes currency swaps with a notional amount of $1,000 million receive 0.22% pay EUR -0.63% expiring in 2022, designated as a cash flow hedge of $1,000 million of bond issues. As of December 31, 2020, the fair value of the swaps was a liability of €38 million.

(d) Includes forward purchases with a notional amount of SGD2,000 million expiring in 2021, designated as a fair value hedge of the exposure of an equivalent amount of intragroup loans to fluctuations in the EUR/SGD spot rate. As of December 31, 2020, the fair value of the contracts was a liability of €22 million.

These hedging instruments generate a net financial gain or loss arising from the interest rate differential between the hedged currency and the euro, given that the foreign exchange gain or loss on the foreign-currency borrowing and loans is offset by the change in the intrinsic value of the hedging instruments. The interest rate differential is recognized within cost of net debt (see Note D.29. to our consolidated financial statements). We may also hedge some future foreign-currency investment or divestment cash flows.

C. Other foreign exchange risks

A significant proportion of our net assets is denominated in US dollars (see Note D.35. to the consolidated financial statements). As a result, any fluctuation in the exchange rate of the US dollar against the euro automatically impacts the amount of our equity as expressed in euros.

In addition, we use the euro as our reporting currency. Consequently, if one or more European Union Member States were to abandon the euro as a currency, the resulting economic upheavals – in particular, fluctuations in exchange rates – could have a significant impact on the terms under which we can obtain financing and on our financial results, the extent and consequences of which are not currently foreseeable.

Liquidity risk

We operate a centralized treasury platform whereby all surplus cash and financing needs of our subsidiaries are invested with or funded by the parent company (where permitted by local legislation). The central treasury department manages our current and projected financing, and ensures that Sanofi is able to meet its financial commitments by maintaining sufficient cash and confirmed credit facilities for the size of our operations and the maturity of our debt (see Notes D.17.1.c and D.17.1.g to the consolidated financial statements).

We diversify our short-term investments with leading counterparties using money-market products with instant access or with a maturity of less than three months.

As of December 31, 2020, cash and cash equivalents amounted to €13,915 million, and our short-term investments predominantly comprised:

- collective investments in euro and US dollar denominated money-market mutual funds. All such funds can be traded on a daily basis and the amount invested in each fund may not exceed 10% of the aggregate amount invested in such funds;
- amounts invested directly with banks and non-financial institutions in the form of instant access deposits, term deposits, and Negotiable European Commercial Paper with a maturity of no more than three months.

In addition, to optimize the liquidity/return profile of our short-term investments, we had €398 million invested in term deposits as of December 31, 2020, expiring in November 2021 and presented within "Other current term financial assets" (see Note D.11.).

As of December 31, 2020 we also had €8 billion of undrawn general corporate purpose confirmed credit facilities, half expiring December 2021 and half December 2025. Those credit facilities are not subject to financial covenant ratios.

Our policy is to diversify our sources of funding through public or private issuances of debt securities, in the United States (shelf registration statement) and Europe (Euro Medium Term Note program). In addition, our A-1+/P-1 short-term rating gives us access to commercial paper programs in the United States, and to Negotiable European Commercial Paper programs in France. The average maturity of our total debt was 5.5 years as of December 31, 2020, compared with 5.4 years as of December 31, 2019. During 2020, we did not draw down on our Negotiable European Commercial Paper programs in France. Average drawdowns under the US commercial paper program during 2020 were €1.4 billion (maximum €3.7 billion); the average maturity of those drawdowns was two months. As of December 31, 2020, neither of those programs was being utilized.

In the event of a liquidity crisis, we could be exposed to difficulties in calling up our available cash, a scarcity of sources of funding including the above-mentioned programs, and/or a deterioration in their terms. This situation could damage our capacity to refinance our debt or to issue new debt on reasonable terms.

Interest rate risk

Sanofi issues debt in two currencies, the euro and the US dollar, and also invests its cash and cash equivalents in those currencies. Sanofi also operates cash pooling arrangements to manage the surplus cash and short-term liquidity needs of foreign subsidiaries located outside the euro zone.

To optimize the cost of debt or reduce the volatility of debt and manage its exposure to financial foreign exchange risk, Sanofi uses derivative instruments (interest rate swaps, currency swaps, foreign exchange swaps and forward contracts) that alter the fixed/floating rate split and the currency split of its net debt.

The projected full-year sensitivity to interest rate fluctuations of our debt, net of cash and cash equivalents for 2021 is as follows:

Change in short-term interest rates	Impact on pre-tax net income (€ million)	Impact on pre-tax income/(expense) recognized directly in equity (€ million)
+100 bp	119	–
+25 bp	30	–
-25 bp	(30)	–
-100 bp	(119)	–

Stock market risk

It is our policy not to trade on the stock market for speculative purposes.

During 2019, Sanofi contracted derivative instruments (collars) on 593,712 shares of Dexcom Inc; the collars were designated as fair value hedges of the Dexcom shares. As of December 31, 2020 they had a negative fair value of €26 million, recognized in full in ***Other comprehensive income***.

Item 12. Description of Securities other than Equity Securities

12.A. Debt securities

Not applicable.

12.B. Warrants and rights

Not applicable.

12.C. Other securities

Not applicable.

12.D. American depositary shares

General

JPMorgan Chase Bank, N.A. ("JPMorgan"), as depositary, issues Sanofi ADSs in certificated form (evidenced by an ADR) or book-entry form. Each ADR is a certificate evidencing a specific number of Sanofi ADSs. Each Sanofi ADS represents one-half of one Sanofi ordinary share (or the right to receive one-half of one Sanofi ordinary share) deposited with the Paris, France office of BNP Paribas, as custodian. Each Sanofi ADS also represents an interest in any other securities, cash or other property that may be held by the depositary under the deposit agreement. The depositary's office is located at 383 Madison Avenue, 11th Floor, New York, New York 10179.

A holder may hold Sanofi ADSs either directly or indirectly through his or her broker or other financial institution. The following description assumes holders hold their Sanofi ADSs directly, in certificated form evidenced by ADRs. Holders who hold the Sanofi ADSs indirectly must rely on the procedures of their broker or other financial institution to assert the rights of ADR holders described in this section. Holders should consult with their broker or financial institution to find out what those procedures are.

Holders of Sanofi ADSs do not have the same rights as holders of Sanofi shares. French law governs shareholder rights. The rights of holders of Sanofi ADSs are set forth in the deposit agreement between Sanofi and JPMorgan and in the ADR. New York law governs the deposit agreement and the ADRs.

The following is a summary of certain terms of the deposit agreement, as amended. Our form of second amended and restated deposit agreement was filed with the SEC as an exhibit to our Post-Effective Amendment No. 1 to Form F-6 filed on February 13, 2015. The form of Amendment No. 1 to our form of second amended and restated deposit agreement was filed as an exhibit to our Post-Effective Amendment No. 2 to Form F-6 filed with the SEC on August 4, 2020. To the extent any portion of the amendment and restatement would prejudice any substantial existing right of holders of ADSs under the first amended and restated deposit agreement, such portion shall not become effective as to such holders until 30 days after holders have received notice thereof. For more complete information, holders should read the entire second amended and restated deposit agreement, Amendment No. 1 and the ADR itself. Holders may also inspect a copy of the current deposit agreement and Amendment No. 1 at the depositary's office.

Share dividends and other distributions

Receipt of dividends and other distributions

The depositary has agreed to pay to holders of Sanofi ADSs the cash dividends or other distributions that it or the custodian receives on the deposited Sanofi ordinary shares and other deposited securities after deducting its fees, charges and expenses and taxes withheld. Holders of Sanofi ADSs will receive these distributions in proportion to the number of Sanofi ADSs that they hold.

Cash. The depositary will convert any cash dividend or other cash distribution paid on the shares into US dollars if, in its judgment, it can do so on a reasonable basis and can transfer the US dollars to the United States. If the depositary determines that such a conversion and transfer is not possible, or if any approval from the French government is needed and cannot be obtained within a reasonable period, then the depositary may (1) distribute the foreign currency received by it to the holders of Sanofi ADSs or (2) hold the foreign currency distribution (uninvested and without liability for any interest) for the account of holders of Sanofi ADSs.

In addition, if any conversion of foreign currency, in whole or in part, cannot be effected to some holders of Sanofi ADSs, the deposit agreement allows the depositary to distribute the dividends only to those ADR holders to whom it is possible to do so. It will hold the foreign currency it cannot convert into US dollars for the account of the ADR holders who have not been paid. It will not invest the funds it holds and it will not be liable for any interest.

Before making a distribution, any withholding taxes that must be paid under French law will be deducted. The depositary will distribute only whole US dollars and cents and will round fractional cents down to the nearest whole cent. ***Exchange rate fluctuations during a period when the depositary cannot convert euros into U.S. dollars may result in holders losing some or all of the value of a distribution.***

Shares. The depositary may, and at our request will, distribute new ADRs representing any shares we distribute as a dividend or free distribution, if we furnish it promptly with satisfactory evidence that it is legal to do so. At its option, the depositary may distribute fractional Sanofi ADSs. If the depositary does not distribute additional Sanofi ADSs, the outstanding ADRs will also represent the new shares. The depositary may withhold any tax or other governmental charges, or require the payment of any required fees and expenses, prior to making any distribution of additional Sanofi ADSs.

Rights to Receive Additional Shares. If we offer holders of Sanofi ordinary shares any rights to subscribe for additional shares or any other rights, the depositary, after consultation with us, will, in its discretion, either (1) make these rights available to holders or (2) dispose of such rights on behalf of holders and make the net proceeds available to holders. The depositary may make rights available to certain holders but not others if it determines it is lawful and feasible to do so. However, if, under the terms of the offering or for any other reason, the depositary may not make such rights available or dispose of such rights and make the net proceeds available, it will allow the rights to lapse. In that case, holders of Sanofi ADSs will receive no value for them.

In circumstances where rights would not otherwise be distributed by the depositary to holders of Sanofi ADSs, a holder of Sanofi ADSs may nonetheless request, and will receive from the depositary, any instruments or other documents necessary to exercise the rights allocable to that holder if the depositary first receives written notice from Sanofi that (1) Sanofi has elected, in its sole discretion, to permit the rights to be exercised and (2) such holder has executed the documents Sanofi has determined, in its sole discretion, are reasonably required under applicable law.

If the depositary makes rights available to holders of Sanofi ADSs, upon instruction from such holders, it will exercise the rights and purchase the shares on such holder's behalf. The depositary will then deposit the shares and deliver ADRs to such holders. It will only exercise rights if holders of Sanofi ADSs pay it the exercise price and any other charges the rights require such holders to pay.

US securities laws may restrict the sale, deposit, cancellation or transfer of ADRs issued upon exercise of rights. For example, holders of Sanofi ADSs may not be able to trade such Sanofi ADSs freely in the United States. In this case, the depositary may deliver Sanofi ADSs under a separate restricted deposit agreement that will contain the same provisions as the deposit agreement, except for changes needed to implement the required restrictions.

Other Distributions. The depositary will distribute to holders of Sanofi ADSs anything else we may distribute on deposited securities (after deduction or upon payment of fees and expenses or any taxes or other governmental charges) by any means it thinks is legal, equitable and practical. If, for any reason, it cannot make the distribution in that way, the depositary may sell what we distributed and distribute the net proceeds of the sale in the same way it distributes cash dividends, or it may choose any other method to distribute the property it deems equitable and practicable.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of Sanofi ADSs. We have no obligation to register Sanofi ADSs, shares, rights or other securities under the US Securities Act of 1933, as amended. We also have no obligation to take any other action to permit the distribution of ADRs, shares, rights or anything else to holders of Sanofi ADSs. This means that holders may not receive the distribution we make on our shares or any value for them if it is illegal or impractical for the depositary to make them available to such holders.

Elective Distributions. Whenever we intend to distribute a dividend payable at the election of shareholders either in cash or in additional shares, we will give prior notice thereof to the depositary and will indicate whether we wish the elective distribution to be made available to holders of Sanofi ADSs. In that case, we will assist the depositary in determining whether that distribution is lawful and reasonably practicable. The depositary will make the election available to holders of Sanofi ADSs only if it is reasonably practicable and if we have provided all the documentation contemplated in the deposit agreement. In that case, the depositary will establish procedures to enable holders of Sanofi ADSs to elect to receive either cash or additional ADSs, in each case as described in the deposit agreement. If the election is not made available to holders of Sanofi ADSs, such holders will receive either cash or additional Sanofi ADSs, depending on what a shareholder in France would receive for failing to make an election, as more fully described in the deposit agreement.

Deposit, withdrawal and cancellation

Delivery of ADRs

The depositary will deliver ADRs if the holder or his or her broker deposit shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of Sanofi ADSs in the names the holder requests and will deliver the ADRs to the persons the holder requests at its office.

Obtaining Sanofi ordinary shares

A holder may turn in his or her ADRs at the depositary's office. Upon payment of its fees and expenses and any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver (1) the underlying shares to an account designated by the holder and (2) any other deposited securities underlying the ADR at the office of a custodian or, at the holder's request, risk and expense, the depositary will deliver the deposited securities at its office.

Voting rights

A holder may instruct the depositary to vote the Sanofi ordinary shares underlying his or her Sanofi ADSs at any meeting of Sanofi shareholders, but only if we request that the depositary ask for holder instructions. Otherwise, holders will not be able to exercise their right to vote unless they withdraw the underlying ordinary shares from the ADR program and vote as an ordinary shareholder. However, holders may not know about the meeting sufficiently in advance to timely withdraw the underlying ordinary shares.

If we ask for holder instructions in connection with a meeting of Sanofi shareholders, the depositary will provide materials to holders of Sanofi ADSs in the manner described under the heading "Notices and Reports; Rights of Holders to Inspect Books" below. For any instructions to be valid, the depositary must receive them on or before the date specified in the materials distributed by the depositary. The depositary will endeavor, in so far as practical, subject to French law and the provisions of our *statuts*, to vote or to have its agents vote the shares or other deposited securities as holders may validly instruct. The depositary will only vote or attempt to vote shares as holders validly instruct.

We cannot guarantee holders that they will receive the voting materials with sufficient time to enable them to return any voting instructions to the depositary in a timely manner to vote their shares. As long as they act in good faith, neither the depositary nor its agents will be responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. ***This means that holders may***

not be able to exercise their right to vote and there may be nothing holders can do if the shares represented by their ADSs are not voted as they requested.

Similar to our shares, Sanofi ADSs evidenced by ADRs that are registered in the name of the same owner for at least two (2) years are eligible for double voting rights so long as certain procedures are followed, as set out in the deposit agreement. For additional information regarding double voting rights, see "Item 10. Additional Information — B. Memorandum and Articles of Association — Voting Rights".

The deposit agreement allows the depositary and Sanofi to change the voting procedures or require additional voting procedures in addition to the ones described above if necessary or appropriate. ***For example, holders might be required to arrange to have their Sanofi ADSs deposited in a blocked account for a specified period of time prior to a shareholders' meeting in order to be allowed to give voting instructions.***

Notices and reports; rights of holders to inspect books

On or before the first date on which we give notice, by publication or otherwise, of any meeting of holders of shares or other deposited securities, or of any adjourned meeting of such holders, or of the taking of any action in respect of any cash or other distributions or the offering of any rights, we will transmit to the depositary a copy of the notice.

Upon notice of any meeting of holders of shares or other deposited securities, if requested in writing by Sanofi, the depositary will, as soon as practicable, mail to the holders of Sanofi ADSs a notice, the form of which is in the discretion of the depositary, containing (1) a summary in English of the information contained in the notice of meeting provided by Sanofi to the depositary, (2) a statement that the holders as of the close of business on a specified record date will be entitled, subject to any applicable provision of French law and of our *statuts*, to instruct the depositary as to the exercise of the voting rights, if any, pertaining to the amount of shares or other deposited securities represented by their respective ADSs and (3) a statement as to the manner in which such instructions may be given. Notwithstanding the above, the depositary may, to the extent not prohibited by law or regulations, or by the requirements of NASDAQ, in lieu of distribution of the materials provided to the depositary as described above, distribute to the holders a notice that provides holders with, or otherwise publicizes to holders, instructions on how to retrieve such materials or receive such materials upon request (i.e., by reference to a website containing the materials for retrieval or a contact for requesting copies of the materials).

The depositary will make available for inspection by ADS holders at the depositary's office any reports and communications, including any proxy soliciting material, received from us that are both (1) received by the depositary as the holder of the deposited securities and (2) made generally available to the holders of such deposited securities by us. The depositary will also, upon written request, send to ADS holders copies of such reports when furnished by us pursuant to the deposit agreement. Any such reports and communications, including any such proxy soliciting material, furnished to the depositary by us will be furnished in English to the extent such materials are required to be translated into English pursuant to any regulations of the SEC.

The depositary will keep books for the registration of ADRs and transfers of ADRs that at all reasonable times will be open for inspection by the holders provided that such inspection is not for the purpose of communicating with holders in the interest of a business or object other than our business or a matter related to the deposit agreement or the ADRs.

Fees and expenses

Fees payable by ADS holders

Pursuant to the deposit agreement, holders of our ADSs may have to pay to JPMorgan, either directly or indirectly, fees or charges up to the amounts set forth in the table below.

Associated Fee	Depositary Action
$5.00 or less per 100 ADSs (or portion thereof)	Execution and delivery of ADRs for distributions and dividends in shares and rights to subscribe for additional shares or rights of any other nature and surrender of ADRs for the purposes of withdrawal, including the termination of the deposit agreement.
$0.05 or less per ADS (or portion thereof)	Any cash distribution made pursuant to the deposit agreement, including, among other things: • cash distributions or dividends; • distributions other than cash, shares or rights; • distributions in shares; and • rights of any other nature, including rights to subscribe for additional shares.
$0.05 or less per ADS per calendar year (or portion thereof)	Services performed in administering the ADRs (which fee may be charged on a periodic basis during each calendar year)
Registration fees in effect for the registration of transfers of shares generally on the share register of the company or foreign registrar and applicable to transfers of shares to or from the name of JPMorgan or its nominee to the custodian or its nominee on the making of deposits and withdrawals	As applicable
A fee equal to the fee for the execution and delivery of ADSs which would have been charged as a result of the deposit of such securities	Distributions of securities other than cash, shares or rights
A fee for the reimbursement of such fees, charges and expenses as are incurred by JPMorgan, its agents (and their agents), including BNP Paribas, as custodian (by deductions from cash dividends or other cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them)	Compliance with foreign exchange control regulations or any law or regulation relating to foreign investment, servicing of shares or other deposited securities, sale of securities, delivery of deposited securities or otherwise
Expenses incurred by JPMorgan	• Cable, telex and facsimile transmission (where expressly provided for in the deposit agreement) • Foreign currency conversion into US dollars

In addition to the fees outlined above, each holder will be responsible for any taxes or other governmental charges payable on his or her Sanofi ADSs or on the deposited securities underlying his or her Sanofi ADSs. The depositary may refuse to transfer a holder's Sanofi ADSs or allow a holder to withdraw the deposited securities underlying his or her Sanofi ADSs until such taxes or other charges are paid. It may apply payments owed to a holder or sell deposited securities underlying a holder's Sanofi ADSs to pay any taxes owed, and the holder will remain liable for any deficiency. If it sells deposited securities, it will, if appropriate, reduce the number of Sanofi ADSs to reflect the sale and pay to the holder any proceeds, or send to the holder any property, remaining after it has paid the taxes. For additional information regarding taxation, see "Item 10. Additional Information — E. Taxation".

Fees paid to Sanofi by the depositary

JPMorgan, as depositary, has agreed to reimburse Sanofi for certain expenses (subject to certain limits) Sanofi incurs relating to legal fees, investor relations servicing, investor-related presentations, ADR-related advertising and public relations in those jurisdictions in which the ADRs may be listed or otherwise quoted, investor relations channel, perception studies, accountants' fees in relation to our annual report on Form 20-F or any other expenses directly or indirectly relating to managing the program or servicing the ADR holders. The depositary has also agreed to provide additional amounts to us based on certain performance indicators relating to the ADR facility and fees collected by it. From January 1, 2020 to December 31, 2020, we received a total amount of $10,714,310.71 from JPMorgan. In addition to these payments, JPMorgan has agreed to waive servicing fees we may incur in connection with routine corporate actions such as annual general meetings and dividend distributions, as well as for other assistance JPMorgan may provide to us, such as preparation of tax and regulatory compliance documents for holders and investor relations advisory services.

Changes affecting deposited securities

If we:

- change the nominal or par value of our Sanofi ordinary shares;
- recapitalize, reorganize, merge or consolidate, liquidate, sell assets, or take any similar action;
- reclassify, split up or consolidate any of the deposited securities; or
- distribute securities on the deposited securities that are not distributed to holders;

then either:

- the cash, shares or other securities received by the depositary will become deposited securities and each Sanofi ADS will automatically represent its equal share of the new deposited securities; or
- the depositary may, and will if we ask it to, distribute some or all of the cash, shares or other securities it receives. It may also deliver new ADRs or ask holders to surrender their outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

Disclosure of interests

The obligation of a holder or other person with an interest in our shares to disclose information under French law and under our *statuts* also applies to holders and any other persons, other than the depositary, who have an interest in the Sanofi ADSs. The consequences for failing to comply with these provisions are the same for holders and any other persons with an interest as a holder of our ordinary shares. For additional information regarding these obligations, see "Item 10. Additional Information — B. Memorandum and Articles of Association - Requirements for Holdings Exceeding Certain Percentages".

Amendment and termination

We may agree with the depositary to amend the deposit agreement and the ADRs without the consent of the ADS holders for any reason. If the amendment adds or increases fees or charges, except for taxes and other governmental charges or registration fees, cable, telex or facsimile transmission costs, delivery costs or other such expenses, or prejudices a substantial right of holders of Sanofi ADSs, it will only become effective 30 days after the depositary notifies such holders of the amendment. However, we may not be able to provide holders of Sanofi ADSs with prior notice of the effectiveness of any modifications or supplements that are required to accommodate compliance with applicable provisions of law, whether or not those modifications or supplements could be considered to be materially prejudicial to the substantial rights of holders of Sanofi ADSs. ***At the time an amendment becomes effective, such holders will be considered, by continuing to hold their ADR, to have agreed to the amendment and to be bound by the ADR and the deposit agreement as amended.***

The depositary will terminate the agreement if we ask it to do so. The depositary may also terminate the agreement if the depositary has told us that it would like to resign and we have not appointed a new depositary bank within 90 days. In both cases, the depositary must notify holders of Sanofi ADSs at least 30 days before termination.

After termination, the depositary and its agents will be required to do only the following under the deposit agreement: (1) collect distributions on the deposited securities, (2) sell rights and other property as provided in the deposit agreement and (3) deliver shares and other deposited securities upon cancellation of ADRs. Six months or more after termination, the depositary may sell any remaining deposited securities by public or private sale. After that, the depositary will hold the money it receives on the sale, as well as any other cash it is holding under the deposit agreement, for the pro rata benefit of the holders of Sanofi ADSs that have not surrendered their Sanofi ADSs. It will have no liability for interest. Upon termination of the deposit agreement, the depositary's only obligations will be to account for the proceeds of the sale and other cash and with respect to indemnification. After termination, our only obligation will be with respect to indemnification and to pay certain amounts to the depositary.

Limitations on obligations and liability to holders of Sanofi ADSs

The deposit agreement expressly limits our obligations and the obligations of the depositary, and it limits our liability and the liability of the depositary. In particular, please note the following:

- we and the depositary are obligated only to take the actions specifically set forth in the deposit agreement without gross negligence or bad faith;
- we and the depositary are not liable if either is prevented or delayed by law or circumstances beyond its control from performing its obligations under the deposit agreement;
- we and the depositary are not liable if either exercises, or fails to exercise, any discretion permitted under the deposit agreement;
- we and the depositary have no obligation to become involved in a lawsuit or other proceeding related to the Sanofi ADSs or the deposit agreement on holders' behalf or on behalf of any other party, unless indemnity satisfactory to it against all expense and liability is furnished as often as may be required;
- we and the depositary are not liable for the acts or omissions made by, or the insolvency of, any securities depository, clearing agency or settlement system or the custodian, subject to certain exceptions and to the extent the custodian is not a branch or affiliate of JPMorgan;
- the depositary is not liable for the price received in connection with any sale of securities, the timing thereof or any delays, acts, omissions to act, errors, defaults or negligence on the part of the party so retained in connection with any such sale or proposed sale;
- we and the depositary may rely without any liability upon any written notice, request, direction, instruction or other document believed by either of us to be genuine and to have been signed or presented by the proper parties; and
- we and the depositary are not liable for any action or nonaction taken in reliance upon the advice of or information from legal counsel, accountants, any person presenting ordinary shares for deposit, any ADS holder, or any other person believed in good faith to be competent to give such advice or information.

In addition, the depositary will not be liable for any acts or omissions made by a successor depositary. Moreover, neither we nor the depositary nor any of our respective agents will be liable to any holder of Sanofi ADSs for any indirect, special, punitive or consequential damages.

Pursuant to the terms of the deposit agreement, we and the depositary have agreed to indemnify each other under certain circumstances.

Requirements for depositary actions

Before the depositary will deliver or register the transfer of Sanofi ADSs, make a distribution on Sanofi ADSs or process a withdrawal of shares, the depositary may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;
- production of satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and

- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver Sanofi ADSs, register transfers of Sanofi ADSs or permit withdrawals of shares when the transfer books of the depositary or our transfer books are closed, or at any time if the depositary or we think it advisable to do so.

Right to receive the shares underlying the Sanofi ADSs

Holders have the right to cancel their Sanofi ADSs and withdraw the underlying Sanofi ordinary shares at any time except:

- when temporary delays arise when we or the depositary have closed our transfer books or the deposit of shares in connection with voting at a shareholders' meeting, or the payment of dividends;
- when the holder or other holders of Sanofi ADSs seeking to withdraw shares owe money to pay fees, taxes and similar charges; or
- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to Sanofi ADSs or to the withdrawal of shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Pre-release of Sanofi ADSs

The provisions of our form of second amended and restated deposit agreement, as amended, do not permit the pre-release of the Sanofi ADSs.

Part II

Item 13. Defaults, Dividend Arrearages and Delinquencies

N/A

Item 14. Material Modifications to the Rights of Security Holders

N/A

Item 15. Controls and Procedures

(a) Our Chief Executive Officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) as of the end of the period covered by this Form 20-F, have concluded that, as of such date, our disclosure controls and procedures were effective to ensure that material information relating to Sanofi was timely made known to them by others within Sanofi.

(b) Report of Management on Internal Control Over Financial Reporting.

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Management assessed the effectiveness of internal control over financial reporting as of December 31, 2020 based on the framework in "Internal Control – Integrated Framework" (2013 framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Based on that assessment, management has concluded that the Company's internal control over financial reporting was effective as of December 31, 2020 to provide reasonable assurance regarding the reliability of its financial reporting and the preparation of its financial statements for external purposes, in accordance with generally accepted accounting principles.

Due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements, and can only provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The effectiveness of the Company's internal control over financial reporting has been audited by PricewaterhouseCoopers Audit and Ernst & Young et Autres, independent registered public accounting firms, as stated in their report on the Company's internal control over financial reporting as of December 31, 2020, which is included herein. See paragraph (c) of the present Item 15., below.

(c) See report of PricewaterhouseCoopers Audit and Ernst & Young et Autres, independent registered public accounting firms, included under "Item 18. Financial Statements" on page F-3.

(d) There were no changes to our internal control over financial reporting that occurred during the period covered by this Form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 16A. Audit Committee Financial Expert

Our Board of Directors has determined that Fabienne Lecorvaisier, Christophe Babule, Gilles Schnepp and Diane Souza, the four directors serving on the Audit Committee, are independent financial experts within the meaning of Section 407 of the Sarbanes-Oxley Act of 2002.

The Board of Directors deemed Fabienne Lecorvaisier to be a financial expert based on her education and experience in corporate finance in various international banks and as Chief Financial Officer of Essilor and Air Liquide. She is now Executive Vice President, in charge of Finance, Operations Control and General Secretariat of Air Liquide Group.

The Board of Directors deemed Christophe Babule to be a financial expert based on his education and experience in audit and corporate finance in major corporations and as Executive Vice President and Chief Financial Officer of L'Oréal. He has also served as director of L'Oréal USA Inc.

The Board of Directors deemed Gilles Schnepp to be a financial expert based on his education and experience in audit and corporate finance in major corporations and as a member of the board of directors of Saint-Gobain and Danone. He also served as Chairman and Chief Executive Officer of Legrand and Vice President of the supervisory board of PSA (now Stellantis).

The Board of Directors deemed Diane Souza to be a financial expert based on her education (she is a certified public accountant) and experience in audit and tax in major international corporations, as Chief Financial Officer of Aetna's Guaranteed Products business, and as Chief Executive Officer of the UnitedHealthcare Specialty Benefits.

The Board of Directors has determined that all four directors meet the independence criteria of US Securities and Exchange Commission Rule 10A-3, although only Fabienne Lecorvaisier, Gilles Schnepp and Diane Souza meet the French AFEP-MEDEF Code criteria of independence applied by the Board of Directors for general corporate governance purposes (see Item 16G, below).

Item 16B. Code of Ethics

We have adopted a financial code of ethics, as defined in Item 16B. of Form 20-F under the Exchange Act. Our financial code of ethics applies to our Chief Executive Officer, Chief Financial Officer, Chief Accounting Officer and other officers performing similar functions, as designated from time to time. Our financial code of ethics is available on our website at www.sanofi.com (information on our website is not incorporated by reference in this annual report). A copy of our financial code of ethics may also be obtained free of charge by addressing a written request to the attention of Individual Shareholder Relations at our headquarters in Paris. We will disclose any amendment to the provisions of such financial code of ethics on our website.

Item 16C. Principal Accountants' Fees and Services

See Note E. to our consolidated financial statements included at Item 18 of this annual report.

Item 16D. Exemptions from the Listing Standards for Audit Committees

N/A

Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

In 2020, Sanofi made the following purchases of its ordinary shares.

Period	(A) Total Number of Shares Purchased	(B) Average Price Paid per Share	(C) Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs[a]	(D) Approximate Value of Shares that May Yet Be Purchased Under the Plans or Programs[b]
January 2020	3,082,800.00	90.06	3,082,800.00	14,691
February 2020	900,139	91.50	900,139	14,609
November 2020	1,421,882	85.06	1,421,882	18,687
December 2020	4,263,544	79.52	4,263,544	18,348

(a) The Company was authorized to repurchase up to €14,968,745,640 of shares for a period of eighteen months (i.e., through October 30, 2020) by the Annual Shareholders' Meeting held on April 30, 2019. Then, the Company was authorized to repurchase up to €18,807,691,650 of shares for a period of eighteen months (i.e., through October 28, 2021) by the Annual Shareholders' Meeting held on April 28, 2020.

(b) Millions of euros.

For more information see "Item 10.B. Memorandum and Articles of Association — Use of Share Repurchase Programs".

Item 16F. Change in Registrant's Certifying Accountant

N/A

Item 16G. Corporate Governance

Sanofi is incorporated under the laws of France, with securities listed on regulated public markets in the United States (NASDAQ Global Select Market) and France (Euronext Paris). Consequently, as described further in our annual report, our corporate governance framework reflects the mandatory provisions of French corporate law, the securities laws and regulations of France and the United States and the rules of the aforementioned public markets.

As a "foreign private issuer," as defined in rules promulgated under the US Securities Exchange Act of 1934, as amended, (the "Exchange Act"), Sanofi is permitted, pursuant to NASDAQ Stock Market Rule 5615(a)(3), to follow its home country practice in lieu of certain NASDAQ corporate governance requirements applicable to US corporations listed on the NASDAQ Stock Market. Sanofi has informed NASDAQ that it intends to follow corporate governance standards under French law to the extent permitted by the NASDAQ Stock Market rules and US securities laws, as further discussed below.

We generally follow the "AFEP-MEDEF" corporate governance recommendations for French listed issuers (hereafter referred to as the "AFEP-MEDEF Code"). As a result, our corporate governance framework is similar in many respects to, and provides investor protections that are comparable to – or in some cases, more stringent than – the corresponding rules of the NASDAQ Global Select Market. Nevertheless, there are important differences to keep in mind.

In line with NASDAQ Stock Market rules applicable to domestic issuers, a majority of Sanofi's Board of Directors is comprised of independent directors. Sanofi evaluates the independence of members of our Board of Directors using the standards of the French AFEP-MEDEF Code as the principal reference. We believe that AFEP-MEDEF's overarching criteria for independence – no relationship of any

kind whatsoever with the Company, its group or the management of either that is such as to color a Board member's judgment – are on the whole consistent with the goals of the NASDAQ Global Select Market's rules although the specific tests proposed under the two standards may vary on some points. We have complied with the Audit Committee independence and other requirements of the Rule 10A-3 under the Exchange Act, adopted pursuant to the Sarbanes-Oxley Act of 2002. Our Audit Committee includes one member, Christophe Babule, who is considered non-independent under the AFEP-MEDEF Code, and which is permitted under the AFEP-MEDEF Code, although this would not be permitted under the rules of the NASDAQ Global Select Market for domestic issuers. Each member of our Compensation Committee meets the independence standards of the AFEP-MEDEF Code and the independence requirements of NASDAQ's listing rules and Rule 10A-3 promulgated under the Sarbanes-Oxley Act of 2002, as amended.

Sanofi follows the recommendation of the AFEP-MEDEF Code that at least one meeting not attended by the company's executive officers be organized each year. Accordingly, Sanofi's Board Charter provides that the Board of Directors shall organize at least two meetings a year without its executive officers, thereby providing the Chairman with the option to include or not directors representing employees or any other Group employee, as the case may require, depending on the agenda of the meeting. Sanofi's practice in that respect departs from NASDAQ's Listing Rule 5605(b)(2), which provides that independent directors must have regularly scheduled meetings at which only independent directors are present.

Under French law, the committees of our Board of Directors are advisory only, and where the NASDAQ Rule 5600 Series would vest certain decision-making powers with specific committees by delegation (e.g. the appointment of Sanofi's auditors by the Audit Committee), under French law, our Board of Directors remains the only competent body to take such decisions, albeit taking into account the recommendation of the relevant committees. Additionally, under French corporate law, it is the shareholders of Sanofi voting at the Shareholders' General Meeting that have the authority to appoint our auditors upon consideration of the proposal of our Board of Directors, although our Board Charter provides that the Board of Directors will make its proposal on the basis of the recommendation of our Audit Committee. We believe that this requirement of French law, together with the additional legal requirement that two sets of statutory auditors be appointed, is in line with the NASDAQ Global Select Market's underlying goal of ensuring that the audit of our accounts be conducted by auditors independent from company management.

In addition to the oversight role of our Compensation Committee for questions of management compensation including by way of equity, under French law any option or restricted share plans or other share capital increases, whether for the benefit of senior management or employees, may only be adopted by the Board of Directors pursuant to and within the limits of a shareholder resolution approving the related capital increase and delegating to the Board the authority to implement such operations.

As described above, a number of issues, which could be resolved directly by a board or its committees in the United States, require the additional protection of direct shareholder consultation in France.

Because we are a "foreign private issuer" as described above, our Chief Executive Officer and our Chief Financial Officer issue the certifications required by §Section 302 and §Section 906 of the Sarbanes-Oxley Act of 2002 on an annual basis (with the filing of our annual report on Form 20-F) rather than on a quarterly basis as would be the case of a US corporation filing quarterly reports on Form 10-Q.

French corporate law provides that the Board of Directors must vote to approve a broadly defined range of transactions that could potentially create conflicts of interest between Sanofi on the one hand and its directors and Chief Executive Officer on the other hand, which are then presented to shareholders for approval at the next annual meeting. This legal safeguard operates in place of certain provisions of the NASDAQ Stock Market Listing Rules.

Sanofi is governed by the French Commercial Code, which provides that an ordinary general meeting of the shareholders may validly deliberate when first convened if the shareholders present or represented hold at least one-fifth of the voting shares. If it is reconvened, no quorum is required. The French Commercial Code further provides that the shareholders at an extraordinary general meeting may validly deliberate when first convened only if the shareholders present or represented hold at least one-quarter of the voting shares and, if reconvened, one-fifth of the voting shares. Therefore, Sanofi will not follow NASDAQ's Rule 5620(c), which provides that the minimum quorum requirement for a meeting of shareholders is 33⅓% of the outstanding common voting shares of the company. In accordance with the provisions of the French Commercial Code, the required majority for the adoption of a decision is a simple majority (for an ordinary general meeting of the shareholders) or a two-thirds majority (for an extraordinary general meeting) of the votes cast by the shareholders present or represented.

Item 16H. Mine Safety Disclosure

N/A

Part III

Item 17. Financial Statements

See Item 18.

Item 18. Financial Statements

See pages F-1 through F-100 incorporated herein by reference.

Item 19. Exhibits

1.1.	Articles of association (statuts) of Sanofi (English translation).
1.2.	Board Charter (Règlement Intérieur) of Sanofi (English translation).
2.	The total amount of long-term debt securities authorized under any instrument does not exceed 10% of the total assets of the Company and its subsidiaries on a consolidated basis. We hereby agree to furnish to the SEC, upon its request, a copy of any instrument defining the rights of holders of long-term debt of the Company or of its subsidiaries for which consolidated or unconsolidated financial statements are required to be filed.
8.1.	List of significant subsidiaries, see “Item 4. Information on the Company - C. Organizational Structure” of this 20-F.
12.1.	Certification by Paul Hudson, Chief Executive Officer, required by Section 302 of the Sarbanes-Oxley Act of 2002.
12.2.	Certification by Jean-Baptiste Chasseloup de Chatillon, Principal Financial Officer, required by Section 302 of the Sarbanes-Oxley Act of 2002.
13.1.	Certification by Paul Hudson, Chief Executive Officer, required by Section 906 of the Sarbanes-Oxley Act of 2002.
13.2.	Certification by Jean-Baptiste Chasseloup de Chatillon, Principal Financial Officer, required by Section 906 of the Sarbanes-Oxley Act of 2002.
23.1.	Consent of Ernst & Young et Autres dated March 4, 2021.
23.2.	Consent of PricewaterhouseCoopers Audit dated March 4, 2021.

Signatures

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Sanofi	
By:	/s/ PAUL HUDSON
Name:	**Paul Hudson**
Title:	**Chief Executive Officer**

Date: March 4, 2021

Report of Independent Registered Public Accounting Firms

To the Shareholders and the Board of Directors of Sanofi,

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Sanofi and its subsidiaries (together the "Company") as of December 31, 2020, 2019, and 2018, and the related consolidated income statements, statements of comprehensive income, statements of changes in equity and statements of cash flows for each of the three years in the period ended December 31, 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020, 2019, and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board and in conformity with International Financial Reporting Standards as endorsed by the European Union.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 4, 2021 expressed an unqualified opinion thereon.

Change in Accounting Principle

As discussed in Note D.3.2 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2019.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are public accounting firms registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Recoverable amount of other intangible assets

Description of the Matter

Other intangible assets amounted to €18,421 million at December 31, 2020. Management recognized an impairment loss of €330 million for the year ended December 31, 2020. As described in Notes B.6.1., D.4. and D.5. to the consolidated financial statements, other intangible assets not yet available for use are tested for impairment annually and whenever events or circumstances indicate that impairment might exist. Other intangible assets that generate separate cash flows and assets included in cash-generating units (CGUs) are assessed for impairment when events or changes in circumstances indicate that the asset or CGU may be impaired. Management estimates the recoverable amount of the asset and recognizes an impairment loss if the carrying amount of the asset exceeds its recoverable amount. The recoverable amount of the asset is the higher of its fair value less costs to sell or its value in use. Value in use is determined by management using estimated future cash flows generated by the asset or CGU which are discounted and prepared using the same methods as those used in the initial measurement of the assets and on the basis of medium-term strategic plans. Management cash flow projections include significant assumptions related to mid and long-term sales forecasts; perpetual growth or attrition rate, where applicable; discount rate; and probability of success of current research and development projects.

The principal considerations for our determination that auditing the recoverable amount of other intangible assets is especially challenging, subjective, and required complex auditor judgment related to the significant judgments made by management when developing the significant assumptions utilized in the future cash flow projections as described above. In addition, the audit effort involved professionals with specialized skills and knowledge to assist in performing the audit procedures and evaluating the audit evidence obtained.

How We Addressed the Matter in Our Audit

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These audit procedures included obtaining an understanding of the process and assessing the design and testing the operating effectiveness of controls relating to management's other intangible assets impairment assessment, including controls over the significant assumptions used in the impairment testing of the other intangible assets. These audit procedures also included, among others, evaluating the appropriateness of the discounted cash flow model; testing the completeness, accuracy, and relevance of underlying data used in the model; and evaluating the significant assumptions used by management as described above. Evaluating management's assumptions involved evaluating whether the assumptions used by management were reasonable by considering the current and past performance of other intangible assets in comparison to management's previous forecasts and current trends, the consistency of forecasts and assumptions with external market and industry data, and whether these assumptions were consistent with evidence obtained in other areas of the audit such as internal company communications and presentations, external communications and analyst reports. We involved our professionals with specialized skills and knowledge to assist us in the assessment of the discount rate used by management.

Valuation of the discounts relating to Sanofi's business in the United States - Medicaid, Medicare and Managed Care Rebates

Description of the Matter

As described in Notes B.13.1. and D.23. to the consolidated financial statements, products sold in the United States are covered by various Government and State programs (of which Medicaid and Medicare are the most significant) and are subject to commercial agreements with healthcare authorities and certain customers and distributors. Estimates of discounts and rebates incentives (hereinafter the "Discounts") to be provided to customers under those arrangements are recognized as a reduction of gross sales in the period in which the underlying sales are recognized. Provisions for the Medicaid, Medicare and Managed Care rebates amounted to €1,015 million, €726 million and €692 million respectively at December 31, 2020. The Discounts estimated by management are based on the nature and patient profile of the underlying product; the applicable regulations or the specific terms and conditions of contracts with governmental authorities, wholesalers and other customers; historical data relating to similar contracts, in the case of qualitative and quantitative rebates ; past experience and sales growth trends for the same or similar products; actual inventory levels in distribution channels, monitored by Sanofi using internal sales data and externally provided data; market trends including competition, pricing and demand.

The principal considerations for our determination that auditing the Discounts relating to the Company's business in the United States is especially challenging and required complex auditor judgment related to the significant judgment by management due to significant measurement uncertainty involved in developing these provisions. These provisions are estimated based on multiple factors as described above.

How We Addressed the Matter in Our Audit

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These audit procedures included obtaining an understanding of the process and assessing the design and testing the operating effectiveness of controls relating to management's estimates of the provisions for the Discounts relating to the Company's business in the United States, including controls over the assumptions used to estimate these Discounts. These procedures also included, among others, developing an independent estimate of the Discounts by utilizing third party data on inventory levels in distribution channels, volume, changes to price, the terms of the specific rebate programs, and the historical trend of actual rebate claims paid. The independent estimate was compared to the rebate accruals recorded by the Company. Additionally, these procedures included testing actual rebate claims paid and evaluating the contractual terms of the Company's rebate agreements.

Provisions for product liability, litigation and other risks and contingent liabilities

Description of the Matter

Provisions for product liability, litigation and other risks were recorded in an amount of €1,262 million as at December 31, 2020. As described in Notes B.12., D.19.3. and D.22. to the consolidated financial statements, the Company records such provisions when an outflow of resources is probable and the amount of the outflow can be reliably estimated. The Company also discloses the contingent liabilities in circumstances where management is unable to make a reasonable estimate of the expected financial effect that will result from ultimate resolution of the proceeding, or a cash outflow is not probable.

The pharmaceutical industry is highly regulated, which increases the inherent risk of litigation and arbitration. The Company is involved in litigation, arbitration and other legal proceedings. These proceedings are typically related to litigation concerning product liability claims, intellectual property rights, competition law and trade practices, as well as claims under warranties or indemnification arrangements relating to business divestments. The issues raised by these claims are highly complex and subject to substantial uncertainties; therefore, the probability of loss and an estimation of damages are difficult to ascertain.

The principal considerations for our determination that auditing the provision for product liability, litigation and other risks, and contingent liabilities is especially challenging, subjective and required complex auditor judgment resulted from the determination that the measurement of the provisions can involve a series of complex judgments about future events and can rely substantially on estimates and assumptions by management. There is inherent uncertainty related to these cases and in estimating the likelihood and outcome of the cases.

How We Addressed the Matter in Our Audit

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These audit procedures included obtaining an understanding of the process and assessing the design and testing the operating effectiveness of controls relating to management's evaluation of the provisions for product liability, litigation and other risks, including controls over determining whether a loss is probable and whether the amount of loss can be reasonably estimated, as well as the need for and the level of financial statement disclosures. These procedures also included, among others, obtaining and evaluating the letters of audit inquiry with internal and external legal counsels, evaluating management's assessment regarding whether an unfavorable outcome is reasonably possible or probable and reasonably estimable through the evaluation of the legal letters and summaries of the proceedings and lawsuit correspondence. We also evaluated the Company's disclosures for contingent liabilities.

Uncertain tax positions

Description of the Matter

As described in Notes B.22., D.14, D.19.4. and D.30. to the consolidated financial statements, the Company has recorded liabilities pertaining to uncertain tax positions of €1,164 million as of December 31, 2020. The Company operates in multiple tax jurisdictions, carrying out potentially complex transactions that require management to make judgments and estimates as to the tax impact of those transactions. The positions adopted by the Company in tax matters are based on its interpretation of tax laws and regulations. Some of those positions may be subject to uncertainty. In such cases, the Company assesses the amount of the tax liability on the basis of the following assumptions: that its position will be examined by one or more tax authorities on the basis of all relevant information; that a technical assessment is carried out with reference to legislation, case law, regulations, and established practice; and that each position is assessed individually (or collectively where appropriate), with no offset or aggregation between positions. Those assumptions are assessed on the basis of facts and circumstances existing at the end of the reporting period. When an uncertain tax liability is regarded as probable, it is measured on the basis of the Company's best estimate.

The principal considerations for our determination that auditing uncertain tax positions is especially challenging, subjective and required complex auditor judgment related to the significant judgment by management when determining the liability for uncertain tax positions, including a high degree of estimation uncertainty of certain assumptions and interpretations of the tax laws and regulations underlying the positions. In addition, we involved tax professionals to assist in performing these procedures and evaluating the audit evidence obtained.

How We Addressed the Matter in Our Audit

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These audit procedures included obtaining an understanding of the process and assessing the design and testing the operating effectiveness of controls relating the identification and recognition of the liability for uncertain tax positions, management's assessment and interpretation of tax laws and its evaluation of which tax positions may not be sustained upon audit and controls over measurement of the liability. These procedures also included, among others, testing the completeness and accuracy of the underlying data used in the calculation of the liability for uncertain tax positions and evaluating the assumptions used by management when determining its tax positions, the status of tax audits and investigations, and the potential impact of past claims. Our tax professionals assisted in evaluating the reasonableness of management's assessments by comparing the positions taken by management with tax regulations and past decisions from tax authorities and where applicable, evaluating opinions from the Company's external tax advisors. We also evaluated the disclosures provided in the notes to the consolidated financial statements concerning uncertain tax positions.

/s/ PricewaterhouseCoopers Audit

/s/ Dominique Ménard

/s/ Ernst & Young et Autres

Ernst & Young et Autres and PricewaterhouseCoopers Audit have respectively served as the Company's auditors since 1986 and 1999.

Neuilly-sur-Seine and Paris-La Défense, March 4, 2021

Report of Independent Registered Public Accounting Firms

To the Shareholders and the Board of Directors of Sanofi,

Opinion on Internal Control over Financial Reporting

We have audited Sanofi and its subsidiaries' (together the "Company") internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) (the "COSO criteria"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2020, 2019 and 2018, and the related consolidated income statements, statements of comprehensive income, statements of changes in equity and statements of cash flows for each of the three years in the period ended December 31, 2020, and the related notes (collectively referred to as the "consolidated financial statements"). Our report dated March 4, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Report of Management on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are public accounting firms registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers Audit

/s/ Dominique Ménard

/s/ Ernst & Young et Autres

Neuilly-sur-Seine and Paris-La Défense, March 4, 2021

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2020 Consolidated financial statements

The financial statements are presented in accordance with International Financial Reporting Standards (IFRS).

Consolidated balance sheets - assets

(€ million)	Note	December 31, 2020	December 31, 2019	December 31, 2018
Property, plant and equipment	**D.3.1.**	9,365	9,717	9,651
Right-of-use assets[(a)]	**D.3.2.**	1,198	1,300	—
Goodwill	**D.4.**	44,364	44,519	44,235
Other intangible assets	**D.4.**	18,421	16,572	21,889
Investments accounted for using the equity method	**D.6.**	201	3,591	3,402
Other non-current assets	**D.7.**	2,734	2,503	2,815
Non-current income tax assets		248	164	156
Deferred tax assets	**D.14.**	4,212	5,434	4,613
Non-current assets		**80,743**	**83,800**	**86,761**
Inventories	**D.9.**	8,352	7,994	7,477
Accounts receivable	**D.10.**	7,491	7,937	7,260
Other current assets	**D.11.**	2,737	2,445	2,023
Current income tax assets		1,208	808	894
Cash and cash equivalents	**D.13. - D.17.1.**	13,915	9,427	6,925
Current assets		**33,703**	**28,611**	**24,579**
Assets held for sale or exchange	**D.8.**	83	325	68
Total assets		**114,529**	**112,736**	**111,408**

(a) Includes the effects of first-time application of IFRS 16 on leases using the modified retrospective approach, effective January 1, 2019.

Consolidated balance sheets - equity and liabilities

(€ million)	Note	December 31, 2020	December 31, 2019	December 31, 2018
Equity attributable to equity holders of Sanofi	D.15.	63,001	58,934	58,876
Equity attributable to non-controlling interests	D.16.	146	174	159
Total equity		**63,147**	**59,108**	**59,035**
Long-term debt	D.17.1.	19,745	20,131	22,007
Non-current lease liabilities[(a)]	D.17.2.	931	987	—
Non-current liabilities related to business combinations and to non-controlling interests	D.18.	387	508	963
Non-current provisions and other non-current liabilities	D.19.	7,536	7,641	7,206
Non-current income tax liabilities	D.19.4.	1,733	1,680	1,407
Deferred tax liabilities	D.14.	1,770	2,294	3,414
Non-current liabilities		**32,102**	**33,241**	**34,997**
Accounts payable		5,295	5,313	5,041
Current liabilities related to business combinations and to non-controlling interests	D.18.	218	292	341
Current provisions and other current liabilities	D.19.5.	10,132	9,703	8,969
Current income tax liabilities		604	258	392
Current lease liabilities[(a)]	D.17.2.	232	261	—
Short-term debt and current portion of long-term debt	D.17.1.	2,767	4,554	2,633
Current liabilities		**19,248**	**20,381**	**17,376**
Liabilities related to assets held for sale or exchange	D.8.	32	6	—
Total equity and liabilities		**114,529**	**112,736**	**111,408**

(a) Includes the effects of first-time application of IFRS 16 on leases using the modified retrospective approach, effective January 1, 2019.

Consolidated income statements

(€ million)	Note	2020	2019	2018
Net sales	**D.35.1.**	**36,041**	**36,126**	**34,463**
Other revenues		1,328	1,505	1,214
Cost of sales		(12,157)	(11,976)	(11,435)
Gross profit		**25,212**	**25,655**	**24,242**
Research and development expenses		(5,529)	(6,018)	(5,894)
Selling and general expenses		(9,390)	(9,883)	(9,859)
Other operating income	**D.25.**	696	825	484
Other operating expenses	**D.26.**	(1,415)	(1,207)	(548)
Amortization of intangible assets	**D.4.**	(1,681)	(2,146)	(2,170)
Impairment of intangible assets	**D.5.**	(330)	(3,604)	(718)
Fair value remeasurement of contingent consideration	**D.12. - D.18.**	124	238	117
Restructuring costs and similar items	**D.27.**	(1,064)	(1,062)	(1,480)
Other gains and losses, and litigation	**D.28.**	136	327	502
Gain on Regeneron investment arising from transaction of May 29, 2020	**D.1.**	7,382	—	—
Operating income		**14,141**	**3,125**	**4,676**
Financial expenses	**D.29.**	(390)	(444)	(435)
Financial income	**D.29.**	53	141	164
Income before tax and investments accounted for using the equity method	**D.35.1.**	**13,804**	**2,822**	**4,405**
Income tax expense	**D.30.**	(1,813)	(139)	(481)
Share of profit/(loss) from investments accounted for using the equity method	**D.31.**	359	255	499
Net income excluding the exchanged/held-for-exchange Animal Health business		**12,350**	**2,938**	**4,423**
Net income/(loss) of the exchanged/held-for-exchange Animal Health business[(a)]		—	(101)	(13)
Net income		**12,350**	**2,837**	**4,410**
Net income attributable to non-controlling interests	**D.32.**	36	31	104
Net income attributable to equity holders of Sanofi		**12,314**	**2,806**	**4,306**
Average number of shares outstanding (million)	**D.15.9.**	1,253.6	1,249.9	1,247.1
Average number of shares after dilution (million)	**D.15.9.**	1,260.1	1,257.1	1,255.2
• Basic earnings per share (in euros)		9.82	2.24	3.45
• Basic earnings per share excluding the exchanged/held-for-exchange Animal Health business (in euros)		9.82	2.33	3.46
• Diluted earnings per share (in euros)		9.77	2.23	3.43
• Diluted earnings per share excluding the exchanged/held-for-exchange Animal Health business (in euros)		9.77	2.31	3.44

(a) Net income/losses arising from the divestment of the Animal Health business are presented separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations).

Consolidated statements of comprehensive income

(€ million)	Note	2020	2019	2018
Net income		**12,350**	**2,837**	**4,410**
Attributable to equity holders of Sanofi		*12,314*	*2,806*	*4,306*
Attributable to non-controlling interests		*36*	*31*	*104*
Other comprehensive income:				
• Actuarial gains/(losses)	**D.15.7.**	(268)	(382)	201
• Change in fair value of equity instruments included in financial assets and financial liabilities	**D.15.7.**	320	106	(537)
• Tax effects	**D.15.7.**	(40)	113	31
Sub-total: items not subsequently reclassifiable to profit or loss (A)		**12**	**(163)**	**(305)**
• Change in fair value of debt instruments included in financial assets	**D.15.7.**	15	28	(4)
• Change in fair value of cash flow hedges	**D.15.7.**	4	(13)	3
• Change in currency translation differences	**D.15.7.**	(3,978)	751	1,194
• Tax effects	**D.15.7.**	(63)	47	71
Sub-total: items subsequently reclassifiable to profit or loss (B)		**(4,022)**	**813**	**1,264**
Other comprehensive income for the period, net of taxes (A+B)		**(4,010)**	**650**	**959**
Comprehensive income		**8,340**	**3,487**	**5,369**
Attributable to equity holders of Sanofi		*8,324*	*3,457*	*5,269*
Attributable to non-controlling interests		*16*	*30*	*100*

Consolidated statements of changes in equity

(€ million)	Share capital	Additional paid-in capital	Treasury shares	Reserves and retained earnings	Stock options and other share-based payments	Other comprehensive income	Attributable to equity holders of Sanofi	Attributable to non-controlling interests	Total equity
Balance at January 1, 2018[a]	**2,508**	**58**	**(14)**	**52,804**	**3,298**	**(584)**	**58,070**	**169**	**58,239**
First-time application of IFRS 9	—	—	—	839	—	(852)	(13)	—	(13)
Other comprehensive income for the period	—	—	—	(305)	—	1,268	963	(4)	959
Net income for the period	—	—	—	4,306	—	—	4,306	104	4,410
Comprehensive income for the period	**—**	**—**	**—**	**4,001**	**—**	**1,268**	**5,269**	**100**	**5,369**
Dividend paid out of 2017 earnings (€3.03 per share)	—	—	—	(3,773)	—	—	(3,773)	—	(3,773)
Payment of dividends to non-controlling interests	—	—	—	—	—	—	—	(97)	(97)
Share repurchase program[b]	—	—	(1,100)	—	—	—	(1,100)	—	(1,100)
Reduction in share capital[b]	(24)	(213)	880	(643)	—	—	—	—	—
Share-based payment plans:									
• Exercise of stock options[b]	2	57	—	—	—	—	59	—	59
• Issuance of restricted shares and vesting of existing restricted shares[b][d]	4	(4)	80	(80)	—	—	—	—	—
• Employee share ownership plan[b]	5	115	—	—	—	—	120	—	120
• Proceeds from sale of treasury shares on exercise of stock options	—	—	1	—	—	—	1	—	1
• Value of services obtained from employees	—	—	—	—	284	—	284	—	284
• Tax effects of the exercise of stock options	—	—	—	—	14	—	14	—	14
Other changes arising from issuance of restricted shares[c]	—	—	—	13	—	—	13	—	13
Change in non-controlling interests without loss of control	—	—	—	(68)	—	—	(68)	3	(65)
Change in non-controlling interests arising from divestment	—	—	—	—	—	—	—	(16)	(16)
Balance at December 31, 2018	**2,495**	**13**	**(153)**	**53,093**	**3,596**	**(168)**	**58,876**	**159**	**59,035**

(€ million)	Share capital	Additional paid-in capital	Treasury shares	Reserves and retained earnings	Stock options and other share-based payments	Other comprehensive income	Attributable to equity holders of Sanofi	Attributable to non-controlling interests	Total equity
Balance at January 1, 2019	**2,495**	**13**	**(153)**	**53,093**	**3,596**	**(168)**	**58,876**	**159**	**59,035**
Other comprehensive income for the period	—	—	—	(162)	—	813	651	(1)	650
Net income for the period	—	—	—	2,806	—	—	2,806	31	2,837
Comprehensive income for the period	**—**	**—**	**—**	**2,644**	**—**	**813**	**3,457**	**30**	**3,487**
Dividend paid out of 2018 earnings (€3.07 per share)	—	—	—	(3,834)	—	—	(3,834)	—	(3,834)
Payment of dividends to non-controlling interests	—	—	—	—	—	—	—	(14)	(14)
Share repurchase program[(b)]	—	—	(12)	—	—	—	(12)	—	(12)
Share-based payment plans:									
• Exercise of stock options[(b)]	6	141	—	—	—	—	147	—	147
• Issuance of restricted shares and vesting of existing restricted shares[(b)(d)]	7	(7)	153	(153)	—	—	—	—	—
• Proceeds from sale of treasury shares on exercise of stock options	—	—	3	—	—	—	3	—	3
• Value of services obtained from employees	—	—	—	—	252	—	252	—	252
• Tax effects of the exercise of stock options	—	—	—	—	15	—	15	—	15
Other changes arising from issuance of restricted shares[(c)]	—	—	—	30	—	—	30	—	30
Change in non-controlling interests without loss of control	—	—	—	(7)	—	—	(7)	(1)	(8)
Other[(e)]	—	—	—	7	—	—	7	—	7
Balance at December 31, 2019	**2,508**	**147**	**(9)**	**51,780**	**3,863**	**645**	**58,934**	**174**	**59,108**

Consolidated statements of changes in equity

(€ million)	Share capital	Additional paid-in capital	Treasury shares	Reserves and retained earnings	Stock options and other share-based payments	Other comprehensive income	Attributable to equity holders of Sanofi	Attributable to non-controlling interests	Total equity
Balance at January 1, 2020	**2,508**	**147**	**(9)**	**51,780**	**3,863**	**645**	**58,934**	**174**	**59,108**
Other comprehensive income for the period	—	—	—	13	—	(4,003)	(3,990)	(20)	(4,010)
Net income for the period	—	—	—	12,314	—	—	12,314	36	12,350
Comprehensive income for the period	**—**	**—**	**—**	**12,327**	**—**	**(4,003)**	**8,324**	**16**	**8,340**
Dividend paid out of 2019 earnings (€3.15 per share)	—	—	—	(3,937)	—	—	(3,937)	—	(3,937)
Payment of dividends to non-controlling interests	—	—	—	—	—	—	—	(44)	(44)
Share repurchase program[(b)]	—	—	(822)	—	—	—	(822)	—	(822)
Share-based payment plans:									
• Exercise of stock options[(b)]	2	49	—	—	—	—	51	—	51
• Issuance of restricted shares and vesting of existing restricted shares[(b)(d)]	3	(3)	126	(126)	—	—	—	—	—
• Employee share ownership plan	5	169	—	—	—	—	174	—	174
• Value of services obtained from employees	—	—	—	—	274	—	274	—	274
• Tax effects of the exercise of stock options	—	—	—	—	1	—	1	—	1
Other changes arising from issuance of restricted shares[(c)]	—	—	—	2	—	—	2	—	2
Balance at December 31, 2020	**2,518**	**362**	**(705)**	**60,046**	**4,138**	**(3,358)**	**63,001**	**146**	**63,147**

(a) Includes the effects of first-time application of IFRS 15 on revenue recognition.

(b) See Notes D.15.1., D.15.3., D.15.4. and D.15.5.

(c) Issuance of restricted shares to former employees of the Animal Health business and the European Generics business subsequent to the date of divestment.

(d) This line includes the use of existing shares to fulfill vested rights under restricted share plans.

(e) This line includes the impact of the settlement of a put option granted to non-controlling interests in connection with a divestment.

Consolidated statements of cash flows

(€ million)	Note	2020	2019	2018
Net income attributable to equity holders of Sanofi		**12,314**	**2,806**	**4,306**
Net (income)/loss of the exchanged/held-for-exchange Animal Health business		—	101	13
Non-controlling interests, excluding BMS[a]	**D.32.**	36	31	22
Share of undistributed earnings from investments accounted for using the equity method		(339)	(192)	(471)
Depreciation, amortization and impairment of property, plant and equipment, right-of-use assets and intangible assets[b]		3,684	7,452	4,279
Gains and losses on disposals of non-current assets, net of tax[c]		(301)	(286)	(797)
Gain on Regeneron investment arising from transaction of May 29, 2020, net of tax[h]	**D.1.**	(6,880)	—	—
Net change in deferred taxes		(214)	(1,753)	(727)
Net change in non-current provisions and other non-current liabilities[d]		(142)	58	(265)
Cost of employee benefits (stock options and other share-based payments)	**D.15.2. - D.15.3. - D.15.8.**	274	252	284
Impact of the workdown of acquired inventories remeasured at fair value	**D.35.1.**	53	3	114
Other profit or loss items with no cash effect[i]		(711)	(309)	69
Operating cash flow before changes in working capital and excluding the exchanged/held-for-exchange Animal Health business		**7,774**	**8,163**	**6,827**
(Increase)/decrease in inventories		(593)	(547)	(701)
(Increase)/decrease in accounts receivable		(134)	(462)	(35)
Increase/(decrease) in accounts payable		86	169	270
Net change in other current assets and other current liabilities		316	421	(814)
Net cash provided by/(used in) operating activities excluding the exchanged/held-for-exchange Animal Health business[e]		**7,449**	**7,744**	**5,547**
Acquisitions of property, plant and equipment and intangible assets	**D.3. - D.4.**	(2,114)	(1,816)	(1,977)
Acquisitions of consolidated undertakings and investments accounted for using the equity method[f]	**D.1. - D.18.**	(5,336)	(488)	(12,857)
Acquisitions of other equity investments	**D.7.**	(137)	(38)	(137)
Proceeds from disposals of property, plant and equipment, intangible assets and other non-current assets, net of tax[g]		918	1,224	2,163
Net proceeds from sale of Regeneron shares on May 29, 2020	**D.1.**	10,370	—	—
Net change in other non-current assets		(113)	(94)	(58)
Net cash provided by/(used in) investing activities excluding the exchanged/held-for-exchange Animal Health business		**3,588**	**(1,212)**	**(12,866)**
Net cash inflow from the exchange of the Animal Health business for BI's Consumer Healthcare business		**—**	**154**	**(6)**
Issuance of Sanofi shares	**D.15.1.**	203	162	177
Dividends paid:				
• to shareholders of Sanofi		(3,937)	(3,834)	(3,773)
• to non-controlling interests, excluding BMS[a]		(44)	(14)	(14)
Payments received/(made) on changes of ownership interest in a subsidiary without loss of control		—	(7)	(77)
Additional long-term debt contracted	**D.17.1.**	2,019	1,997	9,677
Repayments of long-term debt	**D.17.1.**	(3,952)	(2,067)	(787)
Repayments of lease liabilities[b]		(234)	(267)	—
Net change in short-term debt	**D.17.1.**	282	(154)	(168)
Acquisitions of treasury shares	**D.15.4.**	(822)	(9)	(1,101)
Net cash provided by/(used in) financing activities excluding the exchanged/held-for-exchange Animal Health business		**(6,485)**	**(4,193)**	**3,934**
Impact of exchange rates on cash and cash equivalents		**(64)**	**9**	**1**
Net change in cash and cash equivalents		**4,488**	**2,502**	**(3,390)**
Cash and cash equivalents, beginning of period		**9,427**	**6,925**	**10,315**
Cash and cash equivalents, end of period	**D.13.**	**13,915**	**9,427**	**6,925**

(a) See Note C.2.
(b) Includes the effects of first-time application of IFRS16 on leases using the modified retrospective approach, effective January 1,2019.
(c) Includes non-current financial assets.
(d) This line item includes contributions paid to pension funds (see Note D.19.1.).

(e) Including:

	2020	2019	2018
• Income tax paid	(2,051)	(1,695)	(2,058)
• Interest paid	(315)	(379)	(313)
• Interest received	37	92	72
• Dividends received from non-consolidated entities	—	—	1

(f) This line item includes payments made in respect of contingent consideration identified and recognized as a liability in business combinations.

(g) This line item includes proceeds from disposals of investments in consolidated entities and of other non-current financial assets. For 2020, it includes the sale to Baxter of operations relating to Seprafilm® for a selling price before taxes of €311 million and the divestment of certain established prescription products for €97 million before taxes, plus contingent consideration of €167 million before taxes relating to a past divestment. For 2019, it includes the proceeds from the divestments of Sanofi's entire equity interests in Alnylam for €706 million and in MyoKardia for €118 million (see Note D.7.1.). For 2018, it includes an amount of €1,598 million (net of transaction costs) for the divestment of the European Generics business (see Note D.2.2.).

(h) The gain on the sale of Regeneron shares is presented net of taxes, including deferred taxes of €115 million.

(i) This line mainly comprises unrealized foreign exchange gains and losses arising on the remeasurement of monetary items in non-functional currencies, and on instruments used to hedge such items.

Notes to the Consolidated Financial Statements

Introduction

Sanofi, together with its subsidiaries (collectively “Sanofi”, “the Group” or “the Company”), is a global healthcare leader engaged in the research, development and marketing of therapeutic solutions focused on patient needs.

Sanofi is listed in Paris (Euronext: SAN) and New York (Nasdaq: SNY).

The consolidated financial statements for the year ended December 31, 2020, and the notes thereto, were signed off by the Sanofi Board of Directors on February 4, 2021.

A/ Basis of preparation

A.1. International financial reporting standards (IFRS)

The consolidated financial statements cover the twelve-month periods ended December 31, 2020, 2019 and 2018.

In accordance with Regulation No. 1606/2002 of the European Parliament and Council of July 19, 2002 on the application of international accounting standards, Sanofi has presented its consolidated financial statements in accordance with IFRS since January 1, 2005. The term “IFRS” refers collectively to international accounting and financial reporting standards (IASs and IFRSs) and to interpretations of the interpretations committees (SIC and IFRIC) with mandatory application as of December 31, 2020.

The consolidated financial statements of Sanofi as of December 31, 2020 have been prepared in compliance with IFRS as issued by the International Accounting Standards Board (IASB) and with IFRS as endorsed by the European Union as of December 31, 2020. Sanofi has also early adopted, with effect from January 1, 2020, the second amendment to IFRS 9 on interest rate benchmark reform, which was endorsed by the European Union between the end of the reporting period and the date on which the financial statements were closed off (see Note A.2.2.).

IFRS as endorsed by the European Union as of December 31, 2020 are available under the heading “IFRS Financial Statements” via the following web link:

https://www.efrag.org/Endorsement.

The consolidated financial statements have been prepared in accordance with the IFRS general principles of fair presentation, going concern, accrual basis of accounting, consistency of presentation, materiality, and aggregation.

A.2. New standards, amendments and interpretations

A.2.1. New standards applicable from January 1, 2020

During 2018, the IASB published a number of amendments mandatorily applicable at the earliest from January 1, 2020 onwards. These include “Definition of a Business” (amendment to IFRS 3), issued October 22, 2018, which applies prospectively to business combinations from January 1, 2020 onwards. Those amendments do not have a material impact on the consolidated financial statements for the year ended December 31, 2020.

On May 28, 2020, the IASB issued “Covid-19-Related Rent Concessions”, an amendment to IFRS 16. The amendment, which came into force on October 12, 2020, allows lessees not to account for rent concessions as lease modifications if they are a direct consequence of Covid-19 and meet certain conditions. The impact of first-time application of this amendment was immaterial.

In its consolidated financial statements for the year ended December 31, 2019, and with no material impact, Sanofi (i) early adopted the Phase 1 amendment to IFRS 9 relating to interest rate benchmark reform and (ii) in light of the IFRIC agenda decision of November 2019, reviewed the lease term of contracts cancellable without the payment of a penalty, either by the lessor or the lessee, in order to take into account the concept of "economic penalty".

A.2.2. New pronouncements issued by the IASB and applicable from 2021 or later

This note describes standards, amendments and interpretations issued by the IASB that will have mandatory application in 2021 or subsequent years, and Sanofi’s position regarding future application.

On January 23, 2020, the IASB issued “Classification of Liabilities as Current or Non-current”, an amendment to IAS 1. On May 14, 2020, the IASB issued “Reference to the Conceptual Framework”, an amendment to IFRS 3; “Proceeds before Intended Use”, an amendment to IAS 16; “Onerous Contracts – Cost of Fulfilling a Contract”, an amendment to IAS 37; and “Annual Improvements to IFRS standards 2018-2020”. Sanofi does not expect a material impact from those amendments, which are applicable at the earliest from January 1, 2022 (subject to endorsement by the European Union). Sanofi will not early adopt those amendments.

On August 27, 2020, the IASB issued a second amendment (Phase 2) to IFRS 9, relating to interest rate benchmark reform. Sanofi has early adopted that amendment in the consolidated financial statements for the year ended December 31, 2020. The hedging instruments contracted by Sanofi affected by interest rate benchmark reform are the interest rate swaps described in note D.20b.), maturing from 2022.

Fair value hedging relationships consist of swapping fixed-rate euro-denominated bonds to the overnight benchmark rate applicable in euros (Eonia), with a perfect alignment of critical terms between hedged items and hedging instruments. Consequently, those hedging relationships currently have no ineffective portion, and that will remain the case once Eonia is replaced by Ester, the new euro overnight benchmark rate.

Cash flow hedging relationships consist of swapping floating-rate synthetic debt (combination of fixed-rate bonds and fixed-to-Eonia interest rate swaps) to fixed rates, with the same perfect alignment of critical terms between hedged items and hedging instruments. Sanofi expects that Eonia will be replaced by Ester simultaneously in the interest rate swap contracts affected, and hence believes that the cash flow hedging relationships in question will remain fully effective. Consequently, Sanofi does not expect the interest rate benchmark reform to have a material impact on its hedging relationships.

A.3. Use of estimates and judgments

The preparation of financial statements requires management to make reasonable estimates and assumptions based on information available at the date of the finalization of the financial statements. Those estimates and assumptions may affect the reported amounts of assets, liabilities, revenues and expenses in the financial statements, and disclosures of contingent assets and contingent liabilities as of the date of the review of the financial statements. Examples of estimates and assumptions include:

- amounts deducted from sales for projected sales returns, chargeback incentives, rebates and price reductions (see Notes B.13 and D.23.);
- impairment of property, plant and equipment, intangible assets, and investments accounted for using the equity method (see Notes B.6. and D.5.);
- the valuation of goodwill and the valuation and estimated useful life of acquired intangible assets (see Notes B.3.2., B.4., D.4. and D.5.);
- the measurement of equity investments in unquoted entities (see Notes B.8.5. and D.12.);
- the measurement of contingent consideration receivable in connection with asset divestments (see Notes B.8.5. and D.12.) and of contingent consideration payable (see Notes B.3. and D.18.);
- the measurement of financial assets at amortized cost (see Note B.8.5.);
- the amount of post-employment benefit obligations (see Notes B.23. and D.19.1.);
- the amount of liabilities or provisions for restructuring, litigation, tax risks and environmental risks (see Notes B.12., B.19., B.20., D.19. and D.22.); and
- the amount of deferred tax assets resulting from tax losses available for carry-forward and deductible temporary differences (see Notes B.22. and D.14.).

Actual results could differ from these estimates.

A.4. Hyperinflation

Under IAS 29, (Financial Reporting in Hyperinflationary Economies), non-monetary balance sheet items must be restated using a general price index; monetary items are not restated. Items in the income statement and the statement of comprehensive income must be restated by applying the change in the general price index from the dates when the income and expense items were initially recorded in the financial statements.

In Lebanon, the cumulative inflation rate over the last three years is in excess of 100%, based on a combination of indices used to measure inflation in that country. On November 10, 2020, the IPTF (International Practices Task Force) recommended that Lebanon be treated as a hyperinflationary economy. Consequently, Sanofi decided to apply IAS 29 with effect from 2020. The resulting monetary foreign exchange loss in respect of the impact of hyperinflation in Lebanon was recognized in the Sanofi financial statements as of December 31, 2020, and is immaterial.

In 2020, Sanofi continued to account for subsidiaries based in Venezuela using the full consolidation method, on the basis that the criteria for control as specified in IFRS 10 (Consolidated Financial Statements) are still met.

In 2018, the Venezuelan government made further changes to the foreign exchange system. At the end of August 2018 the “DICOM” rate, which had been the compulsory rate since the end of January 2018, was abolished and replaced by the “PETRO” rate with a floating US dollar/bolivar parity. At the same time, the strong bolivar (“VEF”) was also replaced by a new currency known as the sovereign bolivar (“VES”), reflecting a 1-for-100,000 devaluation. Consequently, the contribution of the Venezuelan subsidiaries to the consolidated financial statements is immaterial.

In Argentina, the cumulative rate of inflation over the last three years is in excess of 100%, based on a combination of indices used to measure inflation in that country. Consequently, Sanofi has treated Argentina as a hyperinflationary economy from July 1, 2018 onwards, and applies IAS 29. As a result, an immaterial monetary foreign exchange loss was recognized in the Sanofi financial statements as of December 31, 2020, December 31, 2019 and December 31, 2018 in respect of the impact of hyperinflation in Argentina.

A.5. Withdrawal of the United Kingdom from the European Union

The withdrawal of the United Kingdom from the European Union does not pose any major issues for Sanofi, and Sanofi does not expect a material impact on the consolidated financial statements.

A.6. Covid-19 pandemic

Covid-19, confirmed as a pandemic by the World Health Organization on March 11, 2020, has led to a global health crisis. Sanofi has assessed the impact of the uncertainties created by the pandemic. As of December 31, 2020, those uncertainties have not appreciably called into question the estimates and assumptions made by management (see Note A.3.). Sanofi will continue to reassess those estimates and assumptions as the situation evolves.

Effect of the Covid-19 pandemic on the valuation of goodwill and other intangible assets

In accordance with IAS 36 (Impairment of Assets), Sanofi conducts impairment tests on goodwill allocated to each of its cash generating units and on other intangible assets not yet available for use (such as capitalized in-process research and development) on an annual basis, regardless of whether there is an indication they might have become impaired (see Notes B.6. and D.5.). The impairment tests conducted as of December 31, 2020 found no indications of potential impairment. Sanofi also conducted impairment tests on certain intangible assets as a result of specific circumstances not directly related to the Covid-19 pandemic; the outcomes of those tests are described in Note D.5.

Effect of the Covid-19 pandemic on accounts receivable

As of December 31, 2020, Sanofi estimated the value of its accounts receivable using the expected loss method (see Note B.8.1.). Nothing was identified that would indicate a material increase in expected credit risk, especially as regards Sanofi's principal customers (see Note D.34.).

Effect of the Covid-19 pandemic on the liquidity position

The Covid-19 pandemic has not had a negative impact on Sanofi's liquidity position.

Effect of the Covid-19 pandemic on the presentation of the income statement

The effects of the Covid-19 pandemic are presented in the relevant line items of the income statement, according to the function or nature of the income or expense.

A.7. Agreements relating to the recombinant Covid-19 vaccine candidate developed by Sanofi in collaboration with GSK

On February 18, 2020, Sanofi and the US Department of Health and Human Services extended their research and development partnership to leverage Sanofi's previous development work on a SARS vaccine to attempt to unlock a fast path forward for developing a Covid-19 vaccine. Under the terms of the collaboration, the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response within the US Department of Health and Human Services, is helping to fund the research and development undertaken by Sanofi. Sanofi has recognized the BARDA funding as a deduction from the research and development expenses incurred, in accordance with IAS 20 (Accounting for Government Grants and Disclosure of Government Assistance). The amount of government assistance received and expenses incurred in 2020 is immaterial.

On April 14, 2020, Sanofi and GlaxoSmithKline (GSK) entered into a collaboration agreement to develop a recombinant Covid-19 vaccine candidate, with Sanofi contributing its S-protein Covid-19 antigen (based on recombinant DNA technology) and GSK contributing its pandemic adjuvant technology. Sanofi is leading clinical development and the registration process for the vaccine.

On July 31, 2020, the recombinant Covid-19 vaccine candidate developed by Sanofi in collaboration with GSK was selected by the US government's Operation Warp Speed (OWS) program. Under the OWS, the US government is providing funds to support further development of the vaccine, including clinical trials and scaling-up of manufacturing capacity. The agreement also provides for the supply of 100 million doses of the vaccine, with payment due at the time vaccine doses are provided.

Sanofi has recognized the funding received from the US government as a deduction from (i) the development expenses incurred or (ii) the acquisition cost of property, plant and equipment acquired, in accordance with IAS 20 (Accounting for Government Grants and Disclosure of Government Assistance).

As regards delivery of the 100 million vaccine doses, Sanofi considers this to be a contract with a customer, to be accounted for in accordance with IFRS 15 (Revenue from Contracts with Customers).

In September 2020, Sanofi and GSK signed pre-order contracts with the Canadian and UK governments and with the European Union for doses of the vaccine candidate. As of the date of signature, those contracts do not constitute a firm commitment to purchase since the governments and the EU can decide whether or not to proceed with their purchase based on the results of the clinical trial. If the pre-orders are confirmed, the amounts received by Sanofi on the date of signature of the pre-order contracts will be deducted from the amount due in respect of the firm order for the vaccines.

In accordance with IFRS 15 (see Note B.13.1.), Sanofi recognizes revenue when control over the product is transferred to the customer (for vaccines, transfer of control is usually determined by reference to the terms of release and acceptance of batches of vaccine). The total amount received by Sanofi on signature of the vaccine pre-order contracts was €252 million. In accordance with IFRS 15, those payments are customer contract liabilities (i.e. an obligation for the entity to supply goods to a customer, for which consideration has been received from the customer). They are presented within "Customer contract liabilities" in the balance sheet (see Note D.19.5.), and within "Net change in other current assets and other current liabilities" in the statement of cash flows.

On December 11, 2020, Sanofi and GSK published interim clinical trial results showing an immune response comparable to patients who recovered from Covid-19 in adults aged 18 to 49 years, but an insufficient response in older adults. The two companies reaffirmed their intention to ongoing development of the vaccine candidate but decided to initiate a Phase IIb study with an improved antigen formulation in the first quarter of 2021 in order to provide high-level immune response across all age groups. As of December 31, 2020 this new stage in the development of the vaccine candidate had not altered the funding commitments made by the US government, or the pre-orders placed by Canada, the UK and the EU.

B/ Summary of significant accounting policies

B.1. Basis of consolidation

In accordance with IFRS 10 (Consolidated Financial Statements), the consolidated financial statements of Sanofi include the financial statements of entities that Sanofi controls directly or indirectly, regardless of the level of the equity interest in those entities. An entity is controlled when Sanofi has power over the entity, exposure or rights to variable returns from its involvement with the entity, and the ability to affect those returns through its power over the entity. In determining whether control exists, potential voting rights must be taken into account if those rights are substantive, in other words they can be exercised on a timely basis when decisions about the relevant activities of the entity are to be taken.

Entities consolidated by Sanofi are referred to as “subsidiaries”. Entities that Sanofi controls by means other than voting rights are referred to as “consolidated structured entities”.

In accordance with IFRS 11 (Joint Arrangements), Sanofi classifies its joint arrangements (i.e. arrangements in which Sanofi exercises joint control with one or more other parties) either as a joint operation or a joint venture. In the case of a joint operation, Sanofi recognizes the assets and liabilities of the operation in proportion to its rights and obligations relating to those assets and liabilities. Joint ventures are accounted for using the equity method.

Sanofi exercises joint control over a joint arrangement when decisions relating to the relevant activities of the arrangement require the unanimous consent of Sanofi and the other parties with whom control is shared.

Sanofi exercises significant influence over an entity when it has the power to participate in the financial and operating policy decisions of that entity, but does not have the power to exercise control or joint control over those policies.

In accordance with IAS 28 (Investments in Associates and Joint Ventures), the equity method is used to account for joint ventures (i.e. entities over which Sanofi exercises joint control) and for associates (i.e. entities over which Sanofi exercises significant influence).

Under the equity method, the investment is initially recognized at cost, and subsequently adjusted to reflect changes in the net assets of the associate or joint venture. IAS 28 does not specify the treatment to be adopted on first-time application of the equity method to an investee following a step acquisition. Consequently, by reference to paragraph 10 of IAS 28, Sanofi has opted to apply the cost method, whereby the carrying amount of the investment represents the sum of the historical cost amounts for each step in the acquisition. As of the date on which the equity method is first applied, goodwill (which is included in the carrying amount of the investment) is determined for each acquisition step. The same applies to subsequent increases in the percentage interest in the equity-accounted investment.

When the criteria of IFRS 5 are met, Sanofi recognizes the equity interest within the balance sheet line item ***Assets held for sale or exchange***. The equity method is not applied to equity interests that are classified as held-for-sale assets.

Transactions between consolidated companies are eliminated, as are intragroup profits.

A list of the principal companies included in the consolidation in 2020 is presented in Note F.

B.2. Foreign currency translation

B.2.1. Accounting for foreign currency transactions in the financial statements of consolidated entities

Non-current assets (other than receivables) and inventories acquired in foreign currencies are translated into the functional currency using the exchange rate prevailing at the acquisition date.

Monetary assets and liabilities denominated in foreign currencies are translated using the exchange rate prevailing at the end of the reporting period. The gains and losses resulting from foreign currency translation are recorded in the income statement. However, foreign exchange gains and losses arising from the translation of advances between consolidated subsidiaries for which settlement is neither planned nor likely to occur in the foreseeable future are recognized in equity, in the line item ***Change in currency translation differences***.

B.2.2. Foreign currency translation of the financial statements of foreign entities

Sanofi presents its consolidated financial statements in euros (€). In accordance with IAS 21 (The Effects of Changes in Foreign Exchange Rates), each subsidiary accounts for its transactions in the currency that is most representative of its economic environment (the functional currency).

All assets and liabilities are translated into euros using the exchange rate of the subsidiary’s functional currency prevailing at the end of the reporting period. Income statements are translated using a weighted average exchange rate for the period, except in the case of foreign subsidiaries in a hyperinflationary economy. The resulting currency translation difference is recognized as a separate component of equity in the consolidated statement of comprehensive income, and is recognized in the income statement only when the subsidiary is sold or is wholly or partially liquidated.

B.3. Business combinations and transactions with non-controlling interests

B.3.1. Accounting for business combinations, transactions with non-controlling interests and loss of control

Business combinations are accounted for in accordance with IFRS 3 (Business Combinations) and IFRS 10 (Consolidated Financial Statements).

Business combinations are accounted for using the acquisition method. Under this method, the acquiree's identifiable assets and liabilities that satisfy the recognition criteria of IFRS 3 (Business Combinations) are measured initially at their fair values at the date of acquisition, except for (i) non-current assets classified as held for sale (which are measured at fair value less costs to sell) and (ii) assets and liabilities that fall within the scope of IAS 12 (Income Taxes) and IAS 19 (Employee Benefits). Restructuring liabilities are recognized as a liability of the acquiree only if the acquiree has an obligation as of the acquisition date to carry out the restructuring.

The principal accounting rules applicable to business combinations and transactions with non-controlling interests include:

- Acquisition-related costs are recognized as an expense on the acquisition date, as a component of ***Operating income***.
- Contingent consideration is recognized in equity if the contingent payment is settled by delivery of a fixed number of the acquirer's equity instruments; otherwise, it is recognized in ***Liabilities related to business combinations***. Contingent consideration is recognized at fair value at the acquisition date irrespective of the probability of payment. If the contingent consideration was originally recognized as a financial liability, subsequent adjustments to the liability are recognized in profit or loss in the line item ***Fair value remeasurement of contingent consideration***, unless the adjustment is made within the twelve months following the acquisition date and relates to facts and circumstances existing as of that date.
- Goodwill may be calculated on the basis of either (i) the entire fair value of the acquiree, or (ii) a share of the fair value of the acquiree proportionate to the interest acquired. This option is elected for each acquisition individually.

Purchase price allocations are performed under the responsibility of management, with assistance from an independent valuer in the case of major acquisitions. IFRS 3 does not specify an accounting treatment for contingent consideration arising from a business combination made by an entity prior to the acquisition of control in that entity and carried as a liability in the acquired entity's balance sheet. The accounting treatment applied by Sanofi to such a liability is to measure it at fair value as of the acquisition date and to report it in the line item ***Liabilities related to business combinations and to non-controlling interests***, with subsequent remeasurements recognized in profit or loss. This treatment is consistent with the accounting applied to contingent consideration in the books of the acquirer.

B.3.2. Goodwill

The excess of the cost of an acquisition over Sanofi's interest in the fair value of the identifiable assets and liabilities of the acquiree is recognized as goodwill at the date of the business combination.

Goodwill arising on the acquisition of subsidiaries is shown in a separate balance sheet line item, whereas goodwill arising on the acquisition of investments accounted for using the equity method is recorded in ***Investments accounted for using the equity method***.

Goodwill arising on foreign operations is expressed in the functional currency of the country concerned and translated into euros using the exchange rate prevailing at the end of the reporting period.

In accordance with IAS 36 (Impairment of Assets), goodwill is carried at cost less accumulated impairment (see Note B.6.).

Goodwill is tested for impairment annually and whenever events or circumstances indicate that impairment might exist. Such events or circumstances include significant changes more likely than not to have an other-than-temporary impact on the substance of the original investment.

B.4. Other intangible assets

Other intangible assets are initially measured at acquisition cost or production cost, including any directly attributable costs of preparing the asset for its intended use, or (in the case of assets acquired in a business combination) at fair value as of the date of the business combination. Intangible assets are amortized on a straight line basis over their useful lives.

The useful lives of other intangible assets are reviewed at the end of each reporting period. The effect of any adjustment to useful lives is recognized prospectively as a change in accounting estimate.

Amortization of other intangible assets is recognized in the income statement within ***Amortization of intangible assets*** except for amortization charged against (i) acquired or internally-developed software and (ii) other rights of an industrial or operational nature, which is recognized in the relevant classification of expense by function.

Sanofi does not own any intangible assets with an indefinite useful life, other than goodwill.

Intangible assets (other than goodwill) are carried at cost less accumulated amortization and accumulated impairment, if any, in accordance with IAS 36 (see Note B.6.).

B.4.1. Research and development not acquired in a business combination

Internally generated research and development

Under IAS 38, research expenses are recognized in profit or loss when incurred.

Internally generated development expenses are recognized as an intangible asset if, and only if, all the following six criteria can be demonstrated: (a) the technical feasibility of completing the development project; (b) Sanofi's intention to complete the project; (c) Sanofi's

ability to use the project; (d) the probability that the project will generate future economic benefits; (e) the availability of adequate technical, financial and other resources to complete the project; and (f) the ability to measure the development expenditure reliably.

Due to the risks and uncertainties relating to regulatory approval and to the research and development process, the six criteria for capitalization are usually considered not to have been met until the product has obtained marketing approval from the regulatory authorities. Consequently, internally generated development expenses arising before marketing approval has been obtained, mainly the cost of clinical trials, are generally expensed as incurred within ***Research and development expenses***.

Some industrial development expenses (such as those incurred in developing a second-generation synthesis process) are incurred after marketing approval has been obtained, in order to improve the industrial process for an active ingredient. To the extent that the six IAS 38 criteria are considered as having been met, such expenses are recognized as an asset in the balance sheet within ***Other intangible assets*** as incurred. Similarly, some clinical trials, for example those undertaken to obtain a geographical extension for a molecule that has already obtained marketing approval in a major market, may in certain circumstances meet the six capitalization criteria under IAS 38, in which case the related expenses are recognized as an asset in the balance sheet within ***Other intangible assets***.

Separately acquired research and development

Payments for separately acquired research and development are capitalized within ***Other intangible assets*** provided that they meet the definition of an intangible asset: a resource that is (i) controlled by Sanofi, (ii) expected to provide future economic benefits for Sanofi, and (iii) identifiable (i.e. it is either separable or arises from contractual or legal rights). Under paragraph 25 of IAS 38, the first condition for capitalization (the probability that the expected future economic benefits from the asset will flow to the entity) is considered to be satisfied for separately acquired research and development. Consequently, upfront and milestone payments to third parties related to pharmaceutical products for which marketing approval has not yet been obtained are recognized as intangible assets, and amortized on a straight line basis over their useful lives beginning when marketing approval is obtained.

Payments under research and development arrangements relating to access to technology or to databases, and payments made to purchase generics dossiers, are also capitalized, and amortized over the useful life of the intangible asset.

Subcontracting arrangements, payments for research and development services, and continuous payments under research and development collaborations which are unrelated to the outcome of that collaboration, are expensed over the service term.

B.4.2. Other intangible assets not acquired in a business combination

Licenses other than those related to pharmaceutical products and research projects, in particular software licenses, are capitalized at acquisition cost, including any directly attributable cost of preparing the software for its intended use. Software licenses are amortized on a straight line basis over their useful lives for Sanofi (three to five years).

Internally generated costs incurred to develop or upgrade software are capitalized if the IAS 38 recognition criteria are satisfied, and amortized on a straight line basis over the useful life of the software from the date on which the software is ready for use.

B.4.3. Other intangible assets acquired in a business combination

Other intangible assets acquired in a business combination which relate to in-process research and development and currently marketed products and are reliably measurable are identified separately from goodwill, measured at fair value, and capitalized within ***Other intangible assets*** in accordance with IFRS 3 (Business Combinations) and IAS 38 (Intangible Assets). The related deferred tax liability is also recognized if a deductible or taxable temporary difference exists.

In-process research and development acquired in a business combination is amortized on a straight line basis over its useful life from the date of receipt of marketing approval.

Rights to products currently marketed by Sanofi are amortized on a straight line basis over their useful lives, determined on the basis of cash flow forecasts which take into account the patent protection period of the marketed product.

B.5. Property, plant and equipment owned and leased

B.5.1. Property, plant and equipment owned

Property, plant and equipment is initially measured and recognized at acquisition cost, including any directly attributable cost of preparing the asset for its intended use, or (in the case of assets acquired in a business combination) at fair value as of the date of the business combination. The component-based approach to accounting for property, plant and equipment is applied. Under this approach, each component of an item of property, plant and equipment with a cost which is significant in relation to the total cost of the item and which has a different useful life from the other components must be depreciated separately.

After initial measurement, property, plant and equipment is carried at cost less accumulated depreciation and impairment, except for land which is carried at cost less impairment.

Subsequent costs are not recognized as assets unless (i) it is probable that future economic benefits associated with those costs will flow to Sanofi and (ii) the costs can be measured reliably.

Borrowing costs attributable to the financing of items of property, plant and equipment, and incurred during the construction period, are capitalized as part of the acquisition cost of the item.

Government grants relating to property, plant and equipment are deducted from the acquisition cost of the asset to which they relate.

The depreciable amount of items of property, plant and equipment, net of any residual value, is depreciated on a straight line basis over the useful life of the asset. The useful life of an asset is usually equivalent to its economic life.

The customary useful lives of property, plant and equipment are as follows:

Buildings	15 to 40 years
Fixtures	10 to 20 years
Machinery and equipment	5 to 15 years
Other	3 to 15 years

Useful lives and residual values of property, plant and equipment are reviewed annually. The effect of any adjustment to useful lives or residual values is recognized prospectively as a change in accounting estimate.

Depreciation of property, plant and equipment is recognized as an expense in the income statement, in the relevant classification of expense by function.

B.5.2. Property, plant and equipment leased

Effective from January 1, 2019 leases contracted by Sanofi have been accounted for in accordance with IFRS 16 (Leases). Sanofi recognizes a right-of-use asset and a lease liability for all of its lease contracts, except for (i) leases relating to low-value assets and (ii) short-term leases (12 months or less). Payments made in respect of leases not recognized on the balance sheet are recognized as an operating expense on a straight line basis over the lease term.

On commencement of a lease, the liability for future lease payments is discounted at the incremental borrowing rate, which is a risk-free rate adjusted to reflect the specific risk profile of each Sanofi entity. Because lease payments are spread over the lease term, Sanofi applies a discount rate based on the duration of those payments.

The payments used to determine the liability for future lease payments exclude non-lease components, but include fixed payments that Sanofi expects to make to the lessor over the estimated lease term.

After commencement of the lease, the liability for future lease payments is reduced by the amount of the lease payments made, and increased to reflect interest on the liability. In the event of a reassessment or modification of future lease payments, the lease liability is remeasured. The right-of-use asset - which is initially measured at cost including direct costs of the lessee, prepayments made at or prior to the commencement date, less lease incentives received and restoration costs - is depreciated on a straight line basis over the lease term, and tested for impairment as required.

Sanofi recognizes deferred taxes in respect of right-of-use assets and lease liabilities.

Leasehold improvements are depreciated over their economic life, which is capped at the lease term as determined under IFRS 16.

B.6. Impairment of property, plant and equipment, intangible assets, and investments accounted for using the equity method

B.6.1. Impairment of property, plant and equipment and intangible assets

In accordance with IAS 36 (Impairment of Assets), assets that generate separate cash flows and assets included in cash-generating units (CGUs) are assessed for impairment when events or changes in circumstances indicate that the asset or CGU may be impaired. A CGU is the smallest identifiable group of assets that generates cash inflows that are largely independent of the cash inflows from other assets or groups of assets.

Under IAS 36, each CGU or group of CGUs to which goodwill is allocated must (i) represent the lowest level within the entity at which the goodwill is monitored for internal management purposes, and (ii) not be larger than an operating segment determined in accordance with IFRS 8 (Operating Segments), before application of the IFRS 8 aggregation criteria (see Note B.26.).

Quantitative and qualitative indications of impairment (primarily relating to the status of the research and development portfolio, pharmacovigilance, patent litigation, and the launch of competing products) are reviewed at the end of each reporting period. If there is any internal or external indication of impairment, Sanofi estimates the recoverable amount of the asset or CGU.

Other intangible assets not yet available for use (such as capitalized in-process research and development), and CGUs or groups of CGUs that include goodwill, are tested for impairment annually whether or not there is any indication of impairment, and more frequently if any event or circumstance indicates that they might be impaired. Such assets are not amortized.

When there is an internal or external indication of impairment, Sanofi estimates the recoverable amount of the asset and recognizes an impairment loss if the carrying amount of the asset exceeds its recoverable amount. The recoverable amount of the asset is the higher of its fair value less costs to sell or its value in use. To determine value in use, Sanofi uses estimates of future cash flows generated by the asset or CGU, prepared using the same methods as those used in the initial measurement of the asset or CGU on the basis of medium-term strategic plans.

In the case of goodwill, estimates of future cash flows are based on a five-year strategic plan, an extrapolation of the cash flows over a further five-year period, and a terminal value. In the case of other intangible assets, the period used is based on the economic life of the asset.

Estimated cash flows are discounted at long-term market interest rates that reflect the best estimate by Sanofi of the time value of money, the risks specific to the asset or CGU, and economic conditions in the geographical regions in which the business activity associated with the asset or CGU is located.

Certain assets and liabilities that are not directly attributable to a specific CGU are allocated between CGUs on a basis that is reasonable, and consistent with the allocation of the corresponding goodwill.

Impairment losses arising on property, plant and equipment, on software and on certain rights are recognized in the relevant classification of expense by function.

Impairment losses arising on other intangible assets are recognized within ***Impairment of intangible assets*** in the income statement.

B.6.2. Impairment of investments accounted for using the equity method

In accordance with IAS 28 (Investments in Associates and Joint Ventures), Sanofi determines whether investments accounted for using the equity method may be impaired based on indicators such as default in contractual payments, significant financial difficulties, probability of bankruptcy, or a prolonged or significant decline in quoted market price. If an investment is impaired, the amount of the impairment loss is determined by applying IAS 36 (see Note B.6.1.) and recognized in ***Share of profit/(loss) from investments accounted for using the equity method***.

B.6.3. Reversals of impairment losses charged against property, plant and equipment, intangible assets, and investments accounted for using the equity method

At the end of each reporting period, Sanofi assesses whether events or changes in circumstances indicate that an impairment loss recognized in a prior period in respect of an asset (other than goodwill) or an investment accounted for using the equity method can be reversed. If this is the case, and the recoverable amount as determined based on the revised estimates exceeds the carrying amount of the asset, Sanofi reverses the impairment loss only to the extent of the carrying amount that would have been determined had no impairment loss been recognized for the asset.

Reversals of impairment losses in respect of other intangible assets are recognized within the income statement line item ***Impairment of intangible assets***, while reversals of impairment losses in respect of investments accounted for using the equity method are recognized within the income statement line item ***Share of profit/(loss) from investments accounted for using the equity method***. Impairment losses taken against goodwill are never reversed, unless the goodwill is part of the carrying amount of an investment accounted for using the equity method.

B.7. Assets held for sale or exchange and liabilities related to assets held for sale or exchange

In accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations), non-current assets and groups of assets are classified as held for sale in the balance sheet if their carrying amount will be recovered principally through a sale transaction rather than through continuing use. Within the meaning of IFRS 5, the term “sale” also includes exchanges for other assets.

Non-current assets or asset groups held for sale must be available for immediate sale in their present condition, subject only to terms that are usual and customary for sales of such assets, and a sale must be highly probable. Criteria used to determine whether a sale is highly probable include:

- the appropriate level of management must be committed to a plan to sell;
- an active program to locate a buyer and complete the plan must have been initiated;
- the asset must be actively marketed for sale at a price that is reasonable in relation to its current fair value;
- completion of the sale should be foreseeable within the twelve months following the date of reclassification to ***Assets held for sale or exchange***; and
- actions required to complete the plan should indicate that it is unlikely that significant changes to the plan will be made or that the plan will be withdrawn.

Before initial reclassification of the non-current asset (or asset group) to ***Assets held for sale or exchange***, the carrying amounts of the asset (or of all the assets and liabilities in the asset group) must be measured in accordance with the applicable standards.

Subsequent to reclassification to ***Assets held for sale or exchange***, the non-current asset (or asset group) is measured at the lower of carrying amount or fair value less costs to sell, with any write-down recognized by means of an impairment loss. Once a non-current asset has been reclassified as held for sale or exchange, it is no longer depreciated or amortized.

In a disposal of an equity interest leading to loss of control, all the assets and liabilities of the entity involved are classified as held-for-sale assets or liabilities within the balance sheet line items ***Assets held for sale or exchange*** or ***Liabilities related to assets held for sale or exchange***, provided that the disposal satisfies the IFRS 5 classification criteria.

The profit or loss generated by a held-for-sale asset group is reported in a separate line item in the income statement for the current period and for the comparative periods presented, provided that the asset group:

- represents a separate major line of business or geographical area of operations; or,
- is part of a single coordinated plan to dispose of a separate major line of business or geographical area of operations; or,
- is a subsidiary acquired exclusively with a view to resale.

In accordance with IFRS 10, transactions between companies that are held for sale or treated as discontinued operations and other consolidated companies are eliminated.

Events or circumstances beyond Sanofi's control may extend the period to complete the sale or exchange beyond one year without precluding classification of the asset (or disposal group) in ***Assets held for sale or exchange*** provided that there is sufficient evidence that Sanofi remains committed to the planned sale or exchange. Finally, in the event of changes to a plan of sale that requires an asset no longer to be classified as held for sale, IFRS 5 specifies the following treatment:

- The assets and liabilities previously classified as held for sale are reclassified to the appropriate balance sheet line items, with no restatement of comparative periods.
- Each asset is measured at the lower of (a) its carrying amount before the asset was reclassified as held for sale, adjusted for any depreciation, amortization or revaluation that would have been recognized if the asset had not been reclassified as held for sale, or (b) its recoverable amount at the date of reclassification.
- The backlog of depreciation, amortization and impairment not recognized while non-current assets were classified as held for sale must be reported in the same income statement line item that was used to report impairment losses arising on initial reclassification of assets as held for sale and gains or losses arising on the sale of such assets. In the consolidated income statement, those impacts are reported within the line item ***Other gains and losses, and litigation***.
- The net income of a business previously classified as discontinued or as held for sale or exchange and reported on a separate line in the income statement must be reclassified and included in net income from continuing operations, for all periods presented.
- In addition, segment information relating to the income statement and the statement of cash flows (acquisitions of non-current assets) must be disclosed in the notes to the financial statements in accordance with IFRS 8 (Operating Segments), and must also be restated for all prior periods presented.

B.8. Financial instruments

B.8.1. Non-derivative financial assets

In accordance with IFRS 9 (Financial Instruments) and IAS 32 (Financial Instruments: Presentation), Sanofi has adopted the classification of non-derivative financial assets described below. The classification used depends on (i) the characteristics of the contractual cash flows (i.e. whether they represent interest or principal) and (ii) the business model for managing the asset applied at the time of initial recognition.

Financial assets at fair value through other comprehensive income

These mainly comprise:

- quoted and unquoted equity investments that Sanofi does not hold for trading purposes and that management has designated at "fair value through other comprehensive income" on initial recognition. Gains and losses arising from changes in fair value are recognized in equity within the statement of comprehensive income in the period in which they occur. When such instruments are derecognized, the previously-recognized changes in fair value remain within ***Other comprehensive income***, as does the gain or loss on divestment. Dividends received are recognized in profit or loss for the period, within the line item ***Financial income***; and
- debt instruments whose contractual cash flows represent payments of interest or repayments of principal, and which are managed with a view to collecting cash flows and selling the asset. Gains and losses arising from changes in fair value are recognized in equity within the statement of comprehensive income in the period in which they occur. When such assets are derecognized, the cumulative gains and losses previously recognized in equity are reclassified to profit or loss for the period within the line items ***Financial income*** or ***Financial expenses***.

Financial assets at fair value through profit or loss

These mainly comprise:

- contingent consideration already carried in the books of an acquired entity or granted in connection with a business combination;
- instruments whose contractual cash flows represent payments of interest and repayments of principal, which are managed with a view to selling the asset;
- instruments that management has designated at "fair value through profit or loss" on initial recognition; and
- quoted and unquoted equity investments: equity instruments that are not held for trading and which management did not designate at "fair value through other comprehensive income" on initial recognition, and instruments that do not meet the IFRS definition of "equity instruments".

Gains and losses arising from changes in fair value are recognized in profit or loss within the line items ***Financial income*** or ***Financial expenses***. Dividends received are recognized in profit or loss for the period, within the line item ***Financial income***.

Fair value of equity investments in unquoted entities

On initial recognition of an equity investment in an entity not quoted in an active market, the fair value of the investment is the acquisition cost. Cost ceases to be a representative measure of the fair value of an unquoted equity investment when Sanofi identifies significant changes in the investee, or in the environment in which it operates. In such cases, an internal valuation is carried out, based mainly on growth forecasts or by reference to similar transactions contracted with third parties.

Financial assets measured at amortized cost

Financial assets at amortized cost comprise instruments whose contractual cash flows represent payments of interest and repayments of principal and which are managed with a view to collecting cash flows. The main assets in this category are loans and receivables. They are presented within the line items ***Other non-current assets***, ***Other current assets***, ***Accounts receivable*** and ***Cash and cash***

equivalents. Loans with a maturity of more than 12 months are presented in "Long-term loans and advances" within ***Other non-current assets***. These financial assets are measured at amortized cost using the effective interest method.

Impairment of financial assets measured at amortized cost

The main assets involved are accounts receivable. Accounts receivable are initially recognized at the amount invoiced to the customer. Impairment losses on trade accounts receivable are estimated using the expected loss method, in order to take account of the risk of payment default throughout the lifetime of the receivables. The expected credit loss is estimated collectively for all accounts receivable at each reporting date using an average expected loss rate, determined primarily on the basis of historical credit loss rates. However, that average expected loss rate may be adjusted if there are indications of a likely significant increase in credit risk. If a receivable is subject to a known credit risk, a specific impairment loss is recognized for that receivable. The amount of expected losses is recognized in the balance sheet as a reduction in the gross amount of accounts receivable. Impairment losses on accounts receivable are recognized within ***Selling and general expenses*** in the income statement.

B.8.2. Derivative instruments

Derivative instruments that do not qualify for hedge accounting are initially and subsequently measured at fair value, with changes in fair value recognized in the income statement in ***Other operating income*** or in ***Financial income*** or ***Financial expenses***, depending on the nature of the underlying economic item which is hedged.

Derivative instruments that qualify for hedge accounting are measured using the policies described in Note B.8.3. below.

IFRS 13 (Fair Value Measurement) requires counterparty credit risk to be taken into account when measuring the fair value of financial instruments. That risk is estimated on the basis of observable, publicly-available statistical data.

Policy on offsetting

In order for a financial asset and a financial liability to be presented as a net amount in the balance sheet under IAS 32, there must be:

(a) a legally enforceable right to offset; and

(b) the intention either to settle on a net basis, or to realize the asset and settle the liability simultaneously.

B.8.3. Hedging

As part of its overall market risk management policy, Sanofi enters into various hedging transactions involving derivative or non-derivative instruments; these may include forward contracts, currency swaps or options, interest rate swaps or options, cross-currency swaps, and debt placings or issues.

Such financial instruments are designated as hedging instruments and recognized using the hedge accounting principles of IFRS 9 when (a) there is formal designation and documentation of the hedging relationship, of how the effectiveness of the hedging relationship will be assessed, and of the underlying market risk management objective and strategy; (b) the hedged item and the hedging instrument are eligible for hedge accounting; and (c) there is an economic relationship between the hedged item and the hedging instrument, defined on the basis of a hedge ratio that is consistent with the underlying market risk management strategy, and the residual credit risk does not dominate the value changes that result from that economic relationship.

Fair value hedge

A fair value hedge is a hedge of the exposure to changes in fair value of an asset, liability or firm commitment that is attributable to one or more risk components and could affect profit or loss.

Changes in fair value of the hedging instrument and changes in fair value of the hedged item attributable to the hedged risk components are generally recognized in the income statement, within ***Other operating income*** for hedges related to operating activities, or within ***Financial income*** or ***Financial expenses*** for hedges related to investing or financing activities.

Cash flow hedge

A cash flow hedge is a hedge of the exposure to variability in cash flows from an asset, liability or highly probable forecast transaction that is attributable to one or more risk components and could affect profit or loss.

Changes in fair value of the hedging instrument attributable to the effective portion of the hedge are recognized directly in equity in the consolidated statement of comprehensive income. Changes in fair value attributable to the ineffective portion of the hedge are recognized in the income statement within ***Other operating income*** for hedges related to operating activities, and within ***Financial income*** or ***Financial expenses*** for hedges related to investing or financing activities.

Cumulative changes in fair value of the hedging instrument previously recognized in equity are reclassified to the income statement when the hedged transaction affects profit or loss. Those reclassified gains and losses are recognized within ***Other operating income*** for hedges related to operating activities, and within ***Financial income*** or ***Financial expenses*** for hedges related to investing or financing activities.

When a forecast transaction results in the recognition of a non-financial asset or liability, cumulative changes in the fair value of the hedging instrument previously recognized in equity are incorporated in the initial carrying amount of that asset or liability.

When the hedging instrument expires or is sold, terminated or exercised, the cumulative gain or loss previously recognized in equity remains separately recognized in equity and is not reclassified to the income statement, or recognized as an adjustment to the initial cost of the related non-financial asset or liability, until the forecast transaction occurs. However, if Sanofi no longer expects the forecast transaction to occur, the cumulative gain or loss previously recognized in equity is recognized immediately in profit or loss.

Hedge of a net investment in a foreign operation

In a hedge of a net investment in a foreign operation, changes in the fair value of the hedging instrument attributable to the effective portion of the hedge are recognized directly in equity in the consolidated statement of comprehensive income. Changes in fair value attributable to the ineffective portion of the hedge are recognized in the income statement within ***Financial income*** or ***Financial expenses***. When the investment in the foreign operation is sold, the changes in the fair value of the hedging instrument previously recognized in equity are reclassified to the income statement within ***Financial income*** or ***Financial expenses***.

Cost of hedging

As part of its market risk management policy, Sanofi may designate currency options or interest rate options as hedging instruments, the effectiveness of which is measured on the basis of changes in intrinsic value. In such cases, the time value of the option is treated as a hedging cost and accounted for as follows:

- If the option includes a component that is not aligned on the critical features of the hedged item, the corresponding change in the time value is taken to profit or loss.
- Otherwise, the change in the time value is taken to equity within the statement of comprehensive income, and then:

– if the hedged item is linked to a transaction that results in the recognition of a financial asset or liability, the change in the time value is reclassified to profit or loss symmetrically with the hedged item; or,

– if the hedged item is linked to a transaction that results in the recognition of a non-financial asset or liability, the change in the time value is incorporated in the initial carrying amount of that asset or liability; or,

– if the hedged item is linked to a period of time, the change in time value is reclassified to profit or loss on a straight line basis over the life of the hedging relationship.

In the case of forward contracts and foreign exchange swaps, and of cross-currency swaps that qualify for hedge accounting on the basis of changes in spot rates, Sanofi may elect for each transaction to use the option whereby the premium/discount or foreign currency basis spread are treated in the same way as the time value of an option.

Discontinuation of hedge accounting

Hedge accounting is discontinued when the eligibility criteria are no longer met (in particular, when the hedging instrument expires or is sold, terminated or exercised), or if there is a change in the market risk management objective of the hedging relationship.

B.8.4. Non-derivative financial liabilities

Borrowings and debt

Bank borrowings and debt instruments are initially measured at fair value of the consideration received, net of directly attributable transaction costs.

Subsequently, they are measured at amortized cost using the effective interest method. All costs related to the issuance of borrowings or debt instruments, and all differences between the issue proceeds net of transaction costs and the value on redemption, are recognized within ***Financial expenses*** in the income statement over the term of the debt using the effective interest method.

Liabilities related to business combinations and to non-controlling interests

These line items record the fair value of (i) contingent consideration payable in connection with business combinations and (ii) commitments to buy out equity holders of subsidiaries, including put options granted to non-controlling interests.

Adjustments to the fair value of commitments to buy out equity holders of subsidiaries, including put options granted to non-controlling interests, are recognized in equity.

Other non-derivative financial liabilities

Other non-derivative financial liabilities include trade accounts payable, which are measured at fair value (which in most cases equates to face value) on initial recognition, and subsequently at amortized cost.

B.8.5. Fair value of financial instruments

Under IFRS 13 (Fair Value Measurement) and IFRS 7 (Financial Instruments: Disclosures), fair value measurements must be classified using a hierarchy based on the inputs used to measure the fair value of the instrument. This hierarchy has three levels:

(a) level 1: quoted prices in active markets for identical assets or liabilities (without modification or repackaging);

(b) level 2: quoted prices in active markets for similar assets and liabilities, or valuation techniques in which all important inputs are derived from observable market data; and

(c) level 3: valuation techniques in which not all important inputs are derived from observable market data.

The table below shows the disclosures required under IFRS 7 relating to the measurement principles applied to financial instruments.

					Method used to determine fair value		
						Market data	
Note	Type of financial instrument	Measurement principle	Level in fair value hierarchy	Valuation technique	Valuation model	Exchange rate	Interest rate
D.7.	Financial assets measured at fair value (quoted equity instruments)	Fair value	1	Market value	Quoted market price		N/A
D.7.	Financial assets measured at fair value (quoted debt instruments)	Fair value	1	Market value	Quoted market price		N/A
D.7.	Financial assets measured at fair value (unquoted equity instruments)	Fair value	3	Revenue and/ or market-based approach	If cost ceases to be a representative measure of fair value, an internal valuation is carried out, based mainly on growth forecasts or by reference to similar transactions contracted with third parties.		
D.7.	Financial assets measured at fair value (contingent consideration receivable)	Fair value	3	Revenue-based approach	The fair value of contingent consideration receivable is determined by adjusting the contingent consideration at the end of the reporting period using the method described in Note D.7.3.		
D.7.	Financial assets measured at fair value held to meet obligations under post-employment benefit plans	Fair value	1	Market value	Quoted market price		N/A
D.7.	Financial assets designated at fair value held to meet obligations under deferred compensation plans	Fair value	1	Market value	Quoted market price		N/A
D.7.	Long-term loans and advances and other non-current receivables	Amortized cost	N/A	N/A	The amortized cost of long-term loans and advances and other non-current receivables at the end of the reporting period is not materially different from their fair value.		
D.13.	Investments in mutual funds	Fair value	1	Market value	Net asset value		N/A
D.13.	Negotiable debt instruments, commercial paper, instant access deposits and term deposits	Amortized cost	N/A	N/A	Because these instruments have a maturity of less than 3 months, amortized cost is regarded as an acceptable approximation of fair value as disclosed in the notes to the consolidated financial statements.		
D.17.1.	Debt	Amortized cost[(a)]	N/A	N/A	In the case of debt with a maturity of less than 3 months, amortized cost is regarded as an acceptable approximation of fair value as reported in the notes to the consolidated financial statements. For debt with a maturity of more than 3 months, fair value as reported in the notes to the consolidated financial statements is determined either by reference to quoted market prices at the end of the reporting period (quoted instruments) or by discounting the future cash flows based on observable market data at the end of the reporting period (unquoted instruments).		
D.20.	Forward currency contracts	Fair value	2		Present value of future cash flows	Mid Market	< 1 year: Mid Money Market > 1 year: Mid Zero Coupon
D.20.	Interest rate swaps	Fair value	2	Revenue-based approach	Present value of future cash flows	Mid Market Spot	< 1 year: Mid Money Market and LIFFE interest rate futures > 1 year: Mid Zero Coupon
D.20.	Cross-currency swaps	Fair value	2		Present value of future cash flows	Mid Market Spot	< 1 year: Mid Money Market and LIFFE interest rate futures > 1 year: Mid Zero Coupon
D.18.	Liabilities related to business combinations and to non-controlling interests (CVRs)	Fair value	1	Market value	Quoted market price		
D.18.	Liabilities related to business combinations and to non-controlling interests (other than CVRs)	Fair value[(b)]	3	Revenue-based approach	Under IAS 32, contingent consideration payable in a business combination is a financial liability. The fair value of such liabilities is determined by adjusting the contingent consideration at the end of the reporting period using the method described in Note B.8.4.		

(a) In the case of debt designated as a hedged item in a fair value hedging relationship, the carrying amount in the consolidated balance sheet includes changes in fair value attributable to the hedged risk(s).

(b) For business combinations completed prior to application of IFRS 3, contingent consideration is recognized when payment becomes probable. See Note B.3.1.

The fair value of the Dexcom equity derivatives (see Note D.20.c.) is classified as Level 2 because the valuation is based on a generally accepted technique (the Black & Scholes model) that uses inputs from directly observable market parameters (share price, risk free rate and implied volatility).

B.8.6. Derecognition of financial instruments

Financial assets are derecognized when the contractual rights to cash flows from the asset have ended or have been transferred and when Sanofi has transferred substantially all the risks and rewards of ownership of the asset. If Sanofi has neither transferred nor retained substantially all the risks and rewards of ownership of a financial asset, it is derecognized if Sanofi does not retain control of the asset.

A financial liability is derecognized when Sanofi's contractual obligations in respect of the liability are discharged, cancelled or extinguished.

B.8.7. Risks relating to financial instruments

Market risks in respect of non-current financial assets, cash equivalents, derivative instruments and debt are described in the discussions of risk factors presented in Item 3.D. and Item 11. of Sanofi's Annual Report on Form 20-F for 2020.

Credit risk is the risk that customers may fail to pay their debts. For a description of credit risk, refer to "We are subject to the risk of non-payment by our customers" within Item 3.D. and Item 11. of Sanofi's Annual Report on Form 20-F for 2020.

B.9. Inventories

Inventories are measured at the lower of cost or net realizable value. Cost is calculated using the weighted average cost method or the first-in, first-out method, depending on the nature of the inventory.

The cost of finished goods inventories includes costs of purchase, costs of conversion and other costs incurred in bringing the inventories to their present location and condition.

Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale.

During the launch phase of a new product, any inventories of that product are written down to zero pending regulatory approval. The write-down is reversed once it becomes highly probable that marketing approval will be obtained.

B.10. Cash and cash equivalents

Cash and cash equivalents as shown in the consolidated balance sheet and statement of cash flows comprise cash, plus liquid short-term investments that are readily convertible into cash and are subject to an insignificant risk of changes in value in the event of movements in interest rates.

B.11. Treasury shares

In accordance with IAS 32, Sanofi treasury shares are deducted from equity, irrespective of the purpose for which they are held. No gain or loss is recognized in the income statement on the purchase, sale, impairment or cancellation of treasury shares.

B.12. Provisions for risks

In accordance with IAS 37 (Provisions, Contingent Liabilities and Contingent Assets), Sanofi records a provision when it has a present obligation, whether legal or constructive, as a result of a past event; it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation; and a reliable estimate can be made of the amount of the outflow of resources.

If the obligation is expected to be settled more than twelve months after the end of the reporting period, or has no definite settlement date, the provision is recorded within ***Non-current provisions and other non-current liabilities***.

Provisions relating to the insurance programs in which Sanofi's captive insurance company participates are based on risk exposure estimates calculated by management, with assistance from independent actuaries, using IBNR (Incurred But Not Reported) techniques. Those techniques use past claims experience, within Sanofi and in the market, to estimate future trends in the cost of claims.

Contingent liabilities are not recognized, but are disclosed in the notes to the financial statements unless the possibility of an outflow of economic resources is remote.

Sanofi estimates provisions on the basis of events and circumstances related to present obligations at the end of the reporting period and of past experience, and to the best of management's knowledge at the date of preparation of the financial statements.

Reimbursements offsetting the probable outflow of resources are recognized as assets only if it is virtually certain that they will be received. Contingent assets are not recognized.

Restructuring provisions are recognized if Sanofi has a detailed, formal restructuring plan at the end of the reporting period and has announced its intention to implement this plan to those affected by it.

No provisions are recorded for future operating losses.

Sanofi records non-current provisions for certain obligations, such as legal or constructive obligations, where an outflow of resources is probable and the amount of the outflow can be reliably estimated.

In the case of environmental risks, including at sites where operations are ongoing, Sanofi recognizes a provision where there is a violation of integrity in respect of human health or the environment resulting from past contamination at a site that requires remediation. The amount of the provision is a best estimate of the future expenditures to be incurred on the remediation plan.

Where the effect of the time value of money is material, those provisions are measured at the present value of the expenditures expected to be required to settle the obligation, calculated using a discount rate that reflects an estimate of the time value of money and the risks specific to the obligation.

Increases in provisions to reflect the effects of the passage of time are recognized within ***Financial expenses***.

B.13. Revenue recognition

B.13.1. Net sales

Revenue arising from the sale of goods is presented in the income statement within ***Net sales***. Net sales comprise revenue from sales of pharmaceutical products, consumer healthcare products, active ingredients and vaccines, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities. Analyses of net sales are provided in Note D.35.1. “Segment Information”.

In accordance with IFRS 15 (Revenue from Contracts with Customers), such revenue is recognized when Sanofi transfers control over the product to the customer; control of an asset refers to the ability to direct the use of, and obtain substantially all of the remaining benefits from that asset. For the vast majority of contracts, revenue is recognized when the product is physically transferred, in accordance with the delivery and acceptance terms agreed with the customer.

For contracts entered into by Sanofi Pasteur, transfer of control is usually determined by reference to the terms of release (immediate or deferred) and acceptance of batches of vaccine.

In the case of contracts with distributors, Sanofi does not recognize revenue when the product is physically transferred to the distributor if the products are sold on consignment, or if the distributor acts as agent. In such cases, revenue is recognized when control is transferred to the end customer, and the distributor’s commission is presented within the line item ***Selling and general expenses*** in the income statement.

The amount of revenue recognized reflects the various types of price reductions or rights of return offered by Sanofi to its customers on certain products. Such price reductions and rights of return qualify as variable consideration under IFRS 15.

In particular, products sold in the United States are covered by various Government and State programs (such as Medicare and Medicaid) under which products are sold at a discount. Rebates are granted to healthcare authorities, and under contractual arrangements with certain customers. Some wholesalers are entitled to chargeback incentives based on the selling price to the end customer, under specific contractual arrangements. Cash discounts may also be granted for prompt payment. Returns, discounts, incentives and rebates, as described above, are recognized in the period in which the underlying sales are recognized as a reduction of gross sales.

These amounts are calculated as follows:

- The amount of chargeback incentives is estimated on the basis of the relevant subsidiary’s standard sales terms and conditions, and in certain cases on the basis of specific contractual arrangements with the customer.
- The amount of rebates based on attainment of sales targets is estimated and accrued as each of the underlying sales transactions is recognized.
- The amount of price reductions under Government and State programs, largely in the United States, is estimated on the basis of the specific terms of the relevant regulations or agreements, and accrued as each of the underlying sales transactions is recognized.
- The amount of sales returns is calculated on the basis of management’s best estimate of the amount of product that will ultimately be returned by customers. In countries where product returns are possible, Sanofi operates a returns policy that allows the customer to return products within a certain period either side of the expiry date (usually 12 months after the expiry date). The amount recognized for returns is estimated on the basis of past experience of sales returns. Sanofi also takes into account factors such as levels of inventory in its various distribution channels, product expiry dates, information about potential discontinuation of products, the entry of competing generics into the market, and the launch of over-the-counter medicines. Most product return clauses relate solely to date-expired products, which cannot be resold and are destroyed. Sanofi does not recognize a right of return asset in the balance sheet for contracts that allow for the return of time-expired products, since those products have no value.

The estimated amounts described above are recognized in the income statement within ***Net sales*** as a reduction of gross sales, and within ***Other current liabilities*** in the balance sheet. They are subject to regular review and adjustment as appropriate based on the most recent data available to management. Sanofi believes that it has the ability to measure each of the above amounts reliably, using the following factors in developing its estimates:

- the nature and patient profile of the underlying product;
- the applicable regulations or the specific terms and conditions of contracts with governmental authorities, wholesalers and other customers;
- historical data relating to similar contracts, in the case of qualitative and quantitative rebates and chargeback incentives;
- past experience and sales growth trends for the same or similar products;
- actual inventory levels in distribution channels, monitored by Sanofi using internal sales data and externally provided data;
- the shelf life of Sanofi products; and
- market trends including competition, pricing and demand.

An analysis of provisions for discounts, rebates and sales returns is provided in Note D.23.

B.13.2. Other revenues

Other revenues mainly comprise royalties received from licensing intellectual property rights to third parties, and VaxServe sales of products sourced from third-party manufacturers.

Royalties received under licensing arrangements are recognized over the period during which the underlying sales are recognized.

VaxServe is a Vaccines segment entity whose operations include the distribution within the United States of vaccines and other products manufactured by third parties. VaxServe sales of products sourced from third-party manufacturers are presented within ***Other revenues***.

B.14. Cost of sales

Cost of sales consists primarily of the industrial cost of goods sold, payments made under licensing agreements, and distribution costs. The industrial cost of goods sold includes the cost of materials, depreciation of property, plant and equipment, amortization of software, personnel costs, and other expenses attributable to production.

B.15. Research and development

Note B.4.1. “Research and development not acquired in a business combination” and Note B.4.3. “Other intangible assets acquired in a business combination” describe the principles applied to the recognition of research and development costs.

Contributions or reimbursements received from alliance partners are recorded as a reduction of ***Research and development expenses***.

B.16. Other operating income and expenses

B.16.1. Other operating income

Other operating income includes the share of profits that Sanofi is entitled to receive from alliance partners in respect of product marketing agreements. It also includes revenues generated under certain complex agreements, which may include partnership and co-promotion arrangements.

This line item also includes realized and unrealized foreign exchange gains and losses on operating activities (see Note B.8.3.), and operating gains on disposals not regarded as major disposals (see Note B.20.).

B.16.2. Other operating expenses

Other operating expenses mainly comprise the share of profits that alliance partners are entitled to receive from Sanofi under product marketing agreements.

B.17. Amortization and impairment of intangible assets

B.17.1. Amortization of intangible assets

The expenses recorded in this line item comprise amortization of product rights and other intangible assets (see Note D.4.), given that the benefit of those rights to Sanofi’s commercial, industrial and development functions cannot be separately identified.

Amortization of software, and of other rights of an industrial or operational nature, is recognized as an expense in the income statement, in the relevant line items of expense by function.

B.17.2. Impairment of intangible assets

This line item records impairment losses (other than those associated with restructuring) recognized against intangible assets (including goodwill, but excluding software and other rights of an industrial or operational nature), and any reversals of such impairment losses.

B.18. Fair value remeasurement of contingent consideration

Changes in the fair value of contingent consideration that was (i) already carried in the books of an acquired entity, or (ii) granted in connection with a business combination and initially recognized as a liability in accordance with IFRS 3, are reported in profit or loss. Such adjustments are reported separately in the income statement, in the line item ***Fair value remeasurement of contingent consideration.***

This line item also includes changes in the fair value of contingent consideration receivable in connection with a divestment and classified as a financial asset at fair value through profit or loss.

Finally, it includes the effect of the unwinding of discount, and of exchange rate movements where the asset or liability is expressed in a currency other than the functional currency of the reporting entity.

B.19. Restructuring costs and similar items

Restructuring costs are expenses incurred in connection with the transformation or reorganization of Sanofi’s operations or support functions. Such costs include collective redundancy plans, compensation to third parties for early termination of contracts, and commitments made in connection with transformation or reorganization decisions. They also include accelerated depreciation charges arising from site closures (including closures of leased sites), and losses on asset disposals resulting from such decisions.

In addition, this line item includes expenses incurred in connection with programs implemented as part of the transformation strategy announced in December 2019 (and previously in November 2015), and intended primarily to (i) deliver a global information systems solution; (ii) create a standalone Consumer Healthcare entity; and (iii) as announced on February 24, 2020, create a European leader in the production and marketing to third parties of active pharmaceutical ingredients (API).

B.20. Other gains and losses, and litigation

The line item ***Other gains and losses, and litigation*** includes the impact of material transactions of an unusual nature or amount which Sanofi believes it necessary to report separately in the income statement in order to improve the relevance of the financial statements, such as:

- gains and losses on major disposals of property, plant and equipment, of intangible assets, of assets (or groups of assets and liabilities) held for sale, or of a business within the meaning of IFRS 3, other than those considered to be restructuring costs;
- impairment losses and reversals of impairment losses on assets (or groups of assets and liabilities) held for sale, other than those considered to be restructuring costs;
- gains on bargain purchases;
- costs and provisions relating to major litigation; and
- pre-tax separation costs associated with the process of disinvesting from operations in the event of a major divestment.

B.21. Financial expenses and income

B.21.1. Financial expenses

Financial expenses mainly comprise interest charges on debt financing; negative changes in the fair value of financial instruments (where changes in fair value are recognized in profit or loss); realized and unrealized foreign exchange losses on financing and investing activities; impairment losses on financial instruments; and any reversals of impairment losses on financial instruments.

Financial expenses also include expenses arising from the unwinding of discount on long-term provisions, and the net interest cost related to employee benefits. This line item does not include commercial cash discounts, which are deducted from net sales.

B.21.2. Financial income

Financial income includes interest and dividend income; positive changes in the fair value of financial instruments (where changes in fair value are recognized in profit or loss); realized and unrealized foreign exchange gains on financing and investing activities; and gains on disposals of financial assets at fair value through profit or loss.

B.22. Income tax expense

Income tax expense includes all current and deferred taxes of consolidated companies.

Sanofi accounts for deferred taxes in accordance with IAS 12 (Income Taxes), using the methods described below:

- Deferred tax assets and liabilities are recognized on taxable and deductible temporary differences, and on tax loss carry-forwards. Temporary differences are differences between the carrying amount of an asset or liability in the balance sheet and its tax base.
- French business taxes include a value added based component: “CVAE” (*Cotisation sur la Valeur Ajoutée des Entreprises*). Given that CVAE is (i) calculated as the amount by which certain revenues exceed certain expenses and (ii) borne primarily by companies that own intellectual property rights on income derived from those rights (royalties, and margin on sales to third parties and to Sanofi entities), it is regarded as meeting the definition of income taxes specified in IAS 12, paragraph 2 (“taxes which are based on taxable profits”).
- Deferred tax assets and liabilities are calculated using the tax rate expected to apply in the period when the corresponding temporary differences are expected to reverse, based on tax rates enacted or substantively enacted at the end of the reporting period.
- Deferred tax assets are recognized in respect of deductible temporary differences, tax losses available for carry-forward and unused tax credits to the extent that future recovery is regarded as probable. The recoverability of deferred tax assets is assessed on a case-by-case basis, taking into account the profit forecasts contained in Sanofi’s medium-term business plan.
- A deferred tax liability is recognized for temporary differences relating to interests in subsidiaries, associates and joint ventures, except in cases where Sanofi is able to control the timing of the reversal of the temporary differences. This applies in particular when Sanofi is able to control dividend policy and it is probable that the temporary differences will not reverse in the foreseeable future.
- No deferred tax is recognized on eliminations of intragroup transfers of interests in subsidiaries, associates or joint ventures.
- Each tax entity calculates its own net deferred tax position. All net deferred tax asset and liability positions are then aggregated and shown in separate line items on the relevant side of the consolidated balance sheet. Deferred tax assets and liabilities are offset only if (i) Sanofi has a legally enforceable right to offset current tax assets and current tax liabilities, and (ii) the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority.
- Deferred taxes are not discounted, except implicitly in the case of deferred taxes on assets and liabilities which are already impacted by discounting. In addition, Sanofi has elected not to discount current taxes payable or receivable where the amounts in question are payable or receivable in the long term.
- Withholding taxes on intragroup royalties and dividends, and on royalties and dividends collected from third parties, are accounted for as current income taxes.

In accounting for business combinations, Sanofi complies with IFRS 3 as regards the recognition of deferred tax assets after the initial accounting period. Consequently, any deferred tax assets recognized by the acquiree after the end of that period in respect of temporary differences or tax loss carry-forwards existing at the acquisition date are recognized in profit or loss.

The positions adopted by Sanofi in tax matters are based on its interpretation of tax laws and regulations. Some of those positions may be subject to uncertainty. In such cases, Sanofi assesses the amount of the tax liability on the basis of the following assumptions: that its position will be examined by one or more tax authorities on the basis of all relevant information; that a technical assessment is carried out with reference to legislation, case law, regulations, and established practice; and that each position is assessed individually (or collectively where appropriate), with no offset or aggregation between positions. Those assumptions are assessed on the basis of facts and circumstances existing at the end of the reporting period. When an uncertain tax liability is regarded as probable, it is measured on the basis of Sanofi's best estimate and recognized as a liability; uncertain tax assets are not recognized. The amount of the liability includes any penalties and late payment interest. The line item ***Income tax expense*** includes the effects of tax reassessments and tax disputes, and any penalties and late payment interest arising from such disputes that have the characteristics of income taxes within the meaning of paragraph 2 of IAS 12 ("taxes which are based on taxable profits"). Tax exposures relating to corporate income taxes are presented separately within ***Non-current income tax liabilities*** (see Note D.19.4.).

No deferred taxation is recognized on temporary differences that are liable to be subject to US global intangible low taxed income (GILTI) provisions. The related tax expense is recognized in the year in which it is declared in the tax return to the extent that it arises from the existence of non-US profits that exceed the theoretical return on investment specified in the GILTI provisions and are taxed at a rate lower than the applicable US tax rate.

In accordance with IAS 1 (Presentation of Financial Statements), current income tax assets and liabilities are presented as separate line items in the consolidated balance sheet.

B.23. Employee benefit obligations

Sanofi offers retirement benefits to employees and retirees. Such benefits are accounted for in accordance with IAS 19 (Employee Benefits).

Benefits are provided in the form of either defined contribution plans or defined benefit plans. In the case of defined contribution plans, the cost is recognized immediately in the period in which it is incurred, and equates to the amount of the contributions paid by Sanofi. For defined benefit plans, Sanofi generally recognizes its obligations to pay pensions and similar benefits to employees as a liability, based on an actuarial estimate of the rights vested or currently vesting in employees and retirees, using the projected unit credit method. Estimates are performed at least once a year, and rely on financial assumptions (such as discount rates) and demographic assumptions (such as life expectancy, retirement age, employee turnover, and the rate of salary increases).

Obligations relating to other post-employment benefits (healthcare and life insurance) offered by Sanofi companies to employees are also recognized as a liability based on an actuarial estimate of the rights vested or currently vesting in employees and retirees at the end of the reporting period.

Such liabilities are recognized net of the fair value of plan assets.

In the case of multi-employer defined benefit plans where plan assets cannot be allocated to each participating employer with sufficient reliability, the plan is accounted for as a defined contribution plan, in accordance with paragraph 34 of IAS 19.

The benefit cost for the period consists primarily of current service cost, past service cost, net interest cost, gains or losses arising from plan settlements not specified in the terms of the plan, and actuarial gains or losses arising from plan curtailments. Net interest cost for the period is determined by applying the discount rate specified in IAS 19 to the net liability (i.e. the amount of the obligation, net of plan assets) recognized in respect of defined benefit plans. Past service cost is recognized immediately in profit or loss in the period in which it is incurred, regardless of whether or not the rights have vested at the time of adoption (in the case of a new plan) or of amendment (in the case of an existing plan).

Actuarial gains and losses on defined benefit plans (pensions and other post-employment benefits), also referred to as "Remeasurements of the net defined benefit liability (asset)", arise as a result of changes in financial and demographic assumptions, experience adjustments, and the difference between the actual return and interest cost on plan assets. The impacts of those remeasurements are recognized in ***Other comprehensive income***, net of deferred taxes; they are not subsequently reclassifiable to profit or loss.

B.24. Share-based payment

Share-based payment expense is recognized as a component of operating income, in the relevant classification of expense by function. In measuring the expense, the level of attainment of any performance conditions is taken into account.

B.24.1. Stock option plans

Sanofi has granted a number of equity-settled share-based payment plans (stock option plans) to some of its employees. The terms of those plans may make the award contingent on the attainment of performance criteria for some of the grantees.

In accordance with IFRS 2 (Share-Based Payment), services received from employees as consideration for stock options are recognized as an expense in the income statement, with the opposite entry recognized in equity. The expense corresponds to the fair value of the stock option plans, and is charged to income on a straight-line basis over the four-year vesting period of the plan.

The fair value of stock option plans is measured at the date of grant using the Black-Scholes valuation model, taking into account the expected life of the options. The resulting expense also takes into account the expected cancellation rate of the options. The expense is adjusted over the vesting period to reflect actual cancellation rates resulting from option-holders ceasing to be employed by Sanofi.

B.24.2. Employee share ownership plans

Sanofi may offer its employees the opportunity to subscribe to reserved share issues at a discount to the reference market price. Shares awarded to employees under such plans fall within the scope of IFRS 2. Consequently, an expense is recognized at the subscription date, based on the value of the discount offered to employees.

B.24.3. Restricted share plans

Sanofi may award restricted share plans to certain of its employees. The terms of those plans may make the award contingent on the attainment of performance criteria for some of the grantees.

In accordance with IFRS 2, an expense equivalent to the fair value of such plans is recognized in profit or loss on a straight line basis over the vesting period of the plan, with the opposite entry recognized in equity. The vesting period is three years.

The fair value of restricted share plans is based on the quoted market price of Sanofi shares at the date of grant, adjusted for expected dividends during the vesting period; it also takes account of any vesting conditions contingent on stock market performance. Other vesting conditions are taken into account in the estimate of the number of shares awarded during the vesting period; that number is then definitively adjusted based on the actual number of shares awarded on the vesting date.

B.25. Earnings per share

Basic earnings per share is calculated using the weighted average number of shares outstanding during the reporting period, adjusted on a time-weighted basis from the acquisition date to reflect the number of own shares held by Sanofi. Diluted earnings per share is calculated on the basis of the weighted average number of ordinary shares, computed using the treasury stock method.

This method assumes that (i) all outstanding dilutive options and warrants are exercised, and (ii) Sanofi acquires its own shares at the quoted market price for an amount equivalent to the cash received as consideration for the exercise of the options or warrants, plus the expense arising on unamortized stock options.

B.26. Segment information

In accordance with IFRS 8 (Operating Segments), the segment information reported by Sanofi is prepared on the basis of internal management data provided to the Chief Executive Officer, who is the chief operating decision maker. The performance of those segments is monitored individually using internal reports and common indicators. Disclosures about operating segments required under IFRS 8 are presented in Note D.35. “Segment information” to the consolidated financial statements.

Sanofi has three operating segments: Pharmaceuticals, Consumer Healthcare and Vaccines.

The Pharmaceuticals segment comprises, for all geographical territories, the commercial operations of the following global franchises: Specialty Care (Dupixent®, Multiple Sclerosis, Neurology, Other Inflammatory Diseases & Immunology, Rare Diseases, Oncology, and Rare Blood Disorders) and General Medicines (Diabetes, Cardiovascular, and Established Prescription Products), together with research, development and production activities dedicated to the Pharmaceuticals segment. This segment also includes associates whose activities are related to pharmaceuticals. Following the transaction of May 29, 2020, Regeneron is no longer an associate of Sanofi (see Note D.1.). Consequently, the Pharmaceuticals segment no longer includes Sanofi’s equity-accounted share of Regeneron’s profits for all the periods presented.

The Consumer Healthcare segment comprises, for all geographical territories, the commercial operations for our Consumer Healthcare products, together with research, development and production activities dedicated to those products.

The Vaccines segment comprises, for all geographical territories, the commercial operations of Sanofi Pasteur, together with research, development and production activities dedicated to vaccines.

Inter-segment transactions are not material.

The costs of Sanofi’s global functions (External Affairs, Finance, Human Resources, Legal Affairs, Information Solutions & Technologies, Sanofi Business Services, etc.) are managed centrally at group-wide level, and are presented within the “Other” category. That category also includes other reconciling items such as retained commitments in respect of divested activities.

In 2020, Sanofi adapted its management reporting to reflect the new organizational structure. This resulted in cost reallocations between the Pharmaceuticals, Consumer Healthcare and Vaccines segments and the “Other” category, and product reallocations between Pharmaceuticals and Consumer Healthcare.

Information about operating segments for the years ended December 31, 2020, 2019 and 2018 is presented in Note D.35 “Segment information”.

B.27. Management of capital

In order to maintain or adjust the capital structure, Sanofi can adjust the amount of dividends paid to shareholders, repurchase its own shares, issue new shares, or issue securities giving access to its capital.

The following objectives are defined under the terms of Sanofi’s share repurchase programs:

- the implementation of any stock option plan giving entitlement to purchase shares in the Sanofi parent company;
- the allotment or sale of shares to employees under statutory profit sharing schemes and employee savings plans;
- the consideration-free allotment of shares (i.e. restricted share plans);
- the cancellation of some or all of the repurchased shares;
- market-making in the secondary market by an investment services provider under a liquidity contract in compliance with the ethical code recognized by the *Autorité des marchés financiers* (AMF);

- the delivery of shares on the exercise of rights attached to securities giving access to the capital by redemption, conversion, exchange, presentation of a warrant or any other means;
- the delivery of shares (in exchange, as payment, or otherwise) in connection with mergers and acquisitions;
- the execution by an investment services provider of purchases, sales or transfers by any means, in particular via off-market trading; or
- any other purpose that is or may in the future be authorized under the applicable laws and regulations.

Sanofi is not subject to any constraints on equity capital imposed by third parties.

Total equity includes ***Equity attributable to equity holders of Sanofi*** and ***Equity attributable to non-controlling interests***, as shown in the consolidated balance sheet.

Sanofi defines “Net debt” as (i) the sum of short-term debt, long-term debt and interest rate derivatives and currency derivatives used to hedge debt, minus (ii) the sum of cash and cash equivalents and interest rate derivatives and currency derivatives used to hedge cash and cash equivalents.

C/ Principal alliances

C.1. Alliance arrangements with Regeneron Pharmaceuticals, Inc. (Regeneron)

Collaboration agreements on human therapeutic antibodies

In November 2007, Sanofi and Regeneron signed two agreements (amended in November 2009) relating to human therapeutic antibodies: (i) the Discovery and Preclinical Development Agreement, and (ii) the License and Collaboration Agreement, relating to clinical development and commercialization. Under the License and Collaboration Agreement, Sanofi had an option to develop and commercialize antibodies discovered by Regeneron under the Discovery and Preclinical Development Agreement.

Discovery and development

Under the 2009 amended agreements, Sanofi funded the discovery and pre-clinical development of fully human therapeutic antibodies up to a maximum of $160 million per year through 2017. Because Sanofi decided not to exercise its option to extend the Discovery and Preclinical Development Agreement, that agreement expired on December 31, 2017.

Upon Sanofi’s exercise of an option on an antibody under the Discovery and Preclinical Development Agreement, the antibody became a Licensed Product under the License and Collaboration Agreement, pursuant to which Sanofi and Regeneron co-develop the antibody with Sanofi initially being wholly responsible for funding the development program. On receipt of the first positive Phase III trial results for any antibody being developed under the License and Collaboration Agreement, the subsequent Phase III costs for that antibody are split 80% Sanofi, 20% Regeneron. Amounts received from Regeneron under those arrangements are recognized by Sanofi as a reduction in the line item ***Research and development expenses***. Co-development with Regeneron of the antibodies Dupixent®, Kevzara® and REGN3500 (SAR440340 - itepekimab) is ongoing under the License and Collaboration Agreement at this time.

Once a product begins to be commercialized, and provided that the share of quarterly results under the agreement represents a profit, Sanofi is entitled to an additional portion of Regeneron’s profit-share (capped at 10% of Regeneron’s share of quarterly profits) until Regeneron has paid 50% of the cumulative development costs incurred by the parties in the collaboration (see footnote g(ii) to the table provided in Note D.21.1., "Off balance sheet commitments relating to operating activities").

On the later of (i) 24 months before the scheduled launch date or (ii) the first positive Phase III trial results, Sanofi and Regeneron share the commercial expenses of the antibodies co-developed under the License and Collaboration Agreement.

Commercialization

Sanofi is the lead party with respect to the commercialization of all co-developed antibodies, and Regeneron has certain option rights to co-promote the antibodies. Sanofi recognizes all sales of the antibodies. Profits and losses arising from commercial operations in the United States are split 50/50. Outside the United States, Sanofi is entitled to between 55% and 65% of profits depending on sales of the antibodies, and bears 55% of any losses. The share of profits and losses due to or from Regeneron under the agreement is recognized within the line items ***Other operating income*** or ***Other operating expenses***, which are components of ***Operating income***. In addition, Regeneron is entitled to receive payments of up to $250 million contingent on the attainment of specified levels of aggregate sales on all antibodies outside the United States, on a rolling twelve-month basis.

As of September 30, 2020, sales of antibodies outside the United States exceeded $1.0 billion on a rolling twelve-month basis, triggering a payment by Sanofi to Regeneron of $50.0 million for the first sales milestone.

Amendments to the collaboration agreements

In January 2018, Sanofi and Regeneron signed a set of amendments to their collaboration agreements, including an amendment that allowed for the funding of additional programs on Dupixent® and REGN3500 (SAR440340) with an intended focus on extending the current range of indications, finding new indications, and improving co-morbidity between multiple pathologies.

Effective April 1, 2020, Sanofi and Regeneron signed a Cross License and Commercialization Agreement for Praluent®, whereby Sanofi obtained sole ex-US rights to Praluent®, and Regeneron obtained sole US rights to Praluent® along with a right to 5% royalties on Sanofi’s sales of Praluent® outside the United States. Each party is solely responsible for the development, manufacturing and commercialization of Praluent® in their respective territories. Although each company has responsibility for supplying Praluent® in its respective territory, the companies have entered into agreements to support manufacturing needs for each other.

Sanofi and Regeneron continue to investigate restructuring their collaboration for Kevzara®.

The Zaltrap® Manufacturing and Supply Agreement terminates on December 31, 2021. Regeneron and Sanofi are discussing a potential extension of such agreement.

The terms of the collaboration relating to Dupixent® (dupilumab) and to SAR440340 (REGN3500) are unchanged.

Immuno-oncology (IO) collaboration agreements

On July 1, 2015, Sanofi and Regeneron signed two agreements - the IO Discovery and Development Agreement and the IO License and Collaboration Agreement (IO LCA) - relating to new antibody cancer treatments in the field of immuno-oncology. As part of the agreements, Sanofi made an upfront payment of $640 million to Regeneron.

The two companies agreed to invest approximately $1 billion from discovery through proof of concept (POC) development (usually a Phase IIa study) of monotherapy and novel combinations of immuno-oncology antibody candidates to be funded 25% by Regeneron ($250 million) and 75% by Sanofi ($750 million). The two companies also agreed to reallocate $75 million (spread over three years) to immuno-oncology antibody research and development from Sanofi's $160 million annual contribution under their existing antibody Discovery and Preclinical Development Agreement.

An Amended IO Discovery Agreement, effective from December 31, 2018, was signed on January 2, 2019. It narrows the scope of the existing discovery and development activities conducted by Regeneron ("IO Development Activities") under the original 2015 IO Discovery and Development Agreement to developing therapeutic bispecific antibodies targeting (i) BCMA and CD3 (the "BCMAxCD3 Program") and (ii) MUC16 and CD3 (the "MUC16xCD3 Program") through clinical proof-of-concept. Under the terms of the Amended IO Discovery Agreement, Sanofi paid Regeneron $462 million as consideration for (i) the termination of the 2015 IO Discovery Agreement, (ii) the prepayment for certain IO Development Activities regarding the BCMAxCD3 Program and the MUC16xCD3 Program, and (iii) the reimbursement of costs incurred by Regeneron under the 2015 IO Discovery Agreement during the fourth quarter of 2018. This gives Sanofi increased flexibility to advance its early-stage immuno-oncology pipeline independently, while Regeneron retains all rights to its other immuno-oncology discovery and development programs.

The ongoing development and commercialization collaboration on Libtayo® (cemiplimab) is unaffected by the amendments to the IO Discovery and Development Agreement.

Upon establishment of POC, or when the allocated funding has been expended, whichever is earlier, Sanofi can exercise its opt-in rights to further develop and commercialize under the IO LCA the two candidates derived from the amended IO Discovery Agreement. Sanofi has decided to opt-out with respect to the MUC16xCD3 program. If Sanofi exercises its opt-in rights with respect to the BCMAxCD3 program, Sanofi will lead the development and global commercialization of the BCMAxCD3 candidate antibody and fund the development costs in full; Regeneron will refund 50% of those costs provided that the share of quarterly results under the IO LCA represents a profit, subject to a cap set at 10% of Regeneron's profit-share.

Libtayo® (cemiplimab)

Under the 2015 IO LCA as amended in January 2018, Sanofi and Regeneron committed funding of no more than $1,640 million, split on a 50/50 basis ($820 million per company), for the development of REGN2810 (cemiplimab, trademark Libtayo®), a PD-1 inhibitor antibody. Regeneron is responsible for the commercialization of Libtayo® in the United States, and Sanofi in all other territories. Sanofi has exercised its option to co-commercialize Libtayo® in the United States.

The IO LCA also provided for a one-time milestone payment of $375 million by Sanofi to Regeneron in the event that sales of a PD-1 product and any other collaboration antibody sold for use in combination with a PD-1 product were to exceed, in the aggregate, $2 billion in any consecutive 12-month period.

Under the IO LCA Sanofi and Regeneron share equally in profits and losses in connection with the commercialization of collaboration products, except that Sanofi is entitled to an additional share of profits capped at 10% of the share of Regeneron's quarterly profits in order to reimburse Sanofi for up to 50% of the clinical development costs funded by Sanofi under the IO Discovery Agreement, as amended.

In September 2018, the US Food and Drug Administration (FDA) approved Libtayo® (cemiplimab) for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation. Libtayo® is a fully human monoclonal antibody targeting the immune checkpoint receptor PD-1 (programmed cell death protein-1) and is the first and only treatment specifically approved and available for advanced CSCC in the US. In July 2019, the European Medicines Agency (EMA) granted marketing authorization for Libtayo® for patients with metastatic or locally advanced CSCC who are not candidates for surgery.

In addition to advanced CSCC, clinical trials are ongoing to investigate cemiplimab in non-small cell lung cancer, basal cell carcinoma, cervical cancer, head and neck squamous cell carcinoma, melanoma, colorectal cancer, prostate cancer, multiple myeloma, Hodgkin's disease and non-Hodgkin lymphoma. Those potential indications are still investigational, and the safety and efficacy of Libtayo® have not been evaluated by any regulatory authority for any of them.

Investor agreement

In January 2014, Sanofi and Regeneron amended the investor agreement that had existed between the two companies since 2007. Under the terms of the amendment, Sanofi accepted various restrictions. Sanofi is bound by certain "standstill" provisions, which contractually prohibit Sanofi from seeking to directly or indirectly exert control of Regeneron or acquiring more than 30% of Regeneron's capital stock (consisting of the outstanding shares of common stock and the shares of Class A stock). This prohibition remains in place until the earlier of (i) the later of the fifth anniversaries of the expiration or earlier termination of the Zaltrap® collaboration agreement with Regeneron (related to the development and commercialization of Zaltrap®) or the collaboration agreement with Regeneron on monoclonal antibodies (see "Collaboration agreements on human therapeutic antibodies" above), each as amended and (ii) other specified events.

Sanofi also agreed to vote as recommended by Regeneron's Board of Directors, except that it could elect to vote proportionally with the votes cast by all of Regeneron's other shareholders with respect to certain change-of-control transactions, and to vote in its sole discretion with respect to liquidation or dissolution, stock issuances equal to or exceeding 20% of the outstanding shares or voting rights of Regeneron's Class A Stock and Common Stock (taken together), and new equity compensation plans or amendments if not materially

consistent with Regeneron's historical equity compensation practices. As soon as it had passed the threshold of 20% ownership of the capital stock, Sanofi exercised its right to designate an independent director, who was appointed to the Board of Directors of Regeneron. Sanofi began to account for its interest in Regeneron using the equity method in April 2014. On the conditions set out in the Amended Investor Agreement of January 2014, Sanofi's right to designate a Regeneron board member was contingent on Sanofi maintaining its percentage share of Regeneron's outstanding capital stock (measured on a quarterly basis) at a level no lower than the highest percentage level previously achieved, with the maximum requirement capped at 25%. In addition, Sanofi's interest in Regeneron was subject to a lock-up clause. Those restrictions were amended by the letter agreement of January 2018 (see below).

At Sanofi's request, pursuant to the Amended Investor Agreement, Regeneron appointed a new independent director, N. Anthony "Tony" Coles, M.D. to its Board of Directors in January 2017 as a Sanofi designee. The Amended Investor Agreement also gave Sanofi the right to receive certain reasonable information as might be agreed upon by the parties and which was a factor in Sanofi's ability to account for its investment in Regeneron using the equity method of accounting under IFRS.

In January 2018, Sanofi and Regeneron announced (i) amendments to their collaboration agreements on human therapeutic antibodies; (ii) amendments to the IO LCA on the development of cemiplimab (REGN2810); and (iii) a limited waiver and amendment of the Amended Investor Agreement (the Amended and Restated Investor Agreement) pursuant to a letter agreement (the "2018 Letter Agreement").

Pursuant to the 2018 Letter Agreement, Regeneron agreed to grant a limited waiver of the lock-up clause and the obligation to maintain the "Highest Percentage Threshold" in the Amended and Restated Investor Agreement between the companies, so that Sanofi could elect to sell a small percentage of the Regeneron common stock it owns to fund a portion of the cemiplimab and dupilumab development expansion. This waiver allowed Sanofi to sell up to an aggregate of 1.4 million shares of Regeneron common stock to Regeneron in private transactions through the end of 2020. If Regeneron decided not to purchase the shares, Sanofi would be allowed to sell those shares on the open market, subject to certain volume and timing limitations. Upon expiration of the limited waiver under the 2018 Letter Agreement, the Amended and Restated Investor Agreement would be amended to define "Highest Percentage Threshold" as the lower of (i) 25% of Regeneron outstanding shares of Class A Stock and Common Stock (taken together) and (ii) the higher of (a) Sanofi's percentage ownership of Class A Stock and Common Stock (taken together) on such termination date and (b) the highest percentage ownership of Regeneron outstanding shares of Class A Stock and Common Stock (taken together) Sanofi attains following such termination date.

As of December 31, 2019, Sanofi had sold Regeneron 530,172 shares of Regeneron stock out of the 1.4 million shares covered by the 2018 Letter Agreement.

In December 2019, Sanofi announced that on expiration of the lock-up term and as defined in the Amended and Restated Investor Agreement as amended by the 2018 Letter Agreement (i.e. in principle after December 20, 2020), Sanofi could dispose of its entire interest in Regeneron or of some of the shares of common stock held, on any single occasion or from time to time, via public offering or market transactions or a private sale, using derivatives or other means, at prices and on other terms acceptable to Sanofi depending on Sanofi's capital allocation priorities and alternative investment opportunities, market conditions, the price of Regeneron common stock, and any other factors judged relevant by Sanofi with respect to its investment in Regeneron. Those provisions were to be implemented in accordance with the Amended and Restated Investor Agreement as amended by the 2018 Letter Agreement, including the restrictions contained in Section 5 of the Amended and Restated Investor Agreement.

On May 29, 2020, Sanofi announced the closing of its sale of 13 million shares of Regeneron common stock in a registered offering and a private sale to Regeneron. As a result, Sanofi sold its entire equity investment in Regeneron, except for 400,000 Regeneron shares retained by Sanofi to partially fund investments allocated to the development programs for cemiplimab and dupilumab pursuant to the 2018 Letter Agreement (see Note D.1.).

On May 29, 2020, an amendment to the Investor Agreement became effective, which stipulates inter alia that (i) the "standstill" provisions in the Investor Agreement, which contractually prohibit Sanofi from seeking to directly or indirectly exert control of Regeneron, will continue to apply; (ii) Sanofi will no longer have the right to designate an independent board member on the Regeneron Board of Directors (but with no effect on the term of office of the current Sanofi designee); (iii) the voting commitments contained in the Investor Agreement will continue to apply to shares held by Sanofi.

The registered offering and share repurchase will not affect the ongoing collaboration between Sanofi and Regeneron: the two companies have had a successful and long-standing clinical and commercial collaboration dating back to 2003 that has resulted in five approved treatments to date, with additional candidates currently in clinical development.

As of December 31, 2020, Sanofi had sold an additional 120,234 shares of Regeneron stock out of the 400,000 shares retained as of May 29, 2020, per above, and consequently still holds 279,766 shares of Regeneron stock.

C.2. Alliance arrangements with Bristol-Myers Squibb (BMS)

Two of Sanofi's leading products were jointly developed with BMS: the anti-hypertensive agent irbesartan (Aprovel®/Avapro®/Karvea®) and the anti-atherothrombosis treatment clopidogrel bisulfate (Plavix®/Iscover®).

On September 27, 2012, Sanofi and BMS signed an agreement relating to their alliance following the loss of exclusivity of Plavix® and Avapro®/Avalide® in many major markets.

Under the terms of this agreement, effective January 1, 2013, BMS returned to Sanofi its rights to Plavix® and Avapro®/Avalide® in all markets worldwide with the exception of Plavix® in the United States and Puerto Rico ("Territory B"), giving Sanofi sole control and freedom to operate commercially in respect of those products. In exchange, BMS received royalty payments on Sanofi's sales of branded and unbranded Plavix® and Avapro®/Avalide® worldwide (except for Plavix® in Territory B) until 2018, and also received a payment of $200 million from Sanofi in December 2018, part of which is for buying out the non-controlling interests (see Note D.18.). Rights to Plavix® in Territory B remained unchanged and continued to be governed by the terms of the original agreement until February 28, 2020.

In all of the territories managed by Sanofi (including the United States and Puerto Rico for Avapro®/Avalide®) as defined in the new agreement, Sanofi recognized in its consolidated financial statements the revenue and expenses generated by its own operations. Since

January 2019 onwards, there has no longer been any share of profits reverting to BMS (previously presented within ***Net income attributable to non-controlling interests*** in the income statement).

In Territory B for Plavix®, which was managed by BMS, the Plavix® business was conducted through the Territory B partnerships, which were jointly owned by BMS and Sanofi. Sanofi recognized its share of profits and losses within the line item ***Share of profit/(loss) from investments accounted for using the equity method***.

On February 28, 2020, Sanofi purchased all BMS's interests (50.1%) in each of the Territory B partnerships for a cumulative purchase price of $12 million. Following a transition period, Sanofi has been commercializing Plavix® under its own label since July 1, 2020.

D/ Presentation of the financial statements

D.1. Changes in the scope of consolidation in 2020

Acquisition of Principia

On August 17, 2020, Sanofi and Principia Biopharma Inc. ("Principia"), a late-stage biopharmaceutical company focused on developing treatments for autoimmune diseases, entered into a definitive agreement under which Sanofi was to acquire all the outstanding shares of Principia for $100 per share. The transaction was approved unanimously by the Boards of Directors of Sanofi and Principia. Sanofi's acquisition of Principia was completed on September 28, 2020, with Sanofi holding the entire share capital of Principia upon expiration of the squeeze-out procedure. The provisional purchase price allocation, as presented in the table below, led to the recognition of goodwill of €913 million:

(€ million)	Fair value at acquisition date
Intangible assets other than goodwill	2,534
Other current and non-current assets and liabilities	(38)
Cash and cash equivalents	186
Net deferred tax position	(437)
Net assets of Principia	**2,245**
Goodwill	913
Purchase price	**3,158**

Intangible assets other than goodwill mainly comprise:

- rilzabrutinib (PRN 1008), a molecule undergoing clinical trials for various indications in immuno-inflammatory diseases and rare blood disorders; and
- tolebrutinib (PRN 2246/SAR442168), a molecule currently undergoing clinical trials for the treatment of multiple sclerosis and other diseases of the central nervous system.

Goodwill represents (i) the pipeline of future products in pre-clinical research and development; (ii) the capacity to draw on a specialized structure to refresh the existing product portfolio; and (iii) the competencies of Principia staff.

The goodwill generated on this acquisition did not give rise to any deduction for income tax purposes.

Principia has no commercial operations, and has made a negative contribution of €45 million to Sanofi's consolidated net income since the acquisition date.

Acquisition-related costs recognized in profit or loss in 2020 were recorded within the line item ***Other operating expenses***, and amounted to €13 million.

The cash outflow on this acquisition amounted to €2,972 million, and was recorded in the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** within the consolidated statement of cash flows.

Acquisition of Synthorx

On December 9, 2019, Sanofi and Synthorx Inc. ("Synthorx"), a clinical-stage biotechnology company focused on prolonging and improving the lives of people suffering from cancer and autoimmune disorders, entered into a definitive agreement under which Sanofi was to acquire all of the outstanding shares of Synthorx for $68 per share. The transaction was unanimously approved by both the Sanofi and Synthorx Boards of Directors. On December 23, 2019, Sanofi launched a public tender offer to acquire all of the outstanding ordinary shares of Synthorx for $68 per share in cash, without interest and net of any applicable withholding taxes. The acquisition of Synthorx was completed on January 23, 2020, with Sanofi holding the entire share capital of Synthorx upon expiration of the squeeze-out procedure. The final purchase price allocation, as presented in the table below, led to the recognition of goodwill of €930 million:

(€ million)	Fair value at acquisition date
Intangible assets other than goodwill	1,549
Other current and non-current assets and liabilities	36
Net deferred tax position	(269)
Net assets of Synthorx	**1,316**
Goodwill	930
Purchase price	**2,246**

Intangible assets other than goodwill mainly comprise THOR-707, a molecule currently in Phase I clinical trials that stimulates T lymphocytes, and as such has potential as a cancer immunotherapy.

Goodwill represents (i) the pipeline of future products in pre-clinical research and development; (ii) the capacity to draw on a specialized structure to refresh the existing product portfolio; (iii) the competencies of Synthorx staff; (iv) benefits derived from the creation of new growth platforms; and (v) expected future synergies and other benefits from the combination of Synthorx and Sanofi.

The goodwill generated on this acquisition did not give rise to any deduction for income tax purposes.

Synthorx has no commercial operations, and has made a negative contribution of €106 million to Sanofi's consolidated net income since the acquisition date.

Acquisition-related costs were recognized in profit or loss mainly in the year ended December 31, 2019 within the line item ***Other operating expenses***, and amounted to €8 million.

The cash outflow on this acquisition amounted to €2,245 million, and was recorded in the line item ***Acquisitions of consolidated undertakings and investments accounted for using the equity method*** within the consolidated statement of cash flows.

Transaction related to the equity-accounted investment in Regeneron

From the beginning of April 2014, Sanofi accounted for its investment in Regeneron using the equity method. As from that date, in accordance with the Investor Agreement as amended in early 2014, Sanofi had the right to designate a member of the Regeneron Board of Directors.

On May 29, 2020, Sanofi closed the transaction announced on May 25, 2020 involving the sale of its equity investment in Regeneron (with the exception of 400,000 shares), through (i) a registered public offering in the United States and internationally and (ii) a share repurchase by Regeneron. Sanofi sold 13 million shares of Regeneron common stock (of which 10.6 million were sold by Sanofi) through the public offering at a price of $515 per share, raising a total amount of $6,703 million; and Regeneron repurchased 9.8 million of its own shares of common stock directly from Sanofi for $5,000 million, at the offer price less a subscription discount ($509.85 per share). The total sale proceeds (before transaction-related costs) amounted to €10,575 million. At the same time, Sanofi as a result of this transaction lost the right to designate a member of the Regeneron Board of Directors under the amended Investor Agreement. Finally, as of May 29, 2020 Sanofi retained ownership of 400,000 Regeneron shares in order to continue to partially fund its commitments to invest in the development programs for cemiplimab (REGN2810) and dupilumab, in line with the 2018 Letter Agreement under which Sanofi is permitted to sell up to 1.4 million shares through the end of 2020. As of December 31, 2020, Sanofi had sold 779,320 Regeneron shares under that agreement. The number of Regeneron shares retained by Sanofi is 279,766 as of December 31, 2020 (see Note C.1.).

Sanofi's equity investment in Regeneron was accounted for by the equity method until May 29, 2020. As of that date, the carrying amount of the investment was €3,668 million; that amount was reversed out on closing of the transaction. Before tax effects, the gain on the divestment amounted to €7,382 million, including (i) a gain of €318 million arising on the currency translation reserve associated with Regeneron, which was taken to profit or loss in accordance with IAS 21; (ii) the deduction of transaction-related costs of €64 million; and (iii) a gain of €157 million on the remeasurement of the 400,000 retained shares at their quoted market price as of May 29, 2020 ($612.81). In accordance with IFRS 9 (Financial Instruments), the retained shares were classified in the ***"Equity instruments at fair value through other comprehensive income"*** category on the transaction date, at a value of €221 million (see Note D.7.).

The tax charge arising on the transaction was €502 million.

Given the material impact of this transaction, and to facilitate users' understanding of the financial statements, the pre-tax gain on this transaction is presented as a separate line item in the consolidated income statement, ***Gain on Regeneron investment arising from the transaction of May 29, 2020***.

The net cash inflow from the transaction was €10,370 million, which (for the reason cited above) is presented as a separate line item in the consolidated statement of cash flows, ***Net proceeds from sale of Regeneron shares on May 29, 2020.***

Sale of Seprafilm®

On November 27, 2019, Sanofi entered into a definitive agreement to sell Seprafilm® to Baxter. The sale was completed on February 14, 2020. Sanofi recognized a pre-tax gain of €129 million.

The impact of this sale, reflected in the line item ***Proceeds from disposals of property, plant and equipment, intangible assets and other non-current assets, net of tax*** within the consolidated statement of cash flows, was a net cash inflow before tax of €311 million.

D.2. Principal changes in the scope of consolidation in 2019 and 2018

D.2.1. Principal changes in the scope of consolidation in 2019

The impacts of the acquisitions carried out in 2019 are not material to the Sanofi consolidated financial statements, and Sanofi did not divest any material operations or companies during the year.

Regeneron Pharmaceuticals, Inc. (Regeneron)

Changes in the equity interest held by Sanofi in Regeneron during 2019 and 2018 are set forth below:

(€ million)	2019	2018
Carrying amount[(a)]	3,342	3,055
Equity interest	21.2%	21.7%
Acquisitions of shares	—	—
Disposals of shares[(b)]	33	24

(a) See Note D.6.
(b) Disposals of shares in connection with the funding of R&D activities relating to Libtayo®, Dupixent® and REGN3500 (SAR440340) (see Note C.1.).

As mentioned in Note D.1., following the sale of 22.8 million shares of Regeneron common stock on May 29, 2020, Sanofi ceased to exercise significant influence over Regeneron, as a result of which Sanofi's interest in Regeneron is no longer accounted for using the equity method (see Note D.6.).

D.2.2. Principal changes in the scope of consolidation in 2018

Acquisition of Bioverativ

Following a public tender offer, on March 8, 2018 Sanofi acquired the entire share capital of Bioverativ, a biotechnology company specializing in the development of treatments for hemophilia and other rare blood disorders, for a total consideration of $11.6 billion (€9.4 billion).

The final purchase price allocation resulted in the recognition of goodwill amounting to €2,676 million, as indicated below:

(€ million)	Fair value at acquisition date
Other intangible assets	8,113
Inventories	145
Cash and cash equivalents	422
Other current and non-current assets and liabilities	16
True North Therapeutics contingent consideration liability	(226)
Net deferred tax position	(1,792)
Net assets of Bioverativ	**6,678**
Goodwill	2,676
Purchase price	**9,354**

The other intangible assets recognized mainly comprise the marketed hemophilia products Eloctate® and Alprolix®, and development projects relating to treatments for rare blood disorders.

Goodwill represents (i) the pipeline of future products in early-stage research and development not identified individually at the acquisition date; (ii) the capacity to draw on a specialized structure to refresh the existing product portfolio; (iii) the competencies of Bioverativ staff; (iv) the benefits derived from the creation of new growth platforms; and (v) the expected future synergies and other benefits from the combination of Bioverativ and Sanofi.

The goodwill generated on this acquisition did not give rise to any deduction for income tax purposes.

No material adjustment was required on completion of the final purchase price allocation.

Acquisition of Ablynx

On May 14, 2018, following a public tender offer, Sanofi acquired 95.60% of the share capital of Ablynx, a biopharmaceutical company specializing in the discovery and development of Nanobodies®. On June 19, 2018, following the expiration of the squeeze-out procedure, Sanofi announced that it held the entire share capital of Ablynx, representing a total investment of €3,897 million.

The final purchase price allocation resulted in the recognition of goodwill amounting to €1,360 million, as indicated below:

(€ million)	Fair value at acquisition date
Other intangible assets	2,409
Cash and cash equivalents	258
Other current and non-current assets and liabilities	131
Net deferred tax position	(261)
Net assets of Ablynx	**2,537**
Goodwill	1,360
Purchase price	**3,897**

The other intangible assets acquired mainly comprise rights to (i) Cablivi®, a medicine for the treatment of adults who have experienced an episode of acquired thrombotic thrombocytopenic purpura (aTTP) and (ii) the exploitation of technology developed by Ablynx that uses camelid antibody fragments (Nanobodies®) to discover and identify multi-specific molecules targeting multiple diseases in various therapeutic fields.

Goodwill represents the pipeline of future products in early-stage research and development not identified individually at the acquisition date, and the potential for those products to replace the existing product portfolio over the long term using resources and competencies specific to Ablynx, together with the expected future synergies and other benefits from the combination of Ablynx and Sanofi.

The goodwill generated on this acquisition did not give rise to any deduction for income tax purposes.

No material adjustments were required further to the final purchase price allocation.

Divestment of the European Generics business

On September 30, 2018, Sanofi finalized the divestment of its European Generics business. Sanofi recognized a gain of €510 million before taxes.

An analysis of the assets and liabilities divested is set forth below:

(€ million)	September 30, 2018
Assets	
Property, plant and equipment	120
Goodwill	913
Other intangible assets	75
Other non-current assets	1
Deferred tax assets	83
Inventories	129
Accounts receivable	107
Other current assets	40
Cash and cash equivalents	122
Total assets of the divested European Generics business	**1,590**
Liabilities	
Non-current provisions and other non-current liabilities	27
Deferred tax liabilities	14
Accounts payable	91
Other current liabilities	216
Short-term debt and current portion of long-term debt	46
Total liabilities of the divested European Generics business	**394**

The cash inflow on this divestment amounted to €1,598 million, and was recorded in the line item ***Proceeds from disposals of property, plant and equipment, intangible assets and other non-current assets, net of tax*** within the consolidated statement of cash flows.

D.3. Property, plant and equipment

D.3.1. Property, plant and equipment owned

Property, plant and equipment owned by Sanofi (including property, plant and equipment acquired under finance leases for 2018, prior to the application of IFRS 16) is comprised of the following items:

(€ million)	Land	Buildings	Machinery and equipment	Fixtures, fittings and other	Property, plant and equipment in process	Total
Gross value at January 1, 2018	**318**	**6,768**	**10,145**	**2,450**	**2,297**	**21,978**
Changes in scope of consolidation	—	6	11	4	1	22
Acquisitions and other increases	—	22	48	71	1,318	1,459
Disposals and other decreases	(23)	(227)	(272)	(127)	(20)	(669)
Currency translation differences	—	57	26	17	11	111
Transfers[(a)]	(12)	257	510	164	(1,123)	(204)
Gross value at December 31, 2018	**283**	**6,883**	**10,468**	**2,579**	**2,484**	**22,697**
Acquisitions and other increases	—	10	50	56	1,145	1,261
Disposals and other decreases	(3)	(42)	(148)	(114)	(12)	(319)
Currency translation differences	6	80	64	17	33	200
Transfers[(a)]	(31)	351	619	49	(1,259)	(271)
Gross value at December 31, 2019	**255**	**7,282**	**11,053**	**2,587**	**2,391**	**23,568**
Changes in scope of consolidation	—	6	3	1	—	10
Acquisitions and other increases	—	16	40	46	1,208	1,310
Disposals and other decreases	(11)	(173)	(177)	(123)	(3)	(487)
Currency translation differences	(13)	(264)	(276)	(67)	(91)	(711)
Transfers[(a)]	5	(39)	484	80	(1,051)	(521)
Gross value at December 31, 2020	**236**	**6,828**	**11,127**	**2,524**	**2,454**	**23,169**
Accumulated depreciation & impairment at January 1, 2018	**(20)**	**(3,612)**	**(6,885)**	**(1,804)**	**(78)**	**(12,399)**
Depreciation expense	—	(351)	(595)	(191)	—	(1,137)
Impairment losses, net of reversals	(8)	(24)	(40)	(11)	(12)	(95)
Disposals and other decreases	8	170	235	110	3	526
Currency translation differences	—	(29)	(15)	(14)	—	(58)
Transfers[(a)]	1	50	70	(4)	—	117
Accumulated depreciation & impairment at December 31, 2018	**(19)**	**(3,796)**	**(7,230)**	**(1,914)**	**(87)**	**(13,046)**
Depreciation expense	—	(357)	(586)	(194)	—	(1,137)
Impairment losses, net of reversals	(4)	(33)	(4)	(2)	(55)	(98)
Disposals and other decreases	2	54	140	106	11	313
Currency translation differences	—	(40)	(40)	(12)	—	(92)
Transfers[(a)]	10	107	60	32	—	209
Accumulated depreciation & impairment at December 31, 2019	**(11)**	**(4,065)**	**(7,660)**	**(1,984)**	**(131)**	**(13,851)**
Depreciation expense	—	(356)	(605)	(182)	—	(1,143)
Impairment losses, net of reversals	—	(24)	(12)	(7)	—	(43)
Disposals and other decreases	1	168	166	117	8	460
Currency translation differences	—	127	169	49	—	345
Transfers[(a)]	—	252	150	26	—	428
Accumulated depreciation & impairment at December 31, 2020	**(10)**	**(3,898)**	**(7,792)**	**(1,981)**	**(123)**	**(13,804)**
Carrying amount at December 31, 2018	264	3,087	3,238	665	2,397	9,651
Carrying amount at December 31, 2019	244	3,217	3,393	603	2,260	9,717
Carrying amount at December 31, 2020	**226**	**2,930**	**3,335**	**543**	**2,331**	**9,365**

*(a) This line mainly comprises property, plant and equipment in process brought into service during the period, but also includes the effect of the reclassification of assets to **Assets held for sale or exchange**, and for 2019 the reclassification of assets held under finance leases to **Right-of-use assets** on first-time application of IFRS 16.*

The table below sets forth acquisitions and capitalized interest by operating segment for the years ended December 31, 2020, 2019 and 2018:

(€ million)	2020	2019	2018
Acquisitions	**1,310**	**1,261**	**1,459**
Pharmaceuticals	831	846	1,014
Industrial facilities	*634*	*682*	*769*
Research sites	*152*	*87*	*14*
Other	*45*	*77*	*231*
Vaccines	384	405	440
Consumer Healthcare	95	10	5
Capitalized interest	**11**	**14**	**21**

Off balance sheet commitments relating to property, plant and equipment as of December 31, 2020, 2019 and 2018 are set forth below:

(€ million)	2020	2019	2018
Firm orders of property, plant and equipment	708	398	535
Property, plant and equipment pledged as security for liabilities	—	107	123

Impairment tests of property, plant and equipment conducted using the method described in Note B.6. resulted in the recognition of the following net impairment losses in each of the last three financial periods:

(€ million)	2020	2019	2018
Net impairment losses on property, plant and equipment	**43**	**98**	**94**

Due to the first-time application of IFRS 16 effective January 1, 2019, future minimum lease payments due under finance leases have since that date been recognized as part of the lease liability. Because Sanofi used the modified retrospective approach for transition, historical information has not been restated. However, as the prior standard (IAS 17) was applicable in preceding periods, finance lease assets and future minimum lease payments due under finance leases are shown in the tables below.

The table below shows amounts for items of property, plant and equipment held under finance leases:

(€ million)	2018
Buildings	73
Other property, plant and equipment	14
Total gross value	**87**
Accumulated depreciation and impairment	(64)
Carrying amount	**23**

Future minimum lease payments due under finance leases are shown in the table below:

(€ million)	2018
Future minimum lease payments due under finance leases	**25**
of which interest	*3*

D.3.2. Property, plant and equipment leased - right-of-use assets

On first-time application of IFRS 16 effective January 1, 2019, Sanofi used the modified retrospective approach for transition, and the historical information was not restated.

Right-of-use assets relating to property, plant and equipment leased by Sanofi are analyzed in the table below:

(€ million)	Right-of-use assets
Gross value at January 1, 2019	**1,439**
Acquisitions and other increases	157
Disposals and other decreases	(31)
Currency translation differences	18
Gross value at December 31, 2019	**1,583**
Changes in scope of consolidation	15
Acquisitions and other increases	340
Disposals and other decreases	(121)
Currency translation differences	(85)
Transfers[(a)]	(21)
Gross value at December 31, 2020	**1,711**
Accumulated depreciation & impairment at January 1, 2019	**(8)**
Depreciation and amortization expense[(b)]	(282)
Disposals and other decreases	7
Accumulated depreciation & impairment at December 31, 2019	**(283)**
Depreciation and amortization expense[(b)]	(299)
Disposals and other decreases	44
Currency translation differences	22
Transfers[(a)]	3
Accumulated depreciation & impairment at December 31, 2020	**(513)**
Carrying amount at January 1, 2019[(c)]	1,431
Carrying amount at December 31, 2019	1,300
Carrying amount at December 31, 2020	**1,198**

*(a) This line also includes the effect of the reclassification of assets to **Assets held for sale or exchange** as of December 31, 2020.*

(b) Impairment losses against right of use assets amounted to €31 million as of December 31, 2020. and were immaterial as of December 31, 2019.

(c) Sanofi elected the simplified retrospective method for first-time application of IFRS 16 (Leases), which involved recognizing a right-of-use asset equal to the lease liability, adjusted by the amount of any prepaid or accrued lease payments; impacts of the adoption of IFRS 16 on the balance sheet primarily included the recognition of right-of-use assets of €1,431 million, the recognition of current and non-current lease liabilities of €1,346 million, and an increase in provisions and other current and non-current liabilities of €73 million.

Leased assets mainly comprise office and industrial premises (92%) and the vehicle fleet (8%) as of December 31, 2020.

Annual lease costs on short term leases and low value asset leases amounted to €27 million in the year ended December 31, 2020, and to €50 million in the year ended December 31, 2019. Variable lease payments, sub-leasing activities, and sale-and-leaseback transactions were immaterial.

Total cash outflows on leases (excluding annual lease costs on short term leases and low value asset leases) amounted to €269 million in the year ended December 31, 2020 and to €302 million in the year ended December 31, 2019.

For information purposes, as the previous standard (IAS 17) was applicable in previous years, lease expense amounted to €345 million in 2018.

A maturity analysis of the lease liability is disclosed in Note D.17.2.

Commitments related to short-term leases and low value asset leases, including future payments for lease contracts committed but not yet commenced, are disclosed in Note D.21.

D.4. Goodwill and other intangible assets

Movements in goodwill comprise:

(€ million)	Goodwill
Balance at January 1, 2018	**40,264**
Acquisitions during the period	4,039
Other movements during the period[(a)]	(1,006)
Currency translation differences	938
Balance at December 31, 2018	**44,235**
Acquisitions during the period	—
Other movements during the period[(a)]	(244)
Currency translation differences	528
Balance at December 31, 2019	**44,519**
Acquisitions during the period	1,843
Other movements during the period[(a)]	(75)
Currency translation differences	(1,923)
Balance at December 31, 2020	**44,364**

(a) This line includes the amount of goodwill allocated to divested operations in accordance with paragraph 86 of IAS 36. In 2018, it mainly comprises the goodwill allocated to the European Generics business when it was divested (see Note D.2.2.).

Acquisition of Principia (2020)

The provisional purchase price allocation for Principia resulted in the recognition of intangible assets (other than goodwill) of €2,534 million as of the acquisition date (September 28, 2020), and of goodwill provisionally measured at €913 million as of the acquisition date (see Note D.1.).

Acquisition of Synthorx (2020)

The final purchase price allocation for Synthorx resulted in the recognition of intangible assets (other than goodwill) totaling €1,549 million as of the acquisition date (January 23, 2020), and of goodwill measured at €930 million as of the acquisition date (see Note D.1.).

Acquisition of Bioverativ (2018)

The final purchase price allocation for Bioverativ resulted in the recognition of intangible assets (other than goodwill) totaling €8,113 million at the acquisition date (March 8, 2018), and of goodwill measured at €2,676 million at the acquisition date (see Note D.2.2.).

Acquisition of Ablynx (2018)

The final purchase price allocation for Ablynx resulted in the recognition of intangible assets (other than goodwill) totaling €2,409 million at the acquisition date (May 14, 2018), and of goodwill measured at €1,360 million at the acquisition date (see Note D.2.2.).

Movements in other intangible assets comprise:

(€ million)	Acquired R&D	Products, trademarks and other rights	Software	Total other intangible assets
Gross value at January 1, 2018	**3,679**	**53,638**	**1,368**	**58,685**
Changes in scope of consolidation	3,632	6,889	2	10,523
Acquisitions and other increases	367	16	251	634
Disposals and other decreases	(44)	(920)	(75)	(1,039)
Currency translation differences	218	1,757	10	1,985
Transfers[(a)]	(430)	420	3	(7)
Gross value at December 31, 2018	**7,422**	**61,800**	**1,559**	**70,781**
Acquisitions and other increases	272	19	184	475
Disposals and other decreases	(236)	(569)	(50)	(855)
Currency translation differences	86	889	10	985
Transfers[(a)]	(1,814)	1,814	(5)	(5)
Gross value at December 31, 2019	**5,730**	**63,953**	**1,698**	**71,381**
Changes in scope of consolidation	3,951	132	—	4,083
Acquisitions and other increases	654	58	137	849
Disposals and other decreases	(44)	(243)	(46)	(333)
Currency translation differences	(593)	(2,926)	(39)	(3,558)
Transfers[(a)]	(98)	100	(2)	—
Gross value at December 31, 2020	**9,600**	**61,074**	**1,748**	**72,422**
Accumulated amortization & impairment at January 1, 2018	**(2,204)**	**(42,476)**	**(925)**	**(45,605)**
Amortization expense	—	(2,188)	(115)	(2,303)
Impairment losses, net of reversals[(b)]	(456)	(264)	(10)	(730)
Disposals and other decreases	36	840	68	944
Currency translation differences	(54)	(1,146)	(6)	(1,206)
Transfers[(a)]	—	6	2	8
Accumulated amortization & impairment at December 31, 2018	**(2,678)**	**(45,228)**	**(986)**	**(48,892)**
Amortization expense	—	(2,167)	(134)	(2,301)
Impairment losses, net of reversals[(b)]	(847)	(2,757)	(23)	(3,627)
Disposals and other decreases	158	488	51	697
Currency translation differences	(31)	(648)	(8)	(687)
Transfers[(a)]	2	(2)	1	1
Accumulated amortization & impairment at December 31, 2019	**(3,396)**	**(50,314)**	**(1,099)**	**(54,809)**
Amortization expense	—	(1,707)	(125)	(1,832)
Impairment losses, net of reversals[(b)]	(328)	(2)	—	(330)
Disposals and other decreases	44	232	45	321
Currency translation differences	158	2,460	31	2,649
Transfers[(a)]	14	(14)	—	—
Accumulated amortization & impairment at December 31, 2020	**(3,508)**	**(49,345)**	**(1,148)**	**(54,001)**
Carrying amount at December 31, 2018	4,744	16,572	573	21,889
Carrying amount at December 31, 2019	2,334	13,639	599	16,572
Carrying amount at December 31, 2020	**6,092**	**11,729**	**600**	**18,421**

(a) The "Transfers" line mainly relates to acquired R&D that came into commercial use during the period and is being amortized from the date of marketing approval.
(b) See Note D.5.

"Products, trademarks and other rights" mainly comprise:

- "marketed products", with a carrying amount of €11.4 billion as of December 31, 2020 (versus €13.3 billion as of December 31, 2019 and €15.5 billion as of December 31, 2018) and a weighted average amortization period of approximately 10 years; and
- "technological platforms", with a carrying amount of €0.2 billion as of December 31, 2020 (versus €0.2 billion as of December 31, 2019 and €0.2 billion as of December 31, 2018) and a weighted average amortization period of approximately 10 years.
- "trademarks", with a carrying amount of €0.1 billion as of December 31, 2020 (versus €0.1 billion as of December 31, 2019 and €0.1 billion as of December 31, 2018) and a weighted average amortization period of approximately 12 years.

The table below provides information about the principal "marketed products", which were recognized in connection with business combinations and represented 91% of the carrying amount of that item as of December 31, 2020:

(€ million)	Gross value	Accumulated amortization & impairment	Carrying amount at December 31, 2020	Amortization period (years)[a]	Residual amortization period (years)[b]	Carrying amount at December 31, 2019	Carrying amount at December 31, 2018
Genzyme	9,823	(8,338)	1,485	10	3	2,095	2,988
Boehringer Ingelheim Consumer Healthcare	3,687	(1,198)	2,489	16	14	2,699	3,237
Aventis	32,474	(32,364)	110	9	7	219	409
Chattem	1,192	(590)	602	23	13	711	748
Protein Sciences	751	(197)	554	13	10	667	715
Ablynx	2,279	(418)	1,861	13	11	2,029	376
Bioverativ	6,516	(3,276)	3,240	13	11	3,788	6,385
Total: principal marketed products	**56,722**	**(46,381)**	**10,341**			**12,208**	**14,858**

(a) Weighted averages. The amortization periods for these products vary between 1 and 25 years.
(b) Weighted averages.

Acquisitions of other intangible assets (excluding software) during 2020 amounted to €692 million.

During 2020, some of the acquired research and development came into commercial use, and started being amortized from the date of marketing approval; the main items involved were Sarclisa®, indicated for the treatment of relapsed refractory multiple myeloma, and the meningococcal vaccine MenQuadfi™.

During 2019, some of the acquired research and development came into commercial use, and started being amortized from the date of marketing approval; the item involved was the acquired thrombotic thrombocytopenic purpura (aTTP) treatment Cablivi®.

During 2018, some of the acquired research and development came into commercial use, and started being amortized from the date of marketing approval. The main item involved was the immuno-oncology product Libtayo® (€348 million).

Amortization of other intangible assets is recognized in the income statement within the line item ***Amortization of intangible assets***, except for amortization of software and other rights of an industrial or operational nature which is recognized in the relevant classification of expense by function. An analysis of amortization of software is shown in the table below:

(€ million)	2020	2019	2018
Cost of sales	19	11	21
Research and development expenses	2	3	4
Selling and general expenses	100	114	87
Other operating expenses	4	6	3
Total	**125**	**134**	**115**

D.5. Impairment of intangible assets and property, plant and equipment

Goodwill

In accordance with IAS 36, goodwill is allocated to groups of cash generating units (CGUs) at a level corresponding to the Pharmaceuticals, Consumer Healthcare and Vaccines segments. When testing goodwill annually for impairment, the recoverable amount is determined for each segment on the basis of value in use, determined using discounted estimates of the future cash flows in accordance with the policies described in Note B.6.1.

The allocation of goodwill as of December 31, 2020 is shown below:

(€ million)	Pharmaceuticals	Consumer Healthcare	Vaccines	Total
Goodwill	**36,682**	**6,425**	**1,257**	**44,364**

The value in use of each segment was determined by applying an after-tax discount rate to estimated future after-tax cash flows.

A separate discount rate is used for each segment to reflect the specific economic conditions of that segment.

The rates used for impairment testing in 2020 were 7.25% for the Pharmaceuticals segment, 7.00% for the Consumer Healthcare segment and 7.25% for the Vaccines segment; an identical value in use for Sanofi as a whole would be obtained by applying a uniform 7.2% rate to all three segments.

The pre-tax discount rates applied to estimated pre-tax cash flows are calculated by iteration from the previously-determined value in use. Those pre-tax discount rates were 9.5% for the Pharmaceuticals segment, 8.9% for the Consumer Healthcare segment and 9.7% for the Vaccines segment, and equate to a uniform rate of 9.5% for Sanofi as a whole.

The assumptions used in testing goodwill for impairment are reviewed annually. Apart from the discount rate, the principal assumptions used in 2020 were as follows:

- The perpetual growth rates applied to future cash flows were zero for the Pharmaceuticals and Vaccines segments, and 1% for the Consumer Healthcare segment.
- Sanofi also applies assumptions on the probability of success of current research and development projects, and more generally on its ability to renew the product portfolio in the longer term.

Value in use (determined as described above) is compared with the carrying amount, and this comparison is then subjected to sensitivity analyses by reference to the principal parameters, including:

- changes in the discount rate;
- changes in the perpetual growth rate; and
- fluctuations in operating margin.

No impairment of goodwill would need to be recognized in the event of a reasonably possible change in the assumptions used in 2020.

A value in use calculation for each of the segments would not result in an impairment loss using:

- a discount rate up to 4.5 percentage points above the rates actually used; or
- a perpetual growth rate up to 20.1 percentage points below the rates actually used; or
- an operating margin up to 9.4 percentage points below the rates actually used.

No impairment losses were recognized against goodwill in the years ended December 31, 2020, 2019 or 2018.

Other intangible assets

When there is evidence that an asset may have become impaired, the asset's value in use is calculated by applying an after-tax discount rate to the estimated future after-tax cash flows from that asset. For the purposes of impairment testing, the tax cash flows relating to the asset are determined using a notional tax rate incorporating the notional tax benefit that would result from amortizing the asset if its value in use were regarded as its depreciable amount for tax purposes. Applying after-tax discount rates to after-tax cash flows gives the same values in use as would be obtained by applying pre-tax discount rates to pre-tax cash flows.

The after-tax discount rates used in 2020 for impairment testing of other intangible assets in the Pharmaceuticals, Consumer Healthcare and Vaccines segments were obtained by adjusting Sanofi's weighted average cost of capital to reflect specific country and business risks, giving after-tax discount rates in a range from 7.25% to 8.25%.

In most instances, there are no market data that would enable fair value less costs to sell to be determined other than by means of developing a similar estimate based on future cash flows. Consequently, recoverable amount is in substance equal to value in use. The estimates used to determine value in use are sensitive to assumptions specific to the nature of the asset and to Sanofi's activities. Apart from the discount rate, the principal assumptions used in 2020 were as follows:

- mid-term and long-term sales forecasts;
- perpetual growth or attrition rates, when applicable; and
- probability of success of current research and development projects.

The assumptions used in testing intangible assets for impairment are reviewed at least annually.

In 2020, 2019 and 2018, impairment testing of other intangible assets (excluding software) resulted in the recognition of net impairment losses as shown below:

(€ million)	2020	2019	2018
Impairment of other intangible assets (excluding software)	**330**	**3,604**	**720**
Marketed products	2	2,757	264
Pharmaceuticals[(a)]	*2*	*2,405*	*258*
Vaccines	—	—	*6*
CHC[(b)]	—	*352*	—
Research and development projects[(c)]	328	847	454
Other[(d)]	—	—	2

(a) Impairment tests conducted on other intangible assets as of December 31, 2019 led to (i) the recognition of an impairment loss of €2,236 million on the product Eloctate® (as part of the broader Eloctate® franchise) and (ii) an impairment loss of €163 million on the marketed product Lemtrada®, compared with €183 million as of December 31, 2018.

(b) Impairment tests conducted on other intangible assets as of December 31, 2019 led to the recognition of an impairment loss of €352 million on assets related to Zantac®.

(c) For 2020, this line mainly comprises impairment losses taken against R&D programs within the Specialty Care GBU, and the discontinuation of certain R&D programs and collaboration agreements in Diabetes. For 2019, it relates mainly to (i) the allocation of the impairment loss recognized for the Eloctate® franchise to the BIVV001 project (see (a) above), and (ii) the termination of the development program for sotagliflozin (€275 million). For 2018, this line relates mainly to intangible assets of Ablynx and to other R&D intellectual property assets, including the MyoKardia and efpeglenatide programs in Diabetes.

*(d) Not included within the line item **Impairment of intangible assets** in the consolidated income statements (see Note B.4.).*

Property, plant and equipment

Impairment losses taken against property, plant and equipment are disclosed in Note D.3.

D.6. Investments accounted for using the equity method

Investments accounted for using the equity method comprise associates and joint ventures (see Note B.1.), and are set forth below.

(€ million)	% interest	2020	2019	2018
Regeneron Pharmaceuticals, Inc.[a]	—	—	3,342	3,055
Onduo LLC[b]	19.9	—	—	108
Infraserv GmbH & Co. Höchst KG[c]	31.2	72	70	73
Entities and companies managed by Bristol-Myers Squibb[d]	100.0	—	37	40
Other investments	—	129	142	126
Total		**201**	**3,591**	**3,402**

(a) Following the transaction of May 29, 2020 as described in Note D.1. above, which resulted in the divestment of 22.8 million Regeneron shares, Sanofi no longer exercises significant influence over Regeneron. As of that date, Sanofi retained 0.4 million Regeneron shares, classified in the "Equity instruments at fair value through other comprehensive income" category (see Note D.7.1.). As of December 31, 2020, Sanofi held 279,766 Regeneron shares.

(b) As a result of the restructuring of Onduo LLC, finalized November 11, 2019, Sanofi lost significant influence over that entity on that date; this did not have a material impact on profit or loss in the year ended December 31, 2019. As of that date, Sanofi held a 19.9% equity interest in Onduo. As of December 31, 2020, Sanofi still held a 19.9% equity interest in Onduo.

(c) Joint venture.

(d) On February 28, 2020, Sanofi acquired from Bristol-Myers Squibb the remaining 50.1% equity interest not yet held by Sanofi in the three partnerships that organize the commercialization of Plavix® in the United States and Puerto Rico, for a total consideration of $12 million. The acquisition was accounted for in accordance with IFRS 3 (Business Combinations).

The table below shows Sanofi's overall share of (i) profit or loss and (ii) other comprehensive income from investments accounted for using the equity method, showing the split between associates and joint ventures in accordance with IFRS 12 (the amounts for each individual associate or joint venture are not material):

	2020		2019		2018	
(€ million)	Joint ventures	Associates	Joint ventures	Associates	Joint ventures	Associates
Share of profit/(loss) from investments accounted for using the equity method	4	355 [a]	15	240	17	482
Share of other comprehensive income from investments accounted for using the equity method	8	(311)	(7)	90	(7)	105
Total	**12**	**44**	**8**	**330**	**10**	**587**

(a) Includes €343 million for Sanofi's share of the net income of Regeneron up to and including May 29, 2020 (see Note D.1.)

The financial statements include arm's length commercial transactions between Sanofi and some equity-accounted investments that are classified as related parties. The principal transactions and balances with related parties are summarized below:

(€ million)	2020	2019	2018
Sales	75	24	35
Royalties and other income[a]	97	270	116
Accounts receivable and other receivables	50	151	89
Purchases and other expenses (including research expenses)[a]	747	1,334	1,143
Accounts payable and other payables	15	342	544

(a) For 2020, these amounts include transactions between Sanofi and Regeneron for the period from January 1 through May 29, 2020. The table above does not include the repurchase by Regeneron of its own shares from Sanofi (see Note D.1.).

There were no funding commitments to associates and joint ventures as of December 31, 2020, compared with €67 million as of December 31, 2019.

For off balance sheet commitments of an operational nature involving joint ventures, see Note D.21.1.

Regeneron

As mentioned in Note D.1., as a result of the sale of 22.8 million shares of Regeneron common stock on May 29, 2020, Sanofi ceased to exercise significant influence over Regeneron, and this investment is no longer accounted for using the equity method.

Key items from the 2018 and 2019 consolidated financial statements of Regeneron, after adjustments to comply with IFRS (including those required to align on elective accounting treatments adopted by Sanofi) but before fair value remeasurements, are set forth below:

(€ million)	2019	2018
Net sales and other revenues	7,023	5,680
Net income	1,882	2,476
Other comprehensive income for the period, net of taxes	113	(33)
Comprehensive income	1,995	2,443

(€ million)	December 31, 2019	December 31, 2018
Current assets	6,858	5,621
Non-current assets	6,627	4,731
Total assets	**13,485**	**10,352**
Current liabilities	1,870	1,258
Non-current liabilities	925	772
Total liabilities	**2,795**	**2,030**
Consolidated shareholders' equity of Regeneron	**10,690**	**8,322**

The table below shows a reconciliation to the carrying amount of the investment:

(€ million)	December 31, 2019	December 31, 2018
% interest	21%	22%
Share of equity attributable to Sanofi	2,263	1,806
Goodwill	839	858
Fair value remeasurements of assets and liabilities at the acquisition date	811	873
Other items[(a)]	(571)	(482)
Carrying amount of the investment in Regeneron	3,342	3,055

(a) Mainly comprises the difference arising from Sanofi's share of the accumulated profits and losses and other changes in the net assets of Regeneron for the periods prior to first-time application of the equity method, and thereafter (i) Sanofi's share of the stock option expense recognized against equity in the books of Regeneron, and of the deferred taxes recognized against equity in respect of that expense in accordance with IAS 12 paragraph 68.C. and (ii) the effects of the elimination of internal profits between Sanofi and Regeneron.

The market value of Sanofi's investment in Regeneron as of December 31, 2019 and 2018, based on the quoted stock market price per share in US dollars, is shown below:

	2019	2018
Quoted stock market price per share ($)	375.48	373.50
Market value of investment in Regeneron ($ million)	8,767	8,835
Market value of investment in Regeneron (€ million)	7,820	7,702

D.7. Other non-current assets

Other non-current assets comprise:

(€ million)	2020	2019	2018
Equity instruments at fair value through other comprehensive income (D.7.1.)	588	380	1,037
Debt instruments at fair value through other comprehensive income (D.7.2.)	426	403	359
Other financial assets at fair value through profit or loss (D.7.3.)	890	892	733
Pre-funded pension obligations (Note D.19.1.)	177	155	77
Long-term prepaid expenses	92	115	126
Long-term loans and advances and other non-current receivables	537	521	464
Derivative financial instruments (Note D.20.)	24	37	19
Total	**2,734**	**2,503**	**2,815**

D.7.1. Equity instruments at fair value through other comprehensive income

Quoted equity investments

The main changes in the quoted equity investments included in the “Equity instruments at fair value through other comprehensive income” category during the year ended December 31, 2020 are described below:

- As mentioned in Note D.1., following the sale of 22.8 million shares of Regeneron common stock on May 29, 2020, Sanofi ceased to exercise significant influence over Regeneron, and this investment is no longer accounted for using the equity method (see Note D.6.). In accordance with IFRS 9 (Financial Instruments), the 400,000 shares retained by Sanofi were classified in the **"Equity instruments at fair value through other comprehensive income"** category as of May 29, 2020, at a carrying amount of €221 million. As of December 31, 2020, Sanofi held 279,766 Regeneron shares with a carrying amount of €111 million.
- An equity injection was made into Translate Bio under the terms of the collaboration and license agreement announced on June 23, 2020, with a carrying amount of €74 million as of December 31, 2020 and representing an equity interest of approximately 8% of Translate Bio as of that date.
- Sanofi owns equity interests in quoted biotechnology companies. Movements in the quoted market prices of the shares held in those companies generated a net gain of €357 million, recognized in **"Equity instruments at fair value through other comprehensive income"**.

The main changes in the quoted equity investments included in the “Equity instruments at fair value through other comprehensive income” category during the year ended December 31, 2019 are described below:

- On May 2, 2019, further to the announcement on April 8, 2019 of amendments to the terms of the agreement governing Sanofi’s equity interest in Alnylam, Sanofi divested its entire holding of 10.6 million Alnylam shares, representing approximately 10% of Alnylam's equity capital. Proceeds from the divestment amounted to €706 million, net of taxes. The loss on the divestment was recognized in full in ***Other comprehensive income***. This equity interest had a carrying amount of €671 million as of December 31, 2018.
- The entire equity interest held by Sanofi in MyoKardia, Inc. was divested during the first half of 2019. Proceeds from the divestment amounted to €118 million, net of taxes. The gain arising on the divestment was recognized in full in ***Other comprehensive income***. This equity interest had a carrying amount of €178 million as of December 31, 2018.
- Following the restructuring of Onduo LLC, finalized November 11, 2019, Sanofi received from Onduo a dividend in the form of DexCom shares valued at $122 million. As of December 31, 2020, those shares had a carrying amount of €90 million, versus €104 million as of December 31, 2019.

A 10% decline in stock prices of the quoted equity investments included within “Equity instruments at fair value through other comprehensive income” would have had a negative pre-tax impact of €44 million on ***Other comprehensive income*** as of December 31, 2020.

Unquoted equity investments

The line item “Equity instruments at fair value through other comprehensive income” also includes equity investments not quoted in an active market. The carrying amount of those investments was €149 million as of December 31, 2020 and €266 million as of December 31, 2019.

D.7.2. Debt instruments at fair value through other comprehensive income

The “Debt instruments at fair value through other comprehensive income” category includes quoted euro-denominated senior bonds amounting to €426 million as of December 31, 2020, including €172 million of securities obtained in exchange for financial assets held to meet obligations to employees under post-employment benefit plans.

Sanofi held €403 million of quoted senior bonds as of December 31, 2019 and €359 million as of December 31, 2018.

As regards debt instruments held to meet obligations to employees under post-employment benefit plans, a reduction of 10 basis points in market interest rates as of December 31, 2020 would have had a pre-tax impact of €3 million on ***Other comprehensive income***.

As regards other quoted debt instruments, a reduction of 10 basis points in market interest rates as of December 31, 2020 would have had a pre-tax impact of €1 million on ***Other comprehensive income***.

Other comprehensive income recognized in respect of “Equity instruments at fair value through other comprehensive income” and “Debt instruments at fair value through other comprehensive income” represented unrealized after-tax gains of €200 million as of December 31, 2020, versus unrealized after-tax losses of €80 million as of December 31, 2019 and €148 million as of December 31, 2018.

An analysis of the change in gains and losses recognized in ***Other comprehensive income***, and of items reclassified to profit or loss, is presented in Note D.15.7.

D.7.3. Other financial assets at fair value through profit or loss

The “Other financial assets at fair value through profit or loss” category includes:

- Contingent consideration receivable by Sanofi following the dissolution of the Sanofi Pasteur MSD (SPMSD) joint venture, based on a percentage of MSD’s future sales during the 2017-2024 period of specified products previously distributed by SPMSD (see Notes B.1. and D.12.).

  The fair value of the MSD contingent consideration was determined by applying the royalty percentage stipulated in the contract to discounted sales projections. A reduction of one percentage point in the discount rate would increase the fair value of the MSD contingent consideration by approximately 2%.

Changes in the fair value of this contingent consideration are recognized in the income statement within the line item ***Fair value remeasurement of contingent consideration*** (see Note B.18.). As of December 31, 2020, the contingent consideration asset amounted to €483 million (including a non-current portion of €374 million), versus €492 million (non-current portion: €398 million) as of December 31, 2019 and €373 million as of December 31, 2018.

- A portfolio of financial investments (amounting to €453 million as of December 31, 2020) held to fund a deferred compensation plan provided to certain employees (versus €442 million as of December 31, 2019 and €363 million as of December 31, 2018).
- Unlisted securities not meeting the definition of equity instruments totaling €63 million as of December 31, 2020 (versus €52 million as of December 31, 2019 and €61 million as of December 31, 2018).

D.8. Assets held for sale or exchange and liabilities related to assets held for sale or exchange

Assets held for sale or exchange, and liabilities related to assets held for sale or exchange, comprise:

(€ million)	December 31, 2020	December 31, 2019	December 31, 2018
Assets held for sale or exchange	83	325	68
Liabilities related to assets held for sale or exchange	32	6	—

As of December 31, 2020, assets held for sale mainly related to the planned divestment of an industrial facility in North America.

As of December 31, 2019, assets held for sale mainly comprised assets associated with the sale of Seprafilm®, which was completed in the first half of 2020.

D.9. Inventories

Inventories comprise the following:

	2020			2019			2018		
(€ million)	Gross value	Allowances	Carrying amount	Gross value	Allowances	Carrying amount	Gross value	Allowances	Carrying amount
Raw materials	1,051	(76)	975	1,163	(76)	1,087	1,099	(83)	1,016
Work in process	5,398	(542)	4,856	5,104	(582)	4,522	4,637	(549)	4,088
Finished goods	2,739	(218)	2,521	2,629	(244)	2,385	2,533	(160)	2,373
Total	**9,188**	**(836)**	**8,352**	**8,896**	**(902)**	**7,994**	**8,269**	**(792)**	**7,477**

Allowances include write-downs of products on hand pending marketing approval.
Inventories pledged as security for liabilities amounted to €17 million as of December 31, 2020 (versus €15 million as of December 31, 2019 and €18 million as of December 31, 2018).

D.10. Accounts receivable

Accounts receivable break down as follows:

(€ million)	December 31, 2020	December 31, 2019	December 31, 2018
Gross value	7,633	8,090	7,430
Allowances	(142)	(153)	(170)
Carrying amount	**7,491**	**7,937**	**7,260**

The impact of allowances against accounts receivable in 2020 was a net expense of €30 million (versus a net gain of €5 million in 2019 and a net expense of €15 million in 2018).

The gross value of overdue receivables was €549 million as of December 31, 2020, compared with €642 million as of December 31, 2019 and €547 million as of December 31, 2018.

(€ million)	Overdue accounts gross value	Overdue by <1 month	Overdue by 1 to 3 months	Overdue by 3 to 6 months	Overdue by 6 to 12 months	Overdue by > 12 months
December 31, 2020	**549**	**271**	**97**	**52**	**34**	**95**
December 31, 2019	642	269	171	61	36	105
December 31, 2018	547	257	172	36	21	61

Amounts overdue by more than one month relate mainly to public-sector customers.

Some Sanofi subsidiaries have assigned receivables to factoring companies or banks without recourse. The amount of receivables derecognized was €18 million as of December 31, 2020 (€214 million as of December 31, 2019 and €385 million as of December 31, 2018). The €18 million derecognized in 2020 related to Europe. The residual guarantees relating to such transfers were immaterial as of December 31, 2020.

D.11. Other current assets

An analysis of ***Other current assets*** is set forth below:

(€ million)	2020	2019	2018
Tax receivables, other than corporate income taxes	687	603	564
Other receivables	567	735	627
Prepaid expenses	525	493	469
Interest rate derivatives measured at fair value (see Note D.20.)	—	4	30
Currency derivatives measured at fair value (see Note D.20.)	58	184	134
Other current financial assets[(a)]	900	426	199
Total	**2,737**	**2,445**	**2,023**

(a) For 2019, this line includes an amount of $315 million deposited by Sanofi in an escrow account and released in March 2020 following the signature of an agreement to settle the CVR litigation with the trustee. For 2020, it mainly comprises bank loans and receivables falling due within less than one year with high-grade counterparties.

D.12. Financial assets and liabilities measured at fair value

Under IFRS 7 (Financial Instruments: Disclosures), fair value measurements must be classified using a fair value hierarchy with the following levels:

- level 1: quoted prices in active markets for identical assets or liabilities (without modification or repackaging);
- level 2: quoted prices in active markets for similar assets and liabilities, or valuation techniques in which all important inputs are derived from observable market data;
- level 3: valuation techniques in which not all important inputs are derived from observable market data.

The valuation techniques used are described in Note B.8.5.

The table below shows the balance sheet amounts of assets and liabilities measured at fair value.

		2020			2019			2018		
		Level in the fair value hierarchy			Level in the fair value hierarchy			Level in the fair value hierarchy		
(€ million)	Note	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Financial assets measured at fair value										
Quoted equity investments	**D.7.1.**	439	—	—	114	—	—	859	—	—
Unquoted equity investments	**D.7.1.**	—	—	149	—	—	290	—	—	197
Quoted debt securities	**D.7.2.**	426	—	—	403	—	—	359	—	—
Unquoted debt securities not meeting the definition of equity instruments	**D.7.3.**	—	—	63	—	—	52	—	—	61
Contingent consideration relating to divestments	**D.7.3.**	—	—	483	—	—	492	—	—	373
Financial assets held to meet obligations under deferred compensation plans	**D.7.3. and D.11.**	454	—	—	442	—	—	364	—	—
Non-current derivatives	**D.7.**	—	24	—	—	37	—	—	19	—
Current derivatives	**D.11.**	—	58	—	—	188	—	—	164	—
Mutual fund investments	**D.13.**	8,703	—	—	5,304	—	—	3,189	—	—
Total financial assets measured at fair value		**10,022**	**82**	**695**	**6,263**	**225**	**834**	**4,771**	**183**	**631**
Financial liabilities measured at fair value										
CVRs issued in connection with the acquisition of Genzyme	**D.18.**	—	—	—	—	—	—	99	—	—
Bayer contingent purchase consideration arising from the acquisition of Genzyme	**D.18.**	—	—	104	—	—	156	—	—	472
MSD contingent consideration (European vaccines business)	**D.18.**	—	—	312	—	—	385	—	—	410
Other contingent consideration arising from business combinations	**D.18.**	—	—	189	—	—	259	—	—	301
Liabilities related to non-controlling interests	**D.18.**	—	—	—	—	—	—	—	—	22
Non-current derivatives	**D.19.**	—	92	—	—	10	—	—	7	—
Current derivatives	**D.19.5**	—	205	—	—	89	—	—	90	—
Total financial liabilities measured at fair value		**—**	**297**	**605**	**—**	**99**	**800**	**99**	**97**	**1,205**

No transfers between the different levels of the fair value hierarchy occurred during 2020.

In connection with the dissolution of the Sanofi Pasteur MSD (SPMSD) joint venture, finalized on December 31, 2016, Sanofi recognized contingent consideration receivable as a financial asset at fair value through profit or loss (see Note D.7.3.), and contingent consideration payable in ***Liabilities related to business combinations and to non-controlling interests*** (see Note D.18.). As of December 31, 2020:

- the financial asset relating to contingent consideration receivable by Sanofi based on a percentage of MSD's future sales during the 2017-2024 period of specified products previously distributed by SPMSD amounted to €483 million; and
- the financial liability relating to contingent consideration payable to MSD based on a percentage of future sales made by Sanofi Pasteur during the 2017-2024 period of specified products previously distributed by SPMSD amounted to €312 million.

D.13. Cash and cash equivalents

(€ million)	2020	2019	2018
Cash	1,144	701	661
Cash equivalents[(a)]	12,771	8,726	6,264
Cash and cash equivalents	**13,915**	**9,427**	**6,925**

(a) As of December 31, 2020, cash equivalents mainly comprised the following: (i) €8,703 million invested in euro and US dollar denominated money-market mutual funds (December 31, 2019: €5,304 million; December 31, 2018: €3,189 million); (ii) €3,259 million of term deposits (December 31, 2019: €2,211 million; December 31, 2018: €2,014 million) and (iii) €74 million in commercial paper (December 31, 2019: €446 million; December 31, 2018: €357 million). Cash equivalents also include €425 million held by captive insurance and reinsurance companies in accordance with insurance regulations (December 31, 2019: €456 million; December 31, 2018: €505 million).

D.14. Net deferred tax position

An analysis of the net deferred tax position is set forth below:

(€ million)	2020		2019	2018
Deferred taxes on:				
Consolidation adjustments (intragroup margin in inventory)	1,142		1,270	1,195
Provision for pensions and other employee benefits	1,213		1,327	1,166
Remeasurement of other acquired intangible assets	(3,083)	[(a)]	(2,656)	(3,740)
Recognition of acquired property, plant and equipment at fair value	(27)		(33)	(31)
Equity interests in subsidiaries and investments in other entities[(b)]	(522)		(421)	(437)
Tax losses available for carry-forward	1,327		1,323	1,341
Stock options and other share-based payments	88		142	110
Accrued expenses and provisions deductible at the time of payment[(c)]	1,399		1,405	1,394
Other[(d)]	905		783	201
Net deferred tax asset/(liability)	**2,442**		**3,140**	**1,199**

(a) As of December 31, 2020, includes remeasurements of the acquired intangible assets of Bioverativ (€1,021 million), Principia (€547 million), Genzyme (€367 million) and Synthorx (€315 million).

(b) In some countries, Sanofi is liable for withholding taxes and other tax charges when dividends are distributed. Consequently, Sanofi recognizes a deferred tax liability on the reserves of French and foreign subsidiaries (approximately €47.8 billion) which it regards as likely to be distributed in the foreseeable future. In determining the amount of the deferred tax liability as of December 31, 2020, Sanofi took into account changes in the ownership structure of certain subsidiaries, and the effects of changes in the taxation of dividends in France following the ruling of the Court of Justice of the European Union in the Steria case and the resulting amendments to the 2015 Finance Act.

(c) Includes deferred tax assets related to restructuring provisions, amounting to €307 million as of December 31, 2020, €259 million as of December 31, 2019, and €218 million as of December 31, 2018.

(d) The 2019 movement in the "Other" line mainly comprises the recognition of a deferred tax asset on an internal transfer of intangible assets.

The reserves of Sanofi subsidiaries that would be taxable if distributed but for which no distribution is planned, and for which no deferred tax liability has therefore been recognized, totaled €11.5 billion as of December 31, 2020, compared with €10.9 billion as of December 31, 2019 and €10.2 billion as of December 31, 2018.

Most of Sanofi's tax loss carry-forwards are available indefinitely. For a description of policies on the recognition of deferred tax assets, refer to Note B.22. For each tax consolidation, the recognition of deferred tax assets is determined on the basis of profit forecasts that are consistent with Sanofi's medium-term strategic plan, and taking into consideration the tax consequences of the strategic opportunities available to Sanofi within the period of availability of tax loss carry-forwards and the specific circumstances of each tax consolidation. Deferred tax assets relating to tax loss carry-forwards as of December 31, 2020 amounted to €1,658 million, of which €331 million were not recognized. This compares with €1,640 million as of December 31, 2019 (of which €317 million were not recognized) and €1,651 million as of December 31, 2018 (of which €310 million were not recognized).

The table below shows when tax losses available for carry-forward are due to expire:

(€ million)	Tax losses available for carry-forward[(a)]
2021	53
2022	37
2023	36
2024	10
2025	38
2026 and later	6,341
Total as of December 31, 2020	**6,515**
Total as of December 31, 2019	**6,401**
Total as of December 31, 2018	**6,100**

(a) Excluding tax loss carry-forwards on asset disposals. Such carry-forwards amounted to €6 million as of December 31, 2020, and €1 million as of December 31, 2019 and December 31, 2018.

Use of tax loss carry-forwards is limited to the entity in which they arose. In jurisdictions where tax consolidations are in place, tax losses can be netted against taxable income generated by entities in the same tax consolidation.

Deferred tax assets not recognized because their future recovery was not regarded as probable given the expected results of the entities in question amounted to €346 million in 2020, €340 million in 2019 and €298 million in 2018.

D.15. Consolidated shareholders' equity

D.15.1. Share capital

As of December 31, 2020, the share capital was €2,517,943,476, consisting of 1,258,971,738 shares with a par value of €2. Treasury shares held by Sanofi are as follows:

	Number of shares (million)	% of share capital for the period
December 31, 2020	**8.28**	**0.658%**
December 31, 2019	0.02	0.002%
December 31, 2018	1.94	0.156%
January 1, 2018	0.17	0.014%

Treasury shares are deducted from shareholders' equity. Gains and losses on disposals of treasury shares are recorded directly in equity and are not recognized in net income for the period.

Movements in the share capital of the Sanofi parent company over the last three years are set forth below:

Date	Transaction	Number of shares
December 31, 2017		**1,254,019,904**
During 2018	Capital increase by exercise of stock subscription options[(a)]	1,168,808
During 2018	Capital increase by issuance of restricted shares[(b)]	2,152,183
Board meeting of April 26, 2018	Reduction in share capital by cancellation of treasury shares	(7,239,803)
Board meeting of July 27, 2018	Capital increase reserved for employees	2,401,184
Board meeting of December 18, 2018	Reduction in share capital by cancellation of treasury shares	(5,106,804)
December 31, 2018		**1,247,395,472**
During 2019	Capital increase by exercise of stock subscription options[(a)]	2,745,853
During 2019	Capital increase by issuance of restricted shares[(b)]	3,704,786
December 31, 2019		**1,253,846,111**
During 2020	Capital increase by exercise of stock subscription options[(a)]	868,655
During 2020	Capital increase by issuance of restricted shares[(b)]	1,666,256
Board meeting of July 28, 2020	Capital increase reserved for employees	2,590,716
December 31, 2020		**1,258,971,738**

(a) Shares issued on exercise of Sanofi stock subscription options.
(b) Shares vesting under restricted share plans and issued in the period.

For the disclosures about the management of capital required under IFRS 7, refer to Note B.27.

D.15.2. Restricted share plans

Restricted share plans are accounted for in accordance with the policies described in Note B.24.3. The principal characteristics of those plans are as follows:

	2020		2019	2018	
Type of plan	Performance share plan	Performance share plan	Performance share plan	Performance share plan	Performance share plan
Date of Board meeting approving the plan	April 28, 2020	October 28, 2020	April 30, 2019	July 30, 2018	May 2, 2018
Service period	3 years	3 years	3 years	3 years	3 years
Total number of shares awarded in 2018 and 2019			3,797,582	141,669	4,390,216
Fair value per share awarded (€)[(a)]			67.90	64.35	56.59
Total number of shares awarded in 2020	3,340,501	73,027			
Of which with no market condition	2,536,893	—			
Fair value per share awarded (€)[(a)]	82.36	—			
Of which with market condition	803,608	73,027			
Fair value per share awarded (€)[(b)]	76.11	63.18			
Fair value of plan at the date of grant (€ million)	**270**	**5**	**258**	**9**	**248**

(a) Market price of Sanofi shares at the date of grant, adjusted for dividends expected during the vesting period.
(b) Weighting between (i) fair value determined using the Monte Carlo model and (ii) market price of Sanofi shares at the date of grant, adjusted for dividends expected during the vesting period.

The total expense recognized for all restricted share plans, and the number of restricted shares not yet fully vested, are shown in the table below:

	2020	2019	2018
Total expense for restricted share plans (€ million)	222	247	248
Number of shares not yet fully vested	10,546,612	10,908,503	13,576,464
Under 2020 plans	*3,284,558*	—	—
Under 2019 plans	*3,375,717*	*3,662,806*	—
Under 2018 plans	*3,886,337*	*4,117,795*	*4,406,593*
Under 2017 plans	—	*3,127,902*	*3,314,391*
Under 2016 plans	—	—	*3,690,226*
Under 2015 plans	—	—	*2,165,254*

D.15.3. Capital increases

The characteristics of the employee share ownership plans awarded in the form of a capital increase reserved for employees in 2020 and 2018 are summarized in the table below; there were no capital increases reserved for employees in 2019.

	2020	2018
Date of Board meeting approving the plan	February 5, 2020	March 6, 2018
Subscription price (€)[(a)]	70.67	52.66
Subscription period	June 8-26, 2020	June 11-29, 2018
Number of shares subscribed	2,467,101	2,298,783
Number of shares issued immediately as employer's contribution	123,615	102,401

(a) Subscription price representing 80% of the average of the opening quoted market prices of Sanofi shares during the 20 trading days preceding June 2, 2020 and June 9, 2018, respectively.

The table below sets forth the expense recognized for each plan:

(€ million)	2020	2018
Expense recognized	52	32
of which employer's contribution	*11*	*7*

D.15.4. Repurchase of Sanofi shares

The Annual General Meetings of Sanofi shareholders held on April 28 2020, April 30, 2019, May 2, 2018 and May 10, 2017 each authorized a share repurchase program for a period of 18 months. The following repurchases have been made under those programs:

(in number of shares and € million)	2020		2019		2018	
Year of authorization	Number of shares	Value	Number of shares	Value	Number of shares	Value
2020 program	5,685,426	461	—	—	—	—
2019 program	3,982,939	361	—	—	—	—
2018 program	—	—	147,793	12	6,884,792	501
2017 program	—	—	—	—	8,489,873	602

D.15.5. Reductions in share capital

Reductions in share capital for the accounting periods presented are described in the table included at Note D.15.1. above.

Those reductions have no impact on shareholders' equity.

D.15.6. Currency translation differences

Currency translation differences comprise the following:

(€ million)	2020	2019	2018
Attributable to equity holders of Sanofi	(3,386)	632	(167)
Attributable to non-controlling interests	(55)	(36)	(36)
Total	**(3,441)**	**596**	**(203)**

The balance as of December 31, 2020 includes an after-tax amount of €(136) million relating to hedges of net investments in foreign operations (refer to Note B.8.3. for a description of the relevant accounting policy), versus €(260) million as of December 31, 2019 and €(145) million as of December 31, 2018.

The movement in ***Currency translation differences*** is mainly attributable to the US dollar.

D.15.7. Other comprehensive income

Movements within other comprehensive income are shown below:

(€ million)	2020	2019	2018
Actuarial gains/(losses):			
• Actuarial gains/(losses) excluding investments accounted for using the equity method (see Note D.19.1.)	(267)	(377)	201
• Actuarial gains/(losses) of investments accounted for using the equity method, net of taxes	(1)	(5)	—
• Tax effects	45	161	(69)
Equity instruments included in financial assets and financial liabilities:			
• Change in fair value (excluding investments accounted for using the equity method)	358	30	(529)
• Change in fair value (investments accounted for using the equity method, net of taxes)	(14)	80	(8)
• Equity risk hedging instruments designated as fair value hedges	(24)	(4)	—
• Tax effects	(85)	(48)	100
Items not subsequently reclassifiable to profit or loss	**12**	**(163)**	**(305)**
Debt instruments included in financial assets:			
• Change in fair value (excluding investments accounted for using the equity method)[(a)]	15	28	(4)
• Change in fair value (investments accounted for using the equity method, net of taxes)	—	—	—
• Tax effects	(3)	(5)	—
Cash flow hedges:			
• Change in fair value (excluding investments accounted for using the equity method)[(b)]	4	(13)	3
• Change in fair value (investments accounted for using the equity method, net of taxes)	—	—	—
• Tax effects	(2)	4	(1)
Change in currency translation differences:			
• Currency translation differences on foreign subsidiaries (excluding investments accounted for using the equity method)[(b)]	(3,872)	850	1,273
• Currency translation differences (investments accounted for using the equity method)[(b)]	32	64	106
• Currency translation differences related to the investment in Regeneron and reclassified to profit or loss[(c)]	(318)	—	—
• Hedges of net investments in foreign operations[(b)]	180	(163)	(185)
• Tax effects[(c)]	(58)	48	72
Items subsequently reclassifiable to profit or loss	**(4,022)**	**813**	**1,264**

(a) Amounts reclassified to profit or loss: €5 million in 2020, and immaterial in 2019 and 2018.

(b) Amounts reclassified to profit or loss: €1 million in 2020, €27 million in 2019 and €(7) million in 2018.

(c) Relates to the translation reserve arising on the investment in Regeneron, which was reclassified to profit or loss in accordance with IAS 21 (The Effects of Changes in Foreign Exchange Rates), of which €2 million (net of tax) related to hedges of net investments in foreign operations.

D.15.8. Stock options

Stock option plans awarded and measurement of stock option plans

No stock options were awarded during 2020.

Stock options granted by the Board of Directors in 2019 and 2018 are summarized below, with the assumptions used to determine their fair value:

	2019	2018
Date of Board meeting approving the plan	April 30, 2019	May 2, 2018
Total number of options granted	220,000	220,000
Exercise price (€)	76.71	65.84
Vesting period	4 years	4 years
Plan expiry date	April 30, 2029	May 2, 2028
Fair value of the plan (€ million)	2	1
Fair value per option granted (€)	7.80	6.32
Assumptions used to determine fair value		
Dividend yield	4.31%	4.87%
Volatility of Sanofi shares, computed on a historical basis	22.48%	23.10%
Risk-free interest rate	0.15%	0.36%
Plan maturity	8 years	7 years

The expense recognized through equity for stock option plans is immaterial.

Stock subscription option plans

Details of the terms of exercise of stock subscription options granted under the various plans are presented below in Sanofi share equivalents. These plans were awarded to certain corporate officers and employees of Sanofi companies.

The table shows all Sanofi stock subscription option plans still outstanding or under which options were exercised in the year ended December 31, 2020:

Source	Date of grant	Number of options granted	Start date of exercise period	Expiry date	Exercise price (€)	Number of options outstanding as of 12/31/2020
Sanofi-aventis	03/01/2010	8,121,355	03/03/2014	02/28/2020	54.12	—
Sanofi-aventis	03/09/2011	874,500	03/10/2015	03/09/2021	50.48	32,448
Sanofi-aventis	03/05/2012	814,050	03/06/2016	03/05/2022	56.44	173,867
Sanofi	03/05/2013	788,725	03/06/2017	03/05/2023	72.19	380,256
Sanofi	03/05/2014	1,009,250	03/06/2018	03/05/2024	73.48	634,265
Sanofi	06/24/2015	435,000	06/25/2019	06/24/2025	89.38	339,964
Sanofi	05/04/2016	402,750	05/05/2020	05/04/2026	75.90	284,250
Sanofi	05/10/2017	378,040	05/11/2021	05/10/2027	88.97	294,220
Sanofi	05/02/2018	220,000	05/03/2022	05/02/2028	65.84	220,000
Sanofi	04/30/2019	220,000	05/02/2023	04/30/2029	76.71	220,000
Total						**2,579,270**

The exercise of all outstanding stock subscription options would increase shareholders' equity by approximately €195 million. The exercise of each option results in the issuance of one share.

Summary of stock option plans

A summary of stock options outstanding at each balance sheet date, and of movements during the relevant periods, is presented below:

	Number of options	Weighted average exercise price per share (€)	Total (€ million)
Options outstanding at January 1, 2018	**7,889,020**	**60.08**	**474**
Options exercisable	*5,812,165*	*52.93*	*308*
Options granted	220,000	65.84	14
Options exercised	(1,192,838)	50.02	(60)
Options cancelled[(a)]	(66,609)	82.03	(5)
Options outstanding at December 31, 2018	**6,849,573**	**61.81**	**423**
Options exercisable	*5,468,214*	*56.80*	*311*
Options granted	220,000	76.71	17
Options exercised	(2,816,123)	53.18	(150)
Options cancelled[(a)]	(48,005)	72.84	(3)
Options forfeited	(383,425)	44.90	(17)
Options outstanding at December 31, 2019	**3,822,020**	**70.58**	**270**
Options exercisable	*2,650,375*	*67.14*	*178*
Options exercised	(868,655)	59.20	(52)
Options cancelled[(a)]	(91,305)	87.73	(8)
Options forfeited	(282,790)	54.12	(15)
Options outstanding at December 31, 2020	**2,579,270**	**75.61**	**195**
Options exercisable	*1,845,050*	*74.51*	*137*

(a) Mainly due to the grantees leaving Sanofi.

The table below provides summary information about options outstanding and exercisable as of December 31, 2020:

	Outstanding			Exercisable	
Range of exercise prices per share	Number of options	Weighted average residual life (years)	Weighted average exercise price per share (€)	Number of options	Weighted average exercise price per share (€)
From €50.00 to €60.00 per share	206,315	1.02	55.50	206,315	55.50
From €60.00 to €70.00 per share	220,000	7.34	65.84	—	—
From €70.00 to €80.00 per share	1,518,771	4.08	74.08	1,298,771	73.63
From €80.00 to €90.00 per share	634,184	5.35	89.19	339,964	89.38
Total	**2,579,270**			**1,845,050**	

D.15.9. Number of shares used to compute diluted earnings per share

Diluted earnings per share is computed using the number of shares outstanding plus stock options with dilutive effect and restricted shares.

(million)	2020	2019	2018
Average number of shares outstanding	1,253.6	1,249.9	1,247.1
Adjustment for stock options with dilutive effect	0.4	0.8	1.3
Adjustment for restricted shares	6.1	6.4	6.8
Average number of shares used to compute diluted earnings per share	**1,260.1**	**1,257.1**	**1,255.2**

In 2020, 0.6 million stock options were not taken into account in computing diluted earnings per share because they had no dilutive effect, compared with 0.8 million in 2019 and 2.5 million in 2018.

D.16. Non-controlling interests

Non-controlling interests did not represent a material component of Sanofi's consolidated financial statements in the years ended December 31, 2020, 2019 and 2018.

D.17. Debt, cash and cash equivalents and lease liabilities

D.17.1. Debt, cash and cash equivalents

Changes in Sanofi's financial position during the period were as follows:

(€ million)	2020	2019	2018
Long-term debt	19,745	20,131	22,007
Short-term debt and current portion of long-term debt	2,767	4,554	2,633
Interest rate and currency derivatives used to manage debt	119	(117)	(54)
Total debt	**22,631**	**24,568**	**24,586**
Cash and cash equivalents	(13,915)	(9,427)	(6,925)
Interest rate and currency derivatives used to manage cash and cash equivalents	74	(34)	(33)
Net debt[(a)]	**8,790**	**15,107**	**17,628**

(a) Following the first-time application of IFRS 16 effective January 1, 2019, net debt does not include lease liabilities, which amounted to €1,163 million as of December 31, 2020 and €1,248 million as of December 31, 2019 (see the maturity analysis at Note D.17.2.).

"Net debt" is a non-GAAP financial measure used by management and investors to measure Sanofi's overall net indebtedness.

Reconciliation of carrying amount to value on redemption

				Value on redemption		
(€ million)	Carrying amount at December 31, 2020	Amortized cost	Adjustment to debt measured at fair value	December 31, 2020	December 31, 2019	December 31, 2018
Long-term debt	19,745	70	(21)	19,794	20,180	22,071
Short-term debt and current portion of long-term debt	2,767	(2)	2	2,767	4,553	2,613
Interest rate and currency derivatives used to manage debt	119		23	142	(86)	(12)
Total debt	**22,631**	**68**	**4**	**22,703**	**24,647**	**24,672**
Cash and cash equivalents	(13,915)			(13,915)	(9,427)	(6,925)
Interest rate and currency derivatives used to manage cash and cash equivalents	74			74	(34)	(33)
Net debt	**8,790**	**68**	**4**	**8,862**	**15,186**	**17,714**

a) Principal financing transactions during the year

The table below shows the movement in total debt during the period:

		Cash flows from financing activities		Non-cash items				
(€ million)	December 31, 2019	Repayments	New borrowings	Other cash flows	Currency translation differences	Reclassification from non-current to current	Other items[(a)]	December 31, 2020
Long-term debt	20,131	—	2,019	—	(152)	(2,285)	32	19,745
Short-term debt and current portion of long-term debt	4,554	(3,952)	—	86	(219)	2,285	13	2,767
Interest rate and currency derivatives used to manage debt	(117)	—	—	196	(14)	—	54	119
Total debt	**24,568**	**(3,952)**	**2,019**	**282**	**(385)**	**—**	**99**	**22,631**

(a) Includes fair value remeasurements.

Sanofi carried out one bond issue of €1.5 billion in March 2020 under the Sanofi EMTN program, in two tranches:

- €750 million maturing April 2025 and bearing interest at an annual fixed rate of 1.000%; and
- €750 million maturing April 2030 and bearing interest at an annual fixed rate of 1.500%.

Sanofi also carried out two tap issues in April 2020 of €500 million:

- €250 million on the tranche maturing April 2025 bearing interest at an annual fixed rate of 1.000%; and
- €250 million on the tranche maturing April 2030 bearing interest at an annual fixed rate of 1.500%.

Five bond issues were redeemed in 2020:

- €1 billion issued in September 2016, redeemed on maturity on January 13, 2020;
- €500 million issued in March 2018, redeemed on maturity on March 21, 2020;
- €1 billion issued in March 2018, redeemed on maturity on March 21, 2020;
- €1 billion issued in September 2013 and maturing September 2020, redeemed early on June 4, 2020; and
- €500 million issued by Genzyme Corp in June 2010, redeemed on maturity on June 15, 2020

On December 8, 2020, Sanofi agreed its first two sustainability-linked revolving credit facilities, involving:

- amendments to the existing credit facility expiring December 2021, by adding two extension options each of one year; and
- a new syndicated credit facility of €4 billion expiring December 2025 and including two extension options each of one year; this new facility, which took effect on December 8, 2020, replaced an existing €4 billion facility cancelled on the same day.

In line with Sanofi's commitment to embed sustainable development in the "Play to Win" strategy, the two revolving credit facilities build in an adjustment mechanism that links the credit spread to the attainment of two sustainable development performance indicators: Sanofi's contribution to polio eradication, and the reduction in Sanofi's carbon footprint.

Consequently, as of December 31, 2020 Sanofi had two syndicated credit facilities of €4 billion each available for the purposes of current operations, both of them linked to environmental and social indicators and both them having two one-year extension options.

b) Net debt by type, at value on redemption

	2020			2019			2018		
(€ million)	Non-current	Current	Total	Non-current	Current	Total	Non-current	Current	Total
Bond issues	19,698	2,280	21,978	20,128	4,079	24,207	21,983	2,181	24,164
Other bank borrowings	96	200	296	40	156	196	57	176	233
Finance lease obligations[(b)]	–	–	–	–	–	–	18	4	22
Other borrowings	–	2	2	13	12	25	13	3	16
Bank credit balances	–	285	285	–	305	305	–	249	249
Interest rate and currency derivatives used to manage debt	57	85	142	–	(86)	(86)	–	(12)	(12)
Total debt	**19,851**	**2,852**	**22,703**	**20,181**	**4,466**	**24,647**	**22,071**	**2,601**	**24,672**
Cash and cash equivalents	–	(13,915)	(13,915)	–	(9,427)	(9,427)	–	(6,925)	(6,925)
Interest rate and currency derivatives used to manage cash and cash equivalents	6	68	74	(6)	(28)	(34)	–	(33)	(33)
Net debt[(a)]	**19,857**	**(10,995)**	**8,862**	**20,175**	**(4,989)**	**15,186**	**22,071**	**(4,357)**	**17,714**

(a) Following the first-time application of IFRS 16 effective January 1, 2019, net debt does not include lease liabilities (see the maturity schedule in Note D.17.2.).

*(b) Following the first-time application of IFRS 16 effective January 1, 2019, the finance lease obligation as of that date was reclassified to **Lease liabilities**.*

Bond issues carried out by Sanofi under the Euro Medium Term Note (EMTN) program are as follows:

Issuer	ISIN code	Issue date	Maturity	Annual interest rate	Amount (€ million)
Sanofi	FR0011625433	November 2013	November 2023	2.5%	1,000
Sanofi	FR0012146777	September 2014	March 2022	1.125%	1,000
Sanofi	FR0012146801	September 2014	September 2026	1.75%	1,510
Sanofi	FR0012969020	September 2015	September 2021	0.875%	500
Sanofi	FR0012969038	September 2015	September 2025	1.5%	750
Sanofi	FR0013143997	April 2016	April 2024	0.625%	600
Sanofi	FR0013144003	April 2016	April 2028	1.125%	700
Sanofi	FR0013201621	September 2016	September 2022	- %	850
Sanofi	FR0013201639	September 2016	January 2027	0.5%	1,150
Sanofi	FR0013505104	March 2020	April 2025	1%	1,000
Sanofi	FR0013505112	March 2020	April 2030	1.5%	1,000
Sanofi	FR0013324332	March 2018	March 2023	0.5%	1,750
Sanofi	FR0013324340	March 2018	March 2026	1%	1,500
Sanofi	FR0013324357	March 2018	March 2030	1.375%	2,000
Sanofi	FR0013324373	March 2018	March 2038	1.875%	1,250
Sanofi	FR0013409836	March 2019	March 2022	- %	850
Sanofi	FR0013409844	March 2019	March 2029	0.875%	650
Sanofi	FR0013409851	March 2019	March 2034	1.25%	500

Bond issues carried out by Sanofi under the public bond issue program (shelf registration statement) registered with the US Securities and Exchange Commission (SEC) comprise:

Issuer	ISIN code	Issue date	Maturity	Annual interest rate	Amount ($ million)
Sanofi	US80105NAG07	March 2011	March 2021	4%	2,000
Sanofi	US801060AC87	June 2018	June 2023	3.375%	1,000
Sanofi	US801060AD60	June 2018	June 2028	3.625%	1,000

The “Other borrowings” line mainly comprises participating shares issued between 1983 and 1987, of which 76,986 remain outstanding, with a nominal amount of €12 million.

In order to manage its liquidity needs for current operations, Sanofi has:

- a syndicated credit facility of €4 billion, drawable in euros and in US dollars, due to expire on December 5, 2021 following the exercise of a second extension option in November 2016, and with two further one-year extension options still available; and
- a syndicated credit facility of €4 billion, drawable in euros and in US dollars, due to expire on December 8, 2025, with two one-year extension options still available.

Sanofi also has a €6 billion Negotiable European Commercial Paper program in France and a $10 billion Commercial Paper program in the United States. During 2020 only the US program was used, with an average drawdown of $1.5 billion and a maximum drawdown of $4.0 billion. As of December 31, 2020, neither of those programs was being utilized.

The financing in place as of December 31, 2020 at the level of the holding company (which manages most of Sanofi’s financing needs centrally) is not subject to any financial covenants, and contains no clauses linking fees to the credit rating.

c) Debt by maturity, at value on redemption

December 31, 2020		Current	Non-current				
(€ million)	Total	2021	2022	2023	2024	2025	2026 and later
Bond issues	21,978	2,280	2,700	3,569	600	1,750	11,079
Other bank borrowings	296	200	73	6	2	6	9
Finance lease obligations[(b)]	–	–	–	–	–	–	–
Other borrowings	2	2	–	–	–	–	–
Bank credit balances	285	285	–	–	–	–	–
Interest rate and currency derivatives used to manage debt	142	85	57	–	–	–	–
Total debt	**22,703**	**2,852**	**2,830**	**3,575**	**602**	**1,756**	**11,088**
Cash and cash equivalents	(13,915)	(13,915)	–	–	–	–	–
Interest rate and currency derivatives used to manage cash and cash equivalents	74	68	6	–	–	–	–
Net debt[(a)]	**8,862**	**(10,995)**	**2,836**	**3,575**	**602**	**1,756**	**11,088**

(a) Following the first-time application of IFRS 16 effective January 1, 2019, net debt does not include lease liabilities, which amounted to €1,163 million as of December 31, 2020 and €1,248 million as of December 31, 2019 (see the maturity analysis at Note D.17.2.).

*(b) Following the first-time application of IFRS 16 effective January 1, 2019, the finance lease obligation as of that date was reclassified to **Lease liabilities**.*

December 31, 2019		Current	Non-current				
(€ million)	Total	2020	2021	2022	2023	2024	2025 and later
Bond issues	24,207	4,079	2,284	2,700	3,642	600	10,902
Other bank borrowings	196	156	6	6	23	5	–
Finance lease obligations	–	–	–	–	–	–	–
Other borrowings	25	12	–	–	–	–	13
Bank credit balances	305	305	–	–	–	–	–
Interest rate and currency derivatives used to manage debt	(86)	(86)			–	–	–
Total debt	**24,647**	**4,466**	**2,290**	**2,706**	**3,665**	**605**	**10,915**
Cash and cash equivalents	(9,427)	(9,427)	–	–	–	–	–
Interest rate and currency derivatives used to manage cash and cash equivalents	(34)	(28)	(6)	–	–	–	–
Net debt	**15,186**	**(4,989)**	**2,284**	**2,706**	**3,665**	**605**	**10,915**

December 31, 2018		Current	Non-current				
(€ million)	Total	2019	2020	2021	2022	2023	2024 and later
Bond issues	24,164	2,181	3,936	2,243	1,850	3,622	10,332
Other bank borrowings	233	176	15	3	3	28	8
Finance lease obligations	22	4	3	3	3	4	5
Other borrowings	16	3	—	—	—	—	13
Bank credit balances	249	249	—	—	—	—	—
Interest rate and currency derivatives used to manage debt	(12)	(12)	—	—	—	—	—
Total debt	**24,672**	**2,601**	**3,954**	**2,249**	**1,856**	**3,654**	**10,358**
Cash and cash equivalents	(6,925)	(6,925)	—	—	—	—	—
Interest rate and currency derivatives used to manage cash and cash equivalents	(33)	(33)	—	—	—	—	—
Net debt	**17,714**	**(4,357)**	**3,954**	**2,249**	**1,856**	**3,654**	**10,358**

As of December 31, 2020, the main undrawn confirmed general-purpose credit facilities at holding company level amounted to €8 billion, of which half expires in 2021 and half in 2025.

As of December 31, 2020, no single counterparty represented more than 6% of Sanofi's undrawn confirmed credit facilities.

d) Debt by interest rate, at value on redemption

The table below splits net debt between fixed and floating rate, and by maturity, as of December 31, 2020. The figures shown are values on redemption, before the effects of derivative instruments:

(€ million)	Total	2021	2022	2023	2024	2025	2026 and later
Fixed-rate debt	21,978	2,280	2,700	3,569	600	1,750	11,079
of which euro	*18,703*						
of which US dollar	*3,275*						
% fixed-rate	**97%**						
Floating-rate debt	584	488	73	6	2	6	9
of which euro	*35*						
of which US dollar	*69*						
% floating-rate	**3%**						
Debt	**22,562**	**2,768**	**2,773**	**3,575**	**602**	**1,756**	**11,088**
Cash and cash equivalents	(13,915)	(13,915)	–	–	–	–	–
of which euro	*(9,192)*						
of which US dollar	*(4,278)*						
% floating-rate	**100%**						
Net debt	**8,647**	**(11,147)**	**2,773**	**3,575**	**602**	**1,756**	**11,088**

Sanofi issues debt in two currencies, the euro and the US dollar, and also invests its cash and cash equivalents in those currencies. Sanofi also operates cash pooling arrangements to manage the surplus cash and short-term liquidity needs of foreign subsidiaries located outside the euro zone.

To optimize the cost of debt or reduce the volatility of debt and manage its exposure to financial foreign exchange risk, Sanofi uses derivative instruments (interest rate swaps, currency swaps, foreign exchange swaps and forward contracts) that alter the fixed/floating rate split and the currency split of its net debt:

(€ million)	Total	2021	2022	2023	2024	2025	2026 and later
Fixed-rate debt	20,713	2,358	1,357	3,569	600	1,750	11,079
of which euro	*17,752*						
of which US dollar	*2,960*						
% fixed-rate	**91%**						
Floating-rate debt	1,990	494	1,473	6	2	6	9
of which euro	*415*						
of which US dollar	*69*						
of which Japanese yen	*215*						
% floating-rate	**9%**						
Debt	**22,703**	**2,852**	**2,830**	**3,575**	**602**	**1,756**	**11,088**
Cash and cash equivalents	(13,841)	(13,847)	6				
of which euro	*(4,442)*						
of which US dollar	*(6,333)*						
of which Singapore dollar	*(2,250)*						
% floating-rate	**100%**						
Net debt	**8,862**	**(10,995)**	**2,836**	**3,575**	**602**	**1,756**	**11,088**

The table below shows the fixed/floating rate split of net debt at value on redemption after taking account of derivative instruments as of December 31, 2019 and December 31, 2018:

(€ million)	2019	%	2018	%
Fixed-rate debt	21,713	88%	18,864	76%
Floating-rate debt	2,934	12%	5,808	24%
Debt	**24,647**	**100%**	**24,672**	**100%**
Cash and cash equivalents	(9,461)		(6,958)	
Net debt	**15,186**		**17,714**	

The weighted average interest rate on debt as of December 31, 2020 was 1.6% before derivative instruments and 1.7% after derivative instruments. Cash and cash equivalents were invested as of December 31, 2020 at an average rate of 0.0% before derivative instruments and 0.4% after derivative instruments.

The projected full-year sensitivity of net debt to interest rate fluctuations for 2021 is as follows:

Change in short-term interest rates	Impact on pre-tax net income (€ million)	Impact on pre-tax income/(expense) recognized directly in equity (€ million)
+100 bp	119	–
+25 bp	30	–
-25 bp	(30)	–
-100 bp	(119)	–

e) Debt by currency, at value on redemption

The table below shows net debt by currency at December 31, 2020, before and after derivative instruments contracted to convert the foreign-currency net debt of exposed entities into their functional currency:

(€ million)	Before derivative instruments	After derivative instruments
Euro	9,547	13,725
US dollar	(933)	(3,304)
Singapore dollar	(1)	(2,250)
Japanese yen	—	214
Chinese yuan renminbi	(9)	(179)
Other currencies	43	656
Net debt	**8,647**	**8,862**

The table below shows net debt by currency at December 31, 2019 and 2018, after derivative instruments contracted to convert the foreign currency net debt of exposed entities into their functional currency:

(€ million)	2019	2018
Euro	17,691	16,511
US dollar	(813)	2,197
Other currencies	(1,692)	(994)
Net debt	**15,186**	**17,714**

f) Market value of net debt

The market value of Sanofi's debt, net of cash and cash equivalents and derivatives and excluding accrued interest, is as follows:

(€ million)	2020	2019	2018
Market value	10,500	16,370	18,003
Value on redemption	8,862	15,186	17,714

The fair value of debt is determined by reference to quoted market prices at the balance sheet date in the case of quoted instruments (level 1 in the IFRS 7 hierarchy, see Note D.12.), and by reference to the fair value of interest rate and currency derivatives used to manage net debt (level 2 in the IFRS 7 hierarchy, see Note D.12.).

g) Future contractual cash flows relating to debt and related derivatives

The table below shows the amount of future undiscounted contractual cash flows (principal and interest) relating to debt and to derivative instruments designated as hedges of debt:

December 31, 2020	Payments due by period						
(€ million)	Total	2021	2022	2023	2024	2025	2026 and later
Debt	**24,339**	**2,943**	**3,019**	**3,808**	**791**	**1,937**	**11,841**
Principal	22,392	2,622	2,757	3,571	601	1,751	11,090
Interest[(a)]	1,947	321	262	237	190	186	751
Net cash flows related to derivative instruments	**163**	**135**	**28**	**–**	**–**	**–**	**–**
Total	**24,502**	**3,078**	**3,047**	**3,808**	**791**	**1,937**	**11,841**

(a) Interest flows are estimated on the basis of forward interest rates applicable as of December 31, 2020.

Future contractual cash flows are shown on the basis of the carrying amount in the balance sheet at the reporting date, without reference to any subsequent management decision that might materially alter the structure of Sanofi's debt or its hedging policy.

The tables below show the amount of future undiscounted contractual cash flows (principal and interest) relating to debt and to derivative instruments designated as hedges of debt as of December 31, 2019 and 2018:

December 31, 2019		Payments due by period					
(€ million)	Total	2020	2021	2022	2023	2024	2025 and later
Debt	**26,708**	**4,775**	**2,588**	**2,952**	**3,862**	**771**	**11,760**
Principal	24,596	4,417	2,305	2,710	3,646	604	10,914
Interest[(a)]	2,112	358	283	242	216	167	846
Net cash flows related to derivative instruments	**(117)**	**(97)**	**(11)**	**(9)**			
Total	**26,591**	**4,678**	**2,577**	**2,943**	**3,862**	**771**	**11,760**

(a) Interest flows are estimated on the basis of forward interest rates applicable as of December 31, 2019.

December 31, 2018		Payments due by period					
(€ million)	Total	2019	2020	2021	2022	2023	2024 and later
Debt	**26,881**	**2,855**	**4,300**	**2,519**	**2,088**	**3,856**	**11,263**
Principal	24,550	2,477	3,955	2,250	1,858	3,653	10,357
Interest[(a)]	2,331	378	345	269	230	203	906
Net cash flows related to derivative instruments	**(50)**	**(45)**	**(8)**	**(1)**	**4**	**—**	**—**
Total	**26,831**	**2,810**	**4,292**	**2,518**	**2,092**	**3,856**	**11,263**

(a) Interest flows are estimated on the basis of forward interest rates applicable as of December 31, 2018.

D.17.2. Lease liabilities

A maturity analysis of lease liabilities as of December 31, 2020 and 2019 is set forth below:

		Undiscounted future minimum lease payments				
(€ million)	Total	Less than 1 year	From 1 to 3 years	From 3 to 5 years	More than 5 years	Discounting effect
Total lease liabilities as of December 31, 2020	**1,163**	**247**	**357**	**225**	**482**	**(148)**
Total lease liabilities as of December 31, 2019	**1,248**	**272**	**422**	**232**	**540**	**(218)**

D.18. Liabilities related to business combinations and to non-controlling interests

For a description of the nature of the liabilities reported in the line item ***Liabilities related to business combinations and to non-controlling interests***, refer to Note B.8.5. The principal acquisitions are described in Notes D.1. and D.2.

The liabilities related to business combinations and to non-controlling interests shown in the table below are level 3 instruments under the IFRS 7 fair value hierarchy (see Note D.12.) except for the CVRs issued in connection with the acquisition of Genzyme, which are level 1 instruments.

Movements in liabilities related to business combinations and to non-controlling interests are shown below:

(€ million)	Liabilities related to non-controlling interests[a]	CVRs issued in connection with the acquisition of Genzyme[b]	Bayer contingent consideration arising from the acquisition of Genzyme	MSD contingent consideration (European Vaccines business)	Other	Total[c]
Balance at January 1, 2018	**92**	**75**	**701**	**420**	**81**	**1,369**
New transactions[e]	—	—	—	—	228	228
Payments made	(70)	—	(147)	(57)	(55)	(329)
Fair value remeasurements through profit or loss: (gain)/loss (including unwinding of discount)[d]	—	19	(109)	50	3	(37)
Other movements	—	—	—	—	24	24
Currency translation differences	—	5	27	(3)	20	49
Balance at December 31, 2018	**22**	**99**	**472**	**410**	**301**	**1,304**
Payments made	—	—	(113)	(69)	(55)	(237)
Fair value remeasurements through profit or loss: (gain)/loss (including unwinding of discount)[d]	—	49	(214)	38	81	(46)
Other movements	(22)	(153)	—	—	(73)	(248)
Currency translation differences	—	5	11	6	5	27
Balance at December 31, 2019	**—**	**—**	**156**	**385**	**259**	**800**
Payments made	—	—	(42)	(78)	(2)	(122)
Fair value remeasurements through profit or loss: (gain)/loss (including unwinding of discount)[d]	—	—	9	9	(53)	(35)
Other movements	—	—	(8)	—	(2)	(10)
Currency translation differences	—	—	(11)	(4)	(13)	(28)
Balance at December 31, 2020	**—**	**—**	**104**	**312**	**189**	**605**

(a) Includes put options granted to non-controlling interests expired in 2019, and a commitment to a future buyout of non-controlling interests held by BMS (the payment relating to that buyout had been made as of December 31, 2018: see Note C.2.).

(b) Based on the quoted market price per CVR of $0.72 as of October 30, 2019 and $0.48 as of December 31, 2018. The CVR agreement was terminated in March 2020 following signature of a litigation settlement agreement.

(c) Portion due after more than one year: €387 million as of December 31, 2020 (€508 million as of December 31, 2019 and €963 million as of December 31, 2018); portion due within less than one year: €218 million as of December 31, 2020 (€292 million as of December 31, 2019 and €341 million as of December 31, 2018).

*(d) Amounts reported within the income statement line item **Fair value remeasurement of contingent consideration**, and mainly comprising unrealized gains and losses.*

(e) Includes €226 million for contingent consideration liabilities in favor of True North Therapeutics and €2 million of liabilities owed to Bioverativ employees at the acquisition date.

As of December 31, 2020, ***Liabilities related to business combinations and to non-controlling interests*** mainly comprised:

- A liability arising from the acquisition of True North Therapeutics by Bioverativ. The former shareholders of True North Therapeutics are entitled to milestone payments contingent on the attainment of development, registration and sales objectives; the fair value of the resulting liability was measured at $197 million as of December 31, 2020, compared with $255 million as of December 31, 2019 and $192 million as of December 31, 2018. That fair value is determined based on the contractual terms and on development and sales projections which have been weighted to reflect the probability of success, and discounted. If the discount rate were to fall by one percentage point, the fair value of the True North contingent consideration liability would increase by approximately 1%.
- The Bayer contingent consideration liability arising from Sanofi's acquisition of Genzyme in 2011. As of December 31, 2020, Bayer was still entitled to receive the following potential payments:

– a percentage of sales of alemtuzumab up to a maximum of $1,250 million or over a maximum period of 10 years, whichever is achieved first;

– milestone payments based on specified levels of worldwide sales of alemtuzumab beginning in 2021, unless Genzyme exercises its right to buy out those milestone payments by making a one-time payment not exceeding $900 million.

The fair value of this liability was measured at €104 million as of December 31, 2020, compared with €156 million as of December 31, 2019 and €472 million as of December 31, 2018. The fair value of the Bayer liability is determined by applying the contractual terms to sales projections which have been weighted to reflect the probability of success, and discounted. If the discount rate were to fall by one percentage point, the fair value of the Bayer liability would increase by approximately 1%.

- The MSD contingent consideration liability arising from the 2016 acquisition of the Sanofi Pasteur activities carried on within the former Sanofi Pasteur MSD joint venture, which amounted to €312 million as of December 31, 2020, €385 million as of December 31, 2019 and €410 million as of December 31, 2018 (see Note D.12.). The fair value of this contingent consideration is determined by applying the royalty percentage stipulated in the contract to discounted sales projections. If the discount rate were to fall by one percentage point, the fair value of the MSD contingent consideration liability would increase by approximately 2%.

The table below sets forth the maximum amount of contingent consideration payable and firm commitments to buy out non-controlling interests:

December 31, 2020 (€ million)	Total	Payments due by period			
		Less than 1 year	From 1 to 3 years	From 3 to 5 years	More than 5 years
Commitments relating to contingent consideration in connection with business combinations[(a)]	1,043	228	351	192	272

(a) Includes €0.4 billion for the Bayer contingent consideration and €0.4 billion for the MSD contingent consideration.

The nominal amount of contingent consideration was €3,503 million as of December 31, 2019 and €3,638 million as of December 31, 2018. The reduction in commitments during 2020 mainly reflects the termination of the CVR agreement in March 2020.

D.19. Provisions, income tax liabilities and other liabilities

The line item ***Non current provisions and other non-current liabilities*** comprises the following:

(€ million)	2020	2019	2018
Provisions	7,219	7,353	6,883
Other non-current liabilities[(a)]	317	288	323
Total	**7,536**	**7,641**	**7,206**

(a) Includes derivative financial instruments: €92 million as of December 31, 2020, €10 million as of December 31, 2019, €7 million as of December 31, 2018.

Other current liabilities are described in Note D.19.5.

The table below sets forth movements in non-current provisions for the reporting periods presented:

(€ million)	Provisions for pensions and other post-employment benefits (D.19.1.)	Provisions for other long-term benefits	Restructuring provisions (D.19.2.)	Other provisions (D.19.3.)	Total
Balance at January 1, 2018	**3,959**	**750**	**514**	**1,975**	**7,198**
Changes in scope of consolidation	(6)	(2)	—	37	29
Increases in provisions	251 [(a)]	93	387	306 [(b)]	1,037
Provisions utilized	(529) [(a)]	(101)	(3)	(160)	(793)
Reversals of unutilized provisions	(36) [(a)]	(5)	(15)	(190)	(246)
Transfers	(22)	10	(251)	(26)	(289)
Net interest related to employee benefits, and unwinding of discount	70	4	—	24	98
Unrealized gains and losses	—	—	—	—	—
Currency translation differences	36	12	—	2	50
Actuarial gains and losses on defined-benefit plans[(c)]	(201)	—	—	—	(201)
Balance at December 31, 2018	**3,522**	**761**	**632**	**1,968**	**6,883**
Changes in scope of consolidation	(1)	—	—	—	(1)
Increases in provisions	213 [(a)]	189	393	554 [(b)]	1,349
Provisions utilized	(285) [(a)]	(102)	(3)	(132)	(522)
Reversals of unutilized provisions	(209) [(a)]	(3)	(15)	(511) [(d)]	(738)
Transfers	92	(3)	(411)	168	(154)
Net interest related to employee benefits, and unwinding of discount	83	5	3	18	109
Unrealized gains and losses	—	—	—	—	—
Currency translation differences	35	8	1	6	50
Actuarial gains and losses on defined-benefit plans[(c)]	377	—	—	—	377
Balance at December 31, 2019	**3,827**	**855**	**600**	**2,071**	**7,353**
Changes in scope of consolidation	(3)	—	—	8	5
Increases in provisions	253 [(a)]	169	688	369	1,479
Provisions utilized	(566) [(a)]	(109)	(5)	(113)	(793)
Reversals of unutilized provisions	(233) [(a)]	(5)	(42)	(245)	(525)
Transfers	12	—	(369)	(64)	(421)
Net interest related to employee benefits, and unwinding of discount	57	2	1	8	68
Unrealized gains and losses	—	—	—	—	—
Currency translation differences	(117)	(33)	(5)	(59)	(214)
Actuarial gains and losses on defined-benefit plans[(c)]	267	—	—	—	267
Balance at December 31, 2020	**3,497**	**879**	**868**	**1,975**	**7,219**

(a) In the case of "Provisions for pensions and other post-employment benefits", the "Increases in provisions" line corresponds to rights vesting in employees during the period, and past service cost; the "Provisions utilized" line corresponds to contributions paid into pension funds, and plan settlements; and the "Reversals of unutilized provisions" line corresponds to plan curtailments, settlements and amendments..

(b) Amounts charged during the period include changes to estimates of future expenditures on environmental risks.

*(c) Amounts recognized in **Other comprehensive income** (see Note D.15.7.).*

(d) This amount mainly comprises a reversal of a provision resulting from a settlement of litigation (see Note D.28.).

D.19.1. Provisions for pensions and other post-employment benefits

Sanofi offers its employees pension plans and other post-employment benefit plans. The specific features of the plans (benefit formulas, fund investment policy and fund assets held) vary depending on the applicable laws and regulations in each country where the employees work. These employee benefits are accounted for in accordance with IAS 19 (see Note B.23.).

Sanofi's pension obligations in four major countries represented approximately 89% of the total value of the defined-benefit obligation and approximately 87% of the total value of plan assets as of December 31, 2020. The features of the principal defined-benefit plans in each of those four countries are described below.

France

Lump-sum retirement benefit plans

All employees working for Sanofi in France are entitled on retirement to a lump-sum payment, the amount of which depends both on their length of service and on the rights guaranteed by collective and internal agreements. The employee's final salary is used in calculating the amount of these lump-sum retirement benefits. These plans represent approximately 41% of Sanofi's total obligation in France.

Defined-benefit pension plans

These plans provide benefits from the date of retirement. Employees must fulfil a number of criteria to be eligible for these benefits. All of these plans are now closed, the only plan still open to new entrants having been closed in 2019. These plans represent approximately 59% of Sanofi's total obligation in France.

Germany

Top-up defined-benefit pension plan

The benefits offered under this pension plan are wholly funded by the employer (there are no employee contributions) via a Contractual Trust Agreement (CTA), under which benefits are estimated on the basis of a career average salary. Employees are entitled to receive an annuity under this plan if their salary exceeds the social security ceiling. The amount of the pension is calculated by reference to a range of vesting rates corresponding to salary bands. The plan also includes disability and death benefits. This plan represents approximately 65% of Sanofi's total obligation in Germany.

Sanofi-Aventis plus (SAV plus)

A top-up pension plan (SAV plus) replaced a previous top-up defined-benefit plan. New entrants joining the plan after April 1, 2015 contribute to a defined-contribution plan that is partially funded via the company's CTA.

All employees whose salary exceeds the social security ceiling are automatically covered by the plan. The employer's contribution is 15% of the amount by which the employee's salary exceeds the social security ceiling.

Multi-employer plan (Pensionskasse)

This is a defined-benefit plan treated as a defined-contribution plan, in accordance with the accounting policies described in Note B.23. Currently, contributions cover the level of annuities. Only the portion relating to the future revaluation of the annuities is included in the defined-benefit pension obligation. The obligation relating to this revaluation amounted to €773 million as of December 31, 2020, versus €694 million as of December 31, 2019 and €673 million as of December 31, 2018. This plan represents approximately 22% of Sanofi's total defined-benefit obligation in Germany.

United States

Defined-benefit pension plans

In the United States, there are two types of defined-benefit plan:

- "Qualified" plans within the meaning of the Employee Retirement Income Security Act of 1974 (ERISA), which provide guaranteed benefits to eligible employees during retirement, and in the event of death or disability. Employees can elect to receive a reduced annuity, in exchange for an annuity to be paid in the event of their death to a person designated by them. An annuity is also granted under the plan if the employee dies before retirement age. Eligible employees do not pay any contributions. These plans are closed to new entrants, and the vesting of rights for future service periods is partially frozen. These plans represent approximately 53% of Sanofi's total obligation in the United States.
- "Non-qualified" plans within the meaning of ERISA provide top-up retirement benefits to some eligible employees depending on the employee's level of responsibility and subject to a salary cap. These plans represent approximately 12% of Sanofi's total obligation in the United States.

Healthcare cover and life insurance

Sanofi companies provide some eligible employees with healthcare cover and life insurance during the retirement period (the company's contributions are capped at a specified level). These plans represent approximately 35% (or €734 million) of Sanofi's total obligation and 4% (or €44 million) of total plan assets in the United States.

United Kingdom

Defined-benefit pension plans

Sanofi operates a number of pension plans in the United Kingdom that reflect past acquisitions. The most significant arrangements are defined-benefit plans that have been closed since October 1, 2015. With effect from that date, employees can no longer pay into these plans.

Under these defined-benefit plans, an annuity is paid from the retirement date. This annuity is calculated on the basis of the employee's length of service as of September 30, 2015, and of the employee's final salary (or salary on the date he or she leaves Sanofi).

The rates used for the vesting of rights vary from member to member. For most members, rights vest at the rate of 1.25% or 1.50% of final salary for each qualifying year of service giving entitlement. The notional retirement age varies according to the category to which the member belongs, but in most cases retirement is at age 65. Members may choose to retire before or after the notional retirement age (60 years), in which case the amount of the annual pension is adjusted to reflect the revised estimate of the length of the retirement phase. Pensions are usually indexed to the Retail Price Index (RPI). Members paid a fixed-percentage contribution into their pension plan (the percentage varied according to the employee category), and the employer topped up the contribution to the required amount. These plans represent approximately 100% of Sanofi's total obligation in the United Kingdom.

For service periods subsequent to October 1, 2015, employees belong to a new defined-contribution plan.

Actuarial assumptions used to measure Sanofi's obligations

Actuarial valuations of Sanofi's benefit obligations were computed by management with assistance from external actuaries as of December 31, 2020, 2019 and 2018.

Those calculations were based on the following financial and demographic assumptions:

	2020				2019				2018			
	France	Germany	USA	UK	France	Germany	USA	UK	France	Germany	USA	UK
Discount rate[a][b]	0.00% or 0.55%	0.00% or 0.55%	2.40%	1.35%	0.25% or 0.75%	0.25% or 0.75%	3.00%	2.00%	1.25% or 1.75%	1.25% or 1.75%	4.00%	3.00%
General inflation rate[c]	1.45%	1.45%	2.00%	2.95%	1.30%	1.30%	2.00%	2.85%	1.50%	1.50%	2.00%	3.10%
Pension benefit indexation	1.45%	1.45%	—	2.85%	1.25% to 2.25%	1.30%	—	2.80%	1.25% to 2.25%	1.50%	—	3.00%
Healthcare cost inflation rate	—	— [d]	3.50% to 4.50%	4.45% [e]	2.00%	— [d]	5.52%	4.35%	2.00%	— [d]	5.66%	1.50%
Retirement age	62 to 67	62	55 to70	60 to 65	62 to 67	62	55 to 70	60 to 65	62 to 67	62	55 to 70	60 to 65
Mortality table	TGH/ TGF 05	Heubeck RT 2018 G	RP2012 Proj. G. Scale MP2019 White Collar	SAPS S2	TGH/ TGF 05	Heubeck RT 2018 G	RP2014 G. Scale MP2018	SAPS S2	TGH/ TGF 05	Heubeck RT 2005 G	RP2014 G. Scale MP2016	SAPS S2

(a) The discount rates used were based on market rates for high quality corporate bonds with a duration close to that of the expected benefit payments under the plans. The benchmarks used to determine discount rates were the same for all periods presented.

(b) The rate depends on the duration of the plan (0 to 7 years, 7 to 10 years, or more than 10 years).

(c) Inflation for the euro zone is determined using a multi-criterion method.

(d) No post-employment healthcare benefits are provided in Germany.

(e) Healthcare cost inflation rate in the United Kingdom of 1.50% above the general inflation rate.

Weighted average duration of obligation for pensions and other long-term benefits in principal countries

The table below shows the duration of Sanofi's obligations in the principal countries:

	2020				2019				2018			
(years)	France	Germany	USA	UK	France	Germany	USA	UK	France	Germany	USA	UK
Weighted average duration	13	16	16	18	13	15	14	17	13	15	13	17

Sensitivity analysis

The table below shows the sensitivity of Sanofi's obligations for pensions and other post-employment benefits to changes in key actuarial assumptions:

(€ million)		Pensions and other post-employment benefits, by principal country			
Measurement of defined-benefit obligation	Change in assumption	France	Germany	USA	UK
Discount rate	-0.50%	+140	+272	+171	+337
General inflation rate	+0.50%	+64	+377	+1	+216
Pension benefit indexation	+0.50%	+71	+367	—	+160
Healthcare cost inflation rate	+0.50%	—	—	+14	—
Mortality table	+1 year	+41	+83	+55	+154

The table below reconciles the net obligation in respect of Sanofi's pension and other post-employment benefit plans with the amounts recognized in the consolidated financial statements:

	Pensions and other post-employment benefits		
(€ million)	2020	2019	2018
Measurement of the obligation:			
Beginning of period	13,322	12,055	13,012
Current service cost	218	199	231
Interest cost	194	293	260
Actuarial losses/(gains) due to changes in demographic assumptions	41	(61)	204
Actuarial losses/(gains) due to changes in financial assumptions	946	1,481	(841)
Actuarial losses/(gains) due to experience adjustments	(24)	(119)	(14)
Plan amendments, curtailments or settlements not specified in the terms of the plan[(a)]	(945)	(259)	(96)
Plan settlements specified in the terms of the plan	(75)	(78)	(83)
Benefits paid	(545)	(504)	(647)
Changes in scope of consolidation and transfers	(12)	13	(46)
Currency translation differences	(443)	302	75
Obligation at end of period	**12,677**	**13,322**	**12,055**
Fair value of plan assets:			
Beginning of period	9,651	8,610	9,106
Interest income on plan assets	138	211	190
Difference between actual return and interest income on plan assets	696	926	(450)
Administration costs	(14)	(7)	(8)
Plan settlements specified in the terms of the plan	(75)	(78)	(83)
Plan settlements not specified in the terms of the plan	(739)	(64)	(78)
Contributions from plan members	6	6	6
Employer's contributions	490	250	392
Benefits paid	(469)	(470)	(510)
Changes in scope of consolidation and transfers	—	—	6
Currency translation differences	(326)	267	39
Fair value of plan assets at end of period	**9,358**	**9,651**	**8,610**
Net amount shown in the balance sheet:			
Net obligation	3,319	3,671	3,445
Effect of asset ceiling	1	1	—
Net amount shown in the balance sheet at end of period	**3,320**	**3,672**	**3,445**
Amounts recognized in the balance sheet:			
Pre-funded obligations (see Note D.7.)	(177)	(155)	(77)
Obligations provided for	3,497	3,827	3,522
Net amount recognized at end of period	**3,320**	**3,672**	**3,445**
Benefit cost for the period:			
Current service cost	218	199	231
(Gains)/losses related to plan amendments, curtailments or settlements not specified in the terms of the plan[(a)]	(206)	(195)	(18)
Net interest (income)/cost	57	83	70
Contributions from plan members	(7)	(6)	(6)
Administration costs and taxes paid during the period	14	7	8
Expense recognized directly in profit or loss	**76**	**88**	**285**
Remeasurement of net defined-benefit (asset)/liability (actuarial gains and losses)	267	377	(201)
Expense/(gain) for the period	**343**	**465**	**84**

(a) For 2019, this line mainly comprises the favorable impact of the amendment to the remaining top-up pension plan, following the application of the Pacte law in France. For 2020, it mainly comprises a reduction in post-employment benefit liabilities following the announcement of voluntary redundancy programs, primarily in Europe.

The tables below show Sanofi's net liability in respect of pension plans and other post-employment benefits by geographical region:

(€ million)	Pensions and other post-employment benefits by geographical region					
December 31, 2020	**France**	**Germany**	**USA**	**UK**	**Other**	**Total**
Measurement of obligation	1,999	3,580	2,091	3,561	1,446	12,677
Fair value of plan assets	906	2,661	1,077	3,536	1,178	9,358
Effect of asset ceiling	—	—	—	—	1	1
Net amount shown in the balance sheet at end of period	**1,093**	**919**	**1,014**	**25**	**269**	**3,320**

(€ million)	Pensions and other post-employment benefits by geographical region					
December 31, 2019	**France**	**Germany**	**USA**	**UK**	**Other**	**Total**
Measurement of obligation	2,077	3,470	2,948	3,388	1,439	13,322
Fair value of plan assets	956	2,516	1,774	3,258	1,147	9,651
Effect of asset ceiling	—	—	—	—	1	1
Net amount shown in the balance sheet at end of period	**1,121**	**954**	**1,174**	**130**	**293**	**3,672**

(€ million)	Pensions and other post-employment benefits by geographical region					
December 31, 2018	**France**	**Germany**	**USA**	**UK**	**Other**	**Total**
Measurement of obligation	2,091	3,262	2,597	2,858	1,247	12,055
Fair value of plan assets	931	2,217	1,622	2,862	978	8,610
Net amount shown in the balance sheet at end of period	**1,160**	**1,045**	**975**	**(4)**	**269**	**3,445**

The table below shows the fair value of plan assets relating to Sanofi's pension and other post-employment plans, split by asset category:

	2020	2019	2018
Securities quoted in an active market	**94.8%**	**87.4%**	**99.2%**
Cash and cash equivalents	3.5%	1.8%	1.4%
Equity instruments	24.8%	22.6%	22.3%
Bonds and similar instruments	59.9%	55.8%	66.5%
Real estate	3.4%	3.8%	4.2%
Commodities	0.9%	0.9%	0.7%
Other	2.3%	2.5%	4.1%
Other securities	**5.2%**	**12.6%**	**0.8%**
Hedge funds	0.4%	—%	—%
Insurance policies	4.8%	12.6%	0.8%
Total	**100.0%**	**100.0%**	**100.0%**

Sanofi has a long-term objective of maintaining or increasing the extent to which its pension obligations are covered by assets. To this end, Sanofi uses an asset-liability management strategy, matching plan assets to its pension obligations. This policy aims to ensure the best fit between the assets held on the one hand, and the associated liabilities and expected future payments to plan members on the other. To meet this aim, Sanofi operates a risk monitoring and management strategy (mainly focused on interest rate risk and inflation risk), while investing a growing proportion of assets in high-quality bonds with comparable maturities to those of the underlying obligations and in contracts entered into with leading insurance companies to fund certain post-employment benefit obligations.

The tables below show the service cost for Sanofi's pension and other post-employment benefit plans, by geographical region:

(€ million)	Pensions and other post-employment benefits by geographical region					
Service cost for 2020	**France**	**Germany**	**USA**	**UK**	**Other**	**Total**
Current service cost	62	49	51	—	56	218
(Gains)/losses related to plan amendments, curtailments or settlements not specified in the terms of the plan	(94)	10	(123)	—	1	(206)
Net interest cost/(income) including administration costs and taxes paid during the period	9	13	34	5	10	71
Contributions from plan members	—	—	—	—	(7)	(7)
Expense/(gain) recognized directly in profit or loss	**(23)**	**72**	**(38)**	**5**	**60**	**76**
Remeasurement of net defined-benefit (asset)/ liability (actuarial gains and losses)	24	121	22	115	(15)	267
Expense/(gain) for the period	**1**	**193**	**(16)**	**120**	**45**	**343**

(€ million)	Pensions and other post-employment benefits by geographical region					
Service cost for 2019	**France**	**Germany**	**USA**	**UK**	**Other**	**Total**
Current service cost	62	42	42	—	53	199
(Gains)/losses related to plan amendments, curtailments or settlements not specified in the terms of the plan	(193)	13	(12)	(2)	(1)	(195)
Net interest cost/(income) including administration costs and taxes paid during the period	20	17	40	2	11	90
Contributions from plan members	—	—	—	—	(6)	(6)
Expense/(gain) recognized directly in profit or loss	**(111)**	**72**	**70**	**—**	**57**	**88**
Remeasurement of net defined-benefit (asset)/ liability (actuarial gains and losses)	89	(4)	148	133	11	377
Expense/(gain) for the period	**(22)**	**68**	**218**	**133**	**68**	**465**

(€ million)	Pensions and other post-employment benefits by geographical region					
Service cost for 2018	**France**	**Germany**	**USA**	**UK**	**Other**	**Total**
Current service cost	78	51	46	—	56	231
(Gains)/losses related to plan amendments, curtailments or settlements not specified in the terms of the plan	(5)	(20)	3	5	(1)	(18)
Net interest cost/(income) including administration costs and taxes paid during the period	17	12	35	4	10	78
Contributions from plan members	—	—	—	—	(6)	(6)
Expense/(gain) recognized directly in profit or loss	**90**	**43**	**84**	**9**	**59**	**285**
Remeasurement of net defined-benefit (asset)/liability (actuarial gains and losses)	(155)	(13)	(38)	7	(2)	(201)
Expense/(gain) for the period	**(65)**	**30**	**46**	**16**	**57**	**84**

An analysis of the "Remeasurement of net defined-benefit (asset)/liability (actuarial gains and losses)" line in the preceding tables is set forth below:

	2020				2019				2018			
(€ million)	**France**	**Germany**	**USA**	**UK**	**France**	**Germany**	**USA**	**UK**	**France**	**Germany**	**USA**	**UK**
Actuarial gains/(losses) arising during the period[(a)]	(24)	(121)	(22)	(115)	(89)	5	(148)	(133)	155	13	38	(7)
Comprising:												
Gains/(losses) on experience adjustments[(b)]	26	76	214	341	149	331	210	242	21	(154)	(131)	(118)
Gains/(losses) on demographic assumptions	20	—	(42)	(14)	—	—	—	63	(7)	(67)	7	(144)
Gains/(losses) on financial assumptions	(70)	(197)	(194)	(442)	(238)	(326)	(358)	(438)	141	234	162	255

(a) Gains and losses arising from changes in assumptions are due primarily to changes in the discount rate.
(b) Experience adjustments are mainly due to the effect of trends in the financial markets on plan assets.

The net pre-tax actuarial loss (excluding investments accounted for using the equity method) recognized directly in equity is presented below:

(€ million)	2020	2019	2018
Net pre-tax actuarial loss	(3,471)	(3,207)	(2,834)

The present value of Sanofi's obligations in respect of pension and other post-employment benefit plans at the end of each reporting period is shown below:

(€ million)	2020	2019	2018
Present value of wholly or partially funded obligations in respect of pension and other post-employment benefit plans	11,543	12,057	10,995
Present value of unfunded obligations	1,134	1,265	1,060
Total	**12,677**	**13,322**	**12,055**

The total expense for pensions and other post-employment benefits (€76 million in 2020) is allocated between income statement line items as follows:

(€ million)	2020	2019	2018
Cost of sales	75	46	67
Research and development expenses	62	25	77
Selling and general expenses	(34)	(22)	84
Other operating (income)/expenses, net	(18)	(3)	(21)
Restructuring costs	(66)	(41)	8
Financial expenses	57	83	70
Total	**76**	**88**	**285**

The estimated amounts of employer's contributions to plan assets in 2021 are as follows:

(€ million)	France	Germany	USA	UK	Other	Total
Employer's contributions in 2021 (estimate):						
2021	—	—	—	3	39	42

The table below shows the expected timing of benefit payments under pension and other post-employment benefit plans for the next ten years:

(€ million)	France	Germany	USA	UK	Other	Total
Estimated future benefit payments:						
2021	145	186	95	119	62	607
2022	64	190	88	122	53	517
2023	74	195	88	126	56	539
2024	84	199	91	130	60	564
2025	80	203	85	134	58	560
2026 to 2029	529	1,024	439	734	340	3,066

The table below shows estimates as of December 31, 2020 for the timing of future payments in respect of unfunded pension and other post-employment benefit plans:

		Payments due by period			
(€ million)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Estimated payments	1,134	61	99	102	872

D.19.2. Restructuring provisions

The table below shows movements in restructuring provisions classified in non-current and current liabilities:

(€ million)	2020	2019	2018
Balance, beginning of period	**1,390**	**1,572**	**1,086**
Of which:			
• Classified in non-current liabilities	600	632	514
• Classified in current liabilities	790	940	572
Change in provisions recognized in profit or loss for the period	767	760	1,035
Provisions utilized	(663)	(897)	(605)
Transfers	20	(51)	54
Unwinding of discount	1	3	—
Currency translation differences	(16)	3	2
Balance, end of period	**1,499**	**1,390**	**1,572**
Of which:			
• Classified in non-current liabilities	868	600	632
• Classified in current liabilities	631	790	940

Provisions for employee termination benefits as of December 31, 2020 amounted to €1,260 million (compared with €1,125 million as of December 31, 2019 and €895 million as of December 31, 2018).

The provisions apply mainly to France, and relate to various voluntary redundancy programs:

- collectively-agreed termination programs involving a number of legal entities that were announced at the end of June 2020 as part of the rollout of the "Play to Win" strategy, and that included an end-of-career paid leave plan and an end-of-career transition plan, plus a voluntary redundancy program announced by Sanofi-Aventis Recherche & Développement in connection with the reorganization of R&D operations in France;
- programs announced in 2019 relating to (i) R&D (Sanofi-Aventis Recherche & Développement), and (ii) sales forces (the "SAF 2019" plan implemented by Sanofi-Aventis France);
- collectively-agreed termination programs announced in 2018 relating to reorganization of support functions ("Horizon 2020" plan);
- the program announced in 2016 in connection with Sanofi's new strategic roadmap plan (the "Forward" plan).

The remainder of the provision for France comprises termination benefits associated with previously-announced programs (early retirement plans and end-of-career transition plans).

The provision includes the present values of:

- gross annuities for self-funded plans;
- employer’s social security charges on early retirement annuities for all plans (outsourced and self-funded);
- the levy charged on those annuities under the “Fillon” law (only for plans with termination of employment contracts).

The average residual holding periods under these plans were 1.99 years, 1.72 years and 2.03 years as of December 31, 2020, 2019 and 2018, respectively.

The main other countries covered by restructuring provisions are Germany and the United States.

The timing of future termination benefit payments is as follows:

December 31, 2020		Benefit payments by period			
(€ million)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Employee termination benefits					
• France	889	295	457	124	13
• Other countries	371	195	149	18	9
Total	**1,260**	**490**	**606**	**142**	**22**

December 31, 2019		Benefit payments by period			
(€ million)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Employee termination benefits					
• France	694	314	268	110	2
• Other countries	431	343	79	6	3
Total	**1,125**	**657**	**347**	**116**	**5**

December 31, 2018		Benefit payments by period			
(€ million)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Employee termination benefits					
• France	623	302	242	71	8
• Other countries	272	187	62	6	17
Total	**895**	**489**	**304**	**77**	**25**

Restructuring provisions as of December 31, 2020 also include €110 million (versus €154 million as of December 31, 2019) relating to the transfer to Evotec of the infectious diseases early-stage R&D portfolio and research unit. Restructuring provisions as of December 31, 2019 and December 31, 2018 also included amounts of €22 million and €68 million, respectively, relating to a five-year commitment to Evotec regarding the Toulouse R&D site in France; that commitment expired in 2020.

D.19.3. Other provisions

Other provisions include provisions for risks and litigation relating to environmental, tax, commercial and product liability matters.

(€ million)	2020	2019	2018
Environmental risks	713	737	680
Product liability risks, litigation and other	1,262	1,334	1,288
Total	**1,975**	**2,071**	**1,968**

Provisions for environmental risks relate primarily to contingencies arising from business divestitures, and include remediation costs relating to such environmental risks.

Identified environmental risks are covered by provisions estimated on the basis of the costs Sanofi believes it will be obliged to meet over a period not exceeding (other than in exceptional cases) 30 years. Sanofi expects that €189 million of those provisions will be utilized in 2021, and €234 million over the period from 2022 through 2025.

"Product liability risks, litigation and other" mainly comprises provisions for risks relating to product liability (including IBNR provisions as described in Note B.12.), government investigations, regulatory or antitrust law claims, contingencies arising from business divestitures (other than environmental risks), and remediation costs related to leases.

The main pending legal and arbitral proceedings and government investigations are described in Note D.22.

A full risk and litigation assessment is performed with the assistance of Sanofi's legal advisers, and provisions are recorded as required by circumstances in accordance with the principles described in Note B.12.

D.19.4. Non-current income tax liabilities

Non-current income tax liabilities amounted to €1,733 million as of December 31, 2020 (versus €1,680 million as of December 31, 2019 and €1,407 million as of December 31, 2018).

The estimated tax charge on deemed repatriation attributable to the accumulated earnings of non-US operations and payable over 8 years is recognized as a liability, and amounted to €894 million in 2020 versus €974 million in 2019 and €952 million 2018. The resulting residual tax charge generated a non-current liability of €569 million as of December 31, 2020, versus €649 million in 2019 and €635 million in 2018. In accordance with Sanofi accounting policies, this non-current liability is not discounted.

Non-current income tax liabilities include uncertainties over income tax treatments amounting to €1,164 million as of December 31, 2020, versus €1,031 million as of December 31, 2019 and €772 million as of December 31, 2018.

D.19.5. Current provisions and other current liabilities

Current provisions and other current liabilities comprise the following:

(€ million)	2020	2019	2018
Taxes payable, other than corporate income taxes	347	361	393
Employee-related liabilities	2,042	1,978	1,989
Restructuring provisions (see Note D.19.2.)	631	790	940
Interest rate derivatives (see Note D.20.)	—	2	—
Currency derivatives (see Note D.20.)	205	87	90
Amounts payable for acquisitions of non-current assets	467	413	497
Customer contract liabilities[(a)]	252	—	—
Other current liabilities[(b)]	6,188	6,072	5,060
Total	**10,132**	**9,703**	**8,969**

(a) See Note A.7., "Agreements relating to the recombinant Covid-19 vaccine candidate developed by Sanofi in collaboration with GSK".

(b) As of December 31, 2019, the "Other current liabilities" line included $315 *million deposited by Sanofi in an escrow account, the release of which occurred in March 2020 following the signature of a settlement agreement in the CVR litigation between Sanofi and the Trustee.*

"Other current liabilities" includes provisions for customer rebates and returns, and for discounts and rebates granted to healthcare authorities and governmental programs (see Note D.23.).

D.20. Derivative financial instruments and market risks

The table below shows the fair value of derivative instruments as of December 31, 2020, 2019 and 2018:

(€ million)	Non-current assets	Current assets	Total assets	Non-current liabilities	Current liabilities	Total liabilities	Market value at December 31, 2020 (net)	Market value at December 31, 2019 (net)	Market value at December 31, 2018 (net)
Currency derivatives	—	58	58	(62)	(205)	(267)	(209)	103	44
operating	—	*26*	*26*	—	*(19)*	*(19)*	7	*(15)*	*7*
financial	—	*32*	*32*	*(62)*	*(186)*	*(248)*	(216)	*118*	*37*
Interest rate derivatives	24	—	24	(4)	—	(4)	20	27	42
Equity derivatives	—	—	—	(26)	—	(26)	(26)	(4)	
Total	**24**	**58**	**82**	**(92)**	**(205)**	**(297)**	**(215)**	**126**	**86**

Objectives of the use of derivative financial instruments

Sanofi uses derivative instruments to manage operating exposure to movements in exchange rates, and financial exposure to movements in interest rates and exchange rates (where the debt or receivable is not contracted in the functional currency of the borrower or lender entity). On occasion, Sanofi uses equity derivatives in connection with the management of its portfolio of equity investments.

Sanofi performs periodic reviews of its transactions and contractual agreements in order to identify any embedded derivatives, which are accounted for separately from the host contract in accordance with IFRS 9. Sanofi had no material embedded derivatives as of December 31, 2020, 2019 or 2018.

Counterparty risk

For a description of counterparty risk, refer to "–Item 11. – Quantitative and Qualitative Disclosures about Market Risk".

a) Currency derivatives used to manage operating risk exposures

For a description of Sanofi's objectives, policies and procedures for the management of operating foreign exchange risk, refer to "–Item 11. – Quantitative and Qualitative Disclosures about Market Risk".

The table below shows operating currency hedging instruments in place as of December 31, 2020, with the notional amount translated into euros at the relevant closing exchange rate:

December 31, 2020			Of which derivatives designated as cash flow hedges			Of which derivatives not eligible for hedge accounting	
(€ million)	Notional amount	Fair value	Notional amount	Fair value	Of which recognized in equity	Notional amount	Fair value
Forward currency sales	**3,477**	**7**	**—**	**—**	**—**	**3,477**	**7**
of which US dollar	*1,367*	*10*	*—*	*—*	*—*	*1,367*	*10*
of which Chinese yuan renminbi	*521*	*2*	*—*	*—*	*—*	*521*	*2*
of which Singapore dollar	*287*	*(1)*	*—*	*—*	*—*	*287*	*(1)*
of which Japanese yen	*143*	*1*	*—*	*—*	*—*	*143*	*1*
of which Mexican peso	*121*	*—*	*—*	*—*	*—*	*121*	*—*
Forward currency purchases	**1,932**	**—**	**—**	**—**	**—**	**1,932**	**—**
of which US dollar	*580*	*(1)*	*—*	*—*	*—*	*580*	*(1)*
of which Singapore dollar	*571*	*(1)*	*—*	*—*	*—*	*571*	*(1)*
of which Chinese yuan renminbi	*286*	*1*	*—*	*—*	*—*	*286*	*1*
of which Russian rouble	*61*	*—*	*—*	*—*	*—*	*61*	*—*
of which Japanese yen	*55*	*—*	*—*	*—*	*—*	*55*	*—*
Total	**5,409**	**7**	**—**	**—**	**—**	**5,409**	**7**

The table below shows operating currency hedging instruments in place as of December 31, 2019, with the notional amount translated into euros at the relevant closing exchange rate:

December 31, 2019			Of which derivatives designated as cash flow hedges			Of which derivatives not eligible for hedge accounting	
(€ million)	Notional amount	Fair value	Notional amount	Fair value	Of which recognized in equity	Notional amount	Fair value
Forward currency sales	**3,372**	**(10)**	**–**	**–**	**–**	**3,372**	**(10)**
of which US dollar	*1,186*	*3*	*–*	*–*	*–*	*1,186*	*3*
of which Chinese yuan renminbi	*447*	*—*	*–*	*–*	*–*	*447*	*—*
of which Singapore dollar	*410*	*—*	*–*	*–*	*–*	*410*	*—*
of which Russian rouble	*184*	*(3)*	*–*	*–*	*–*	*184*	*(3)*
of which Saudi riyal	*133*	*1*	*–*	*–*	*–*	*133*	*1*
Forward currency purchases	**1,835**	**(5)**	**–**	**–**	**–**	**1,835**	**(5)**
of which US dollar	*602*	*(6)*	*–*	*–*	*–*	*602*	*(6)*
of which Singapore dollar	*525*	*1*	*–*	*–*	*–*	*525*	*1*
of which Chinese yuan renminbi	*130*	*—*	*–*	*–*	*–*	*130*	*—*
of which Hungarian forint	*60*	*—*	*–*	*–*	*–*	*60*	*—*
of which Russian rouble	*49*	*—*	*–*	*–*	*–*	*49*	*—*
Total	**5,207**	**(15)**	**–**	**–**	**–**	**5,207**	**(15)**

The table below shows operating currency hedging instruments in place as of December 31, 2018, with the notional amount translated into euros at the relevant closing exchange rate:

December 31, 2018			Of which derivatives designated as cash flow hedges			Of which derivatives not eligible for hedge accounting	
(€ million)	Notional amount	Fair value	Notional amount	Fair value	Of which recognized in equity	Notional amount	Fair value
Forward currency sales	**4,002**	**—**	**—**	**—**	**—**	**4,002**	**—**
of which US dollar	*1,723*	*(7)*	*—*	*—*	*—*	*1,723*	*(7)*
of which Singapore dollar	*652*	*1*	*—*	*—*	*—*	*652*	*1*
of which Chinese yuan renminbi	*451*	*(1)*	*—*	*—*	*—*	*451*	*(1)*
of which Saudi riyal	*100*	*1*	*—*	*—*	*—*	*100*	*1*
of which Russian rouble	*88*	*5*	*—*	*—*	*—*	*88*	*5*
Forward currency purchases	**2,036**	**7**	**—**	**—**	**—**	**2,036**	**7**
of which US dollar	*514*	*8*	*—*	*—*	*—*	*514*	*8*
of which Singapore dollar	*500*	*1*	*—*	*—*	*—*	*500*	*1*
of which Japanese yen	*197*	*3*	*—*	*—*	*—*	*197*	*3*
of which Chinese yuan renminbi	*163*	*(1)*	*—*	*—*	*—*	*163*	*(1)*
of which Canadian dollar	*106*	*(2)*	*—*	*—*	*—*	*106*	*(2)*
Total	**6,038**	**7**	**—**	**—**	**—**	**6,038**	**7**

b) Currency and interest rate derivatives used to manage financial exposure

For a description of Sanofi's objectives, policies and procedures for the management of financial foreign exchange risk and interest rate risk, refer to "–Item 11. – Quantitative and Qualitative Disclosures about Market Risk".

The table below shows financial currency hedging instruments in place, with the notional amount translated into euros at the relevant closing exchange rate:

	2020			2019			2018		
(€ million)	Notional amount	Fair value	Expiry	Notional amount	Fair value	Expiry	Notional amount	Fair value	Expiry
Forward currency sales	**5,064**	**10**		**8,515**	**40**		**7,762**	**17**	
of which US dollar	*3,721* (a)	*20*	*2021*	*6,331*	*51*	*2020*	*5,500*	*38*	*2019*
of which Japanese yen	*283*	*—*	*2021*	*516*	*(5)*	*2020*	*973*	*(24)*	*2019*
of which Pound sterling	*257*	*(6)*	*2021*	*297*	*1*	*2020*	*184*	*—*	*2019*
Forward currency purchases	**9,004**	**(226)**		**10,975**	**78**		**7,291**	**20**	
of which US dollar	*6,068* (b) (c)	*(200)*	*2022*	*7,363*	*42*	*2020*	*4,165*	*(17)*	*2019*
of which Singapore dollar	*2,250* (d)	*(27)*	*2021*	*2,332*	*32*		*2,022*	*33*	*2019*
of which Chinese yuan renminbi	*195*	*1*	*2021*	*270*	*2*	*2020*	*427*	*—*	*2019*
Total	**14,068**	**(216)**		**19,490**	**118**		**15,053**	**37**	

(a) Includes forward sales with a notional amount of $3,615 million expiring in 2021, designated as a hedge of Sanofi's net investment in Bioverativ. As of December 31, 2020, the fair value of these forward contracts represented an asset of €13 million; the opposite entry was recognized in ***Other comprehensive income****, with the impact on financial income and expense being immaterial.*

(b) Includes forward purchases with a notional amount of $3,000 million expiring in 2021 and 2022, designated as a fair value hedge of the exposure of $3,000 million of bond issues to fluctuations in the EUR/USD spot rate. As of December 31, 2020, the fair value of the contracts was a liability of €109 million.

(c) Includes currency swaps with a notional amount of $1,000 million, receive 0.22% pay EUR -0.63% expiring in 2022, designated as a cash flow hedge of $1,000 million of bond issues. As of December 31, 2020, the fair value of the swaps was a liability of €38 million.

(d) Includes forward purchases with a notional amount of SGD2,000 million expiring in 2021, designated as a fair value hedge of the exposure of an equivalent amount of intragroup loans to fluctuations in the EUR/SGD spot rate. As of December 31, 2020, the fair value of the contracts was a liability of €22 million.

The table below shows interest rate hedging instruments in place as of December 31, 2020:

(€ million)	Notional amounts by expiry date as of December 31, 2020							Fair value	Of which designated as fair value hedges		Of which designated as cash flow hedges		
	2021	2022	2023	2024	2025	2026	Total		Notional amount	Fair value	Notional amount	Fair value	Of which recognized in equity
Interest rate swaps													
pay capitalized Eonia / receive 0.06%	—	2,000	—	—	—	—	2,000	23	2,000	23	—	—	—
pay -0.57% / receive capitalized Eonia	—	600	—	—	—	—	600	1	—	—	600	1	1
receive capitalized Eonia / pay 1.48%[(a)]	—	42	57	—	—	—	99	(4)	99	(4)	—	—	—
Total	—	2,642	57	—	—	—	2,699	20	2,099	19	600	1	1

(a) These interest rate swaps hedge fixed-rate bonds with a nominal of €99 million held in a Professional Specialized Investment Fund dedicated to Sanofi and recognized within "Loans, advances and other long-term receivables" (see Note D.7.).

The table below shows interest rate hedging instruments in place as of December 31, 2019:

(€ million)	Notional amounts by expiry date as of December 31, 2019							Fair value	Of which designated as fair value hedges		Of which designated as cash flow hedges		
	2020	2021	2022	2023	2024	2025	Total		Notional amount	Fair value	Notional amount	Fair value	Of which recognized in equity
Interest rate swaps													
pay capitalized Eonia / receive 0.06%	—	—	2,000	—	—	—	2,000	28	2,000	28	—	—	—
pay -0.57% / receive capitalized Eonia	—	—	600	—	—	—	600	3	—	—	600	3	3
pay 1.81% / receive 3-month US dollar Libor	446	—	—	—	—	—	446	(2)	—	—	446	(2)	—
pay 3-month US dollar Libor / receive 2.22%	446	—	—	—	—	—	446	4	446	4	—	—	—
receive capitalized Eonia / pay 1.48%	—	—	42	57	—	—	99	(6)	99	(6)	—	—	—
Total	892	—	2,642	57	—	—	3,591	27	2,545	26	1,046	1	3

The table below shows interest rate hedging instruments in place as of December 31, 2018:

(€ million)	Notional amounts by expiry date as of December 31, 2018							Fair value	Of which designated as fair value hedges		Of which designated as cash flow hedges		
	2019	2020	2021	2022	2023	2024	Total		Notional amount	Fair value	Notional amount	Fair value	Of which recognized in equity
Interest rate swaps													
pay capitalized Eonia / receive 1.58%	1,550	—	—	—	—	—	1,550	30	1,550	30	—	—	—
pay capitalized Eonia / receive 0.06%	—	—	—	2,000	—	—	2,000	15	2,000	15	—	—	—
pay 1.81% / receive 3-month US dollar Libor	—	436	—	—	—	—	436	5	—	—	436	5	7
pay 3-month US dollar Libor / receive 2.22%	—	436	—	—	—	—	436	(1)	436	(1)	—	—	—
receive capitalized Eonia / pay 1.48%	—	—	—	42	57	—	99	(6)	99	(6)	—	—	—
Total	1,550	872	—	2,042	57	—	4,521	42	4,085	38	436	5	7

c) Equity derivatives

During 2019, Sanofi contracted derivative instruments (collars) on 593,712 shares of Dexcom Inc; the collars were designated as fair value hedges of the Dexcom shares. As of December 31, 2020 they had a negative fair value of €26 million, recognized in full in ***Other comprehensive income***.

d) Actual or potential effects of netting arrangements

The table below is prepared in accordance with the accounting policies described in Note B.8.3.:

(€ million)	2020		2019		2018	
	Derivative financial assets	Derivative financial liabilities	Derivative financial assets	Derivative financial liabilities	Derivative financial assets	Derivative financial liabilities
Gross carrying amounts before offset (a)	82	(297)	225	(99)	183	(97)
Gross amounts offset (in accordance with IAS 32) (b)	—	—	—	—	—	—
Net amounts as reported in the balance sheet (a) - (b) = (c)	**82**	**(297)**	**225**	**(99)**	**183**	**(97)**
Effects of other netting arrangements (not fulfilling the IAS 32 criteria for offsetting) (d)	—	—				
Financial instruments	(81)	81	(89)	89	(81)	81
Fair value of financial collateral	N/A	N/A	N/A	N/A	N/A	N/A
Net exposure (c) + (d)	**1**	**(216)**	**136**	**(10)**	**102**	**(16)**

D.21. Off balance sheet commitments

The off balance sheet commitments presented below are shown at their nominal value.

D.21.1. Off balance sheet commitments relating to operating activities

Off balance sheet commitments relating to Sanofi's operating activities comprise the following:

December 31, 2020		Payments due by period			
(€ million)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Leases with a term of less than 12 months, low value asset leases and lease contracts committed but not yet commenced[a][b]	950	39	118	118	675
Irrevocable purchase commitments[c]					
• given[d]	7,153	4,072	1,482	572	1,027
• received	(608)	(236)	(168)	(51)	(153)
Research and development license agreements - commitments given					
• commitments related to R&D and other commitments[e]	500	261	217	10	12
• probable milestone payments[f]	2,456	163	714	972	607
Total - net commitments given[g]	**10,451**	**4,299**	**2,363**	**1,621**	**2,168**

(a) Includes future variable lease payments not recognized in Lease liabilities as of December 31, 2020. The principal commitment on this line is a new lease in the United States that will commence in 2021. As of December 31, 2019, the amount of such commitments was €1,067 million.

(b) Lease commitments given to joint ventures were immaterial as of December 31, 2020.

(c) These comprise irrevocable commitments to suppliers of (i) property, plant and equipment, net of down-payments (see Note D.3.) and (ii) goods and services. As of December 31, 2019, irrevocable commitments amounted to €6,726 million given and €(648) million received.

(d) Irrevocable purchase commitments given as of December 31, 2020 include €989 million of commitments to joint ventures.

(e) Commitments related to R&D, and other commitments, amounted to €784 million as of December 31, 2019.

(f) This line includes only contingent milestone payments on development projects in progress. The reduction relative to December 31, 2019 (when probable milestone payments amounted to €3,040 million) is mainly due to (i) the discontinuation of the collaboration with Hanmi and (ii) the ending of a pre-existing agreement with Principia Biopharma Inc. following the acquisition of that company by Sanofi in September 2020.

(g) This line excludes:

(i) commitments given relating to projects in the research phase (€6.7 billion in 2020, €6.7 billion in 2019) and payments contingent upon the attainment of sales targets once a product is commercialized (€8.1 billion in 2020, €10.6 billion in 2019);

(ii) commitments received in respect of the additional share of quarterly profits to which Sanofi is entitled under the collaboration agreements with Regeneron on monoclonal antibodies (capped at 10% of Regeneron's share of quarterly profits), until Regeneron has paid 50% of the cumulative development costs incurred by the parties in the collaboration (see Note C.1.). Such commitments received were €2.6 billion in 2020 (€2.7 billion in 2019), relative to cumulative development costs of €6.6 billion as of December 31, 2020 (€3.3 billion 100% financed by Sanofi, €3.3 billion financed 80% Sanofi, 20% Regeneron); and

(iii) commitments received under other agreements amounting to €3.3 billion in 2020 (€3.2 billion in 2019), including discovery, development and commercialization agreements arising from (i) the acquisition of Ablynx on May 14, 2018 (see Note D.1.), amounting to €1.1 billion as of December 31, 2020 (€1.1 billion in 2019) and (ii) the sale to Celgene of Sanofi's equity interest in Impact Biomedicines in January 2018, amounting to €0.5 billion as of December 31, 2020 (€0.5 billion in 2019).

Research and development license agreements

In pursuance of its strategy, Sanofi may acquire technologies and rights to products. Such acquisitions may be made in various contractual forms: acquisitions of shares, loans, license agreements, joint development, and co-marketing. These arrangements generally involve upfront payments on signature of the agreement, development milestone payments, and royalties. Some of these complex agreements include undertakings to fund research programs in future years and payments contingent upon achieving specified development milestones, the granting of approvals or licenses, or the attainment of sales targets once a product is commercialized.

The “Research and development license agreements” line comprises future service commitments to fund research and development or technology, and probable contingent milestone payments regarded as reasonably achievable (i.e. all potential milestone payments relating to projects in the development phase, for which the future financial consequences are known or probable and for which there is a sufficiently reliable estimate).

The major agreements entered into by Sanofi in 2020 are described below:

- On June 23, 2020, it was announced that the collaboration and license agreement between Sanofi Pasteur and Translate Bio on the development of mRNA vaccines for infectious diseases would be extended to include development of a novel mRNA vaccine against the virus responsible for COVID-19. Under the terms of the extended agreement, finalized July 20, 2020, Sanofi made an upfront payment of $425 million to Translate Bio ($300 million in cash plus a private equity injection of $125 million) to acquire (i) exclusive worldwide rights to develop, manufacture and commercialize infectious disease vaccines using Translate Bio technology and (ii) an equity interest in the form of 4.9 million shares of Translate Bio common stock, valued at $95 million at the quoted market price as of that date. In addition, Translate Bio will be eligible for potential future milestone and other payments of up to $1.9 billion, including $450 million for milestones already specified in the 2018 agreement between the two companies.
- In July 2020, Sanofi entered into a license agreement with Kiadis, a biopharmaceutical company developing "off-the-shelf" natural killer (NK) cell therapies for patients with life-threatening diseases. On November 2, 2020, Sanofi and Kiadis entered into a definitive agreement whereby Sanofi was to make a public offer to acquire the entire share capital of Kiadis (see Note D.21.3.).
- On August 10, 2020, Sanofi signed an agreement with Kymera to develop and commercialize protein degrader therapies targeting IRAK4 in patients with immune-inflammatory diseases. Under the terms of the agreement, Sanofi has made an upfront payment of $150 million to Kymera, and could pay up to $2.2 billion subject to attainment of specified milestones.

Other major agreements entered into by Sanofi in prior years are described below:

- Roche (2019): to obtain exclusive over-the-counter (OTC) US rights to Tamiflu® for the prevention and treatment of influenza. Under the terms of the agreement, Sanofi is responsible for leading FDA negotiations for the OTC switch; for subsequent exclusive marketing and distribution of Tamiflu® in the US consumer health care market; and for associated scientific engagement. Tamiflu® was previously currently sold in the US for prescription use by Genentech, a member of the Roche Group.
- Regeneron (2018): (i) amendments to the 2015 Discovery and Preclinical Development Agreement and the License and Collaboration Agreement on human therapeutic antibodies; (ii) amendments to the 2015 Immuno-Oncology License and Collaboration Agreement on the development of cemiplimab (REGN2810); (iii) limited waiver and amendment of the Amended and Restated Investor Agreement pursuant to a letter agreement (the “2018 Letter Agreement”); and (iv) the 2020 Cross License and Commercialization Agreement for Praluent® (see Note C.1.).
- AnaBios Corporation (2018): partnership agreement to develop and commercialize new treatments for irregular heartbeat, primarily atrial fibrillation.
- SK Chemicals (2018): partnership agreement between Sanofi Pasteur and SK Chemicals under which Sanofi acquired exclusive development and commercialization rights in the United States and Europe for vaccines derived from the cell-based technology developed by SK Chemicals.
- Revolution Medicines (2018): partnership agreement in oncology to jointly develop the principal candidate derived from Revolution Medicines biological research: RMC 4630, an inhibitor of SHP2, a cellular enzyme in the protein tyrosine phosphatase family that plays an important role in multiple forms of cancer.
- Translate Bio (2018): partnership agreement between Sanofi Pasteur and Translate Bio to develop messenger RNA (mRNA) vaccines derived from Translate Bio technology for five infectious disease pathogens, with an option to extend to additional pathogens. If that option is exercised, the total value of the transaction would rise to $805 million.
- Sangamo Therapeutics, Inc. (2018): agreement to research, develop, and commercialize therapeutics for hemoglobinopathies, in particular beta thalassemia and sickle cell disease, based on Sangamo’s gene therapy platform; this agreement was assumed by Sanofi on the acquisition of Bioverativ on March 8, 2018 (see Note D.2.).
- Denali Therapeutics Inc. (2018): collaboration agreement on the development of multiple molecules with the potential to treat a range of neurological and systemic inflammatory diseases. The two lead molecules are DNL747 in multiple sclerosis and amyotrophic lateral sclerosis, and DNL758 in systemic inflammatory diseases such as rheumatoid arthritis and psoriasis.
- Immunext (2017): agreement to develop a novel antibody to treat auto-immune diseases such as multiple sclerosis and lupus. Under the agreement, Sanofi acquired an exclusive worldwide license to INX-021, a monoclonal CD40L antibody currently in preclinical development. A second parallel agreement was signed to support clinical trials.
- MedImmune (a division of AstraZeneca) (2017): agreement to develop and commercialize a monoclonal antibody (MEDI8897) for the prevention of Respiratory Syncytial Virus (RSV) associated illness in newborns and infants.
- ImmunoGen (2017): amendment to the license and collaboration agreement signed in 2003. ImmunoGen granted Sanofi a fully paid and exclusive license to develop, manufacture and commercialize the full series of compounds developed by Sanofi using ImmunoGen technology.
- DiCE Molecules (2016): five-year global collaboration to discover potential new therapeutics for up to 12 targets that encompass all disease areas of strategic interest to Sanofi.
- Innate Pharma (2016): collaboration and licensing agreement to apply Innate Pharma’s new proprietary technology to the development of innovative bispecific antibody formats engaging natural killer (NK) cells to kill tumor cells through the activating receptor NKp46.
- BioNTech A.G. (2015): exclusive collaboration and license agreement to discover and develop up to five cancer immunotherapies.
- Evotec AG and Apeiron Biologics AG (2015): collaboration and license agreement to discover and develop first-in-class small molecule-based immuno-oncology therapies to treat solid and hematological cancers.

- Lead Pharma (2015): research collaboration and license agreement for the discovery, development and commercialization of small-molecule therapies directed against “ROR gamma t” nuclear hormone receptors to treat auto-immune diseases.
- Eli Lilly and Company (2014): agreement to pursue regulatory approval for non-prescription Cialis® (tadalafil).
- Regulus Therapeutics Inc. (2010): discovery, development and commercialization of novel micro-RNA therapeutics in fibrosis.

Sanofi and its alliance partners have decided to terminate the following agreements (the related commitments are no longer included in Sanofi’s off balance sheet disclosures as of December 31, 2020):

- On July 23, 2020 Sanofi and Ascendis terminated their licensing and patent transfer agreement on Transcon Linker and Hydrogel Carrier technology.
- On October 1, 2020, Sanofi and Evotec International GmbH terminated their research collaboration, aimed at developing beta cell-modulating diabetes treatments.

Finally, Sanofi completed the acquisition of Principia Biopharma Inc. on September 28, 2020, thereby ending the license agreement signed in 2017 to develop Principia's Bruton’s tyrosine kinase (BTK) inhibitor (PRN2246) in the treatment of multiple sclerosis and (potentially) other disorders of the central nervous system.

Other agreements

Sanofi entered into an agreement with Royalty Pharma in December 2014 relating to development programs under which Royalty Pharma bears a portion of the remaining development costs of the project on a quarterly basis in return for royalties on future sales. This transaction is a co-investment, whereby the partner acquires an interest in the jointly-developed product by providing funding towards the development program. Consequently, the amounts received by Sanofi are recorded as a reduction in development costs, to the extent that the development costs incurred by Sanofi are recognized in profit or loss in accordance with the policies described in Note B.4.1. The products in development under the December 2014 agreement with Royalty Pharma have been launched in the United States and Europe, marking the end of the joint development programs.

On February 27, 2017, Sanofi and Lonza announced a strategic partnership in the form of a joint venture to build and operate a large-scale mammalian cell culture facility for monoclonal antibody production in Visp, Switzerland. An initial investment of approximately €0.3 billion to finance construction of the facility, split 50/50 between the two partners, has now been made in full. In addition, Sanofi could pay Lonza in the region of €0.6 billion over the next fifteen years partly as its share of operating expenses and the cost of producing future batches, and partly to reserve capacity in the new facility.

In February 2014, pursuant to the “Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits” (still effective as of December 31, 2020), Sanofi Pasteur and the World Health Organization (WHO) signed a bilateral “Standard Material Transfer Agreement” (SMTA 2). This agreement stipulates that Sanofi Pasteur will, during declared pandemic periods, (i) donate 7.5% of its real-time production of pandemic vaccines against any strain with potential to cause a pandemic, and (ii) reserve a further 7.5% of such production on affordable terms. The agreement cancels and replaces all preceding commitments to donate pandemic vaccines to the WHO.

D.21.2. Off balance sheet commitments relating to financing activities

Credit facilities

Undrawn credit facilities are as follows:

December 31, 2020		Expiry			
(€ million)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
General-purpose credit facilities	8,000	4,000	—	4,000	—

As of December 31, 2020, total credit facilities amounted to €8,000 million (versus €8,000 million as of December 31, 2019 and €8,000 million as of December 31, 2018).

Guarantees

The table below shows the amount of guarantees given and received:

(€ million)	2020	2019	2018
Guarantees given:	**3,291**	**3,103**	**3,010**
• Guarantees provided to banks in connection with credit facilities	695	1,263	1,307
• Other guarantees given	2,596	1,840	1,703
Guarantees received	**(964)**	**(703)**	**(190)**

D.21.3. Off balance sheet commitments relating to Sanofi entities and business combinations

On November 2, 2020, Sanofi and Kiadis entered into a definitive agreement for Sanofi to make a public offer to acquire the entire share capital of Kiadis for €5.45 per share, representing an aggregate equity value of approximately €308 million (adjusted for the value of share warrants that may be exercised in shares or settled in cash).

On January 11, 2021, Sanofi and Kymab entered into an agreement under which Sanofi will acquire Kymab for an upfront payment of approximately $1.1 billion, plus up to $350 million on attainment of specified milestones (see Note G.).

Off balance sheet funding commitments to associates and joint ventures are disclosed in Note D.6.

The maximum amount of contingent consideration relating to business combinations is disclosed in Note D.18.

D.22. Legal and arbitral proceedings

Sanofi and its affiliates are involved in litigation, arbitration and other legal proceedings. These proceedings typically are related to product liability claims, intellectual property rights (particularly claims against generic companies seeking to limit the patent protection of Sanofi products), competition law and trade practices, commercial claims, employment and wrongful discharge claims, tax assessment claims, waste disposal and pollution claims, and claims under warranties or indemnification arrangements relating to business divestitures. Provisions related to legal and arbitral proceedings are recorded in accordance with the principles described in Note B.12.

Most of the issues raised by these claims are highly complex and subject to substantial uncertainties; therefore, the probability of loss and an estimation of damages are difficult to ascertain. Contingent liabilities are cases for which either we are unable to make a reasonable estimate of the expected financial effect that will result from ultimate resolution of the proceeding, or a cash outflow is not probable. In either case, a brief description of the nature of the contingent liability is disclosed and, where practicable, an estimate of its financial effect, an indication of the uncertainties relating to the amount and timing of any outflow, and the possibility of any reimbursement are provided in application of paragraph 86 of IAS 37.

In the cases that have been settled or adjudicated, or where quantifiable fines and penalties have been assessed, we have indicated our losses or the amount of provision accrued that is the estimate of the probable loss.

In a limited number of ongoing cases, while we are able to make a reasonable estimate of the expected loss or range of the possible loss and have accrued a provision for such loss, we believe that publication of this information on a case-by-case basis or by class would seriously prejudice the Company's position in the ongoing legal proceedings or in any related settlement discussions. Accordingly, in those cases, we have disclosed information with respect to the nature of the contingency but have not disclosed our estimate of the range of potential loss, in accordance with paragraph 92 of IAS 37.

These assessments can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions. Our assessments are based on estimates and assumptions that have been deemed reasonable by management. We believe that the aggregate provisions recorded for the above matters are adequate based upon currently available information. However, given the inherent uncertainties related to these cases and involved in estimating contingent liabilities, we could in the future incur judgments that could have a material adverse effect on our net income in any particular period.

Long term provisions are disclosed in Note D.19. They include:

- Provisions for product liability risks, litigation and other amount to €1,262 million in 2020. These provisions are mainly related to product liabilities, government investigations, competition law, regulatory claims, warranties in connection with certain contingent liabilities arising from business divestitures other than environmental matters and other claims.
- Provisions for environmental risks and remediation amount to €713 million in 2020, the majority of which are related to contingencies that have arisen from business divestitures.

a) Products

Sanofi Pasteur Hepatitis B Vaccine Product Litigation

Since 1996, more than 180 lawsuits have been filed in various French civil courts against Sanofi Pasteur and/or Sanofi Pasteur MSD S.N.C., the former French subsidiary of Sanofi, and the latter a joint venture company with Merck & Co., Inc. now terminated, for which past ongoing litigation is now managed by the originating party. In such lawsuits, the plaintiffs allege that they suffer from a variety of neurological disorders and autoimmune diseases, including multiple sclerosis and Guillain-Barré syndrome as a result of receiving the hepatitis B vaccine.

In January 2008, both the legal entity Sanofi Pasteur MSD S.N.C., and a corporate officer of this company, as well as a former corporate officer of Sanofi Pasteur, were placed under investigation in an ongoing criminal inquiry in France relating to alleged side effects caused by the hepatitis B vaccine. In March 2012, Sanofi Pasteur and its former pharmacist in charge (i.e. the deputy Chief Executive Officer) were placed under an "advised witness" ("*témoin assisté*") status. In March 2016, the investigating judges decided to dismiss the proceedings. Several civil parties appealed against this decision. In June 2018, the Prosecutor General requested confirmation of the dismissal. In June 2019, the Investigation Chamber of the Paris Court of Appeals confirmed the decision taken by the investigating judges in March 2016 to dismiss the proceedings. Several plaintiffs have decided to appeal such decision before the French Supreme Court (*Cour de cassation*).

In October 2017, the French Supreme Court (*Cour de cassation*) dismissed two appeals filed by the plaintiffs against two decisions of the Appeal Court of Paris (*Cour d'appel*).

In January 2018, the Appeal Court of Bordeaux found a causal link between hepatitis B vaccine and multiple sclerosis. Sanofi Pasteur Europe appealed this decision before the French Supreme Court (*Cour de cassation*). In July 2019, the French Supreme Court (*Cour de cassation*) cancelled the judgment of the Appeal Court of Bordeaux and referred the case back to the Appeal Court of Toulouse. The hearing is planned for December 6, 2021.

Taxotere® Product Litigation in the US

As of December 31, 2020, there were approximately 10,137 plaintiffs in courts across the country, with approximately 871 of those plaintiffs being spouses who have filed loss of consortium claims.

Suits have been filed against affiliates of Sanofi under US state law for personal injuries allegedly sustained in connection with the use of Taxotere®. The actions are held in several jurisdictions, including the federal and/or state courts of Louisiana, New Jersey, California, and Delaware. A first bellwether trial took place in September 2019 and issued a verdict in Sanofi's favor. The next bellwether trial is currently

scheduled to begin in May 2021. It is not possible, at this stage, to reliably assess the outcome of these lawsuits or the potential financial impact on the Company.

Taxotere® - Mississippi Attorney General Litigation in the US

In October 2018, the Attorney General for the State of Mississippi filed a civil action in Hinds County, Mississippi, Chancery Court against various Sanofi Defendants related to Taxotere®. The State asserts one cause of action based on the Mississippi Consumer Protection Act ("MCPA") and seeks a permanent injunction prohibiting Defendants' conduct and civil penalties of up to $10,000 for each violation. In December 2018, Sanofi removed the matter to the US District Court for the Southern District of Mississippi. It is not possible, at this stage, to assess reliably the outcome of this lawsuit or the potential financial impact on the Company.

Zantac® Litigation in the US

In September 2019, the US Food and Drug Administration ("FDA") announced it was investigating the claims of an online pharmacy's Citizen Petition that the medication Zantac® (the brand name for ranitidine) used for stomach heartburn contains or can generate the chemical N-Nitrosodimethylamine ("NDMA"), an alleged human carcinogen. As a precautionary measure, Sanofi initiated a voluntary recall of branded over-the-counter Zantac® in October 2019. Concurrent with FDA's investigation, multiple personal injury lawsuits and class actions alleging that Zantac® causes various cancers and seeking damages for either alleged personal injuries or alleged economic injuries were filed. Most of those cases have been coordinated into an MDL in the Southern District of Florida. That Court entered a case management schedule that provides for 18 months of discovery leading up to motions on general causation and briefing on class certification. Other cases are pending in various state courts. In addition, in November 2019, Sanofi received a Civil Investigative Demand ("CID") related to this issue from the Arizona Attorney General.

In June 2020, the New Mexico Attorney General filed a complaint against Sanofi, the previous marketing authorization holders for branded Zantac®, a dozen generic manufacturers, and several retailers. The complaint brings claims for alleged violations of the New Mexico Unfair Practices Act, violations of the New Mexico False Advertising Act, violations of the New Mexico Public Nuisance Statute, common law public nuisance, and negligence.

In June 2020, Sanofi received a notice from the US Department of Justice Civil Division and US Attorney's Office for the Eastern District of Pennsylvania of an investigation into allegations that pharmaceutical manufacturers violated the False Claims Act, 31 U.S.C. § 3729, in relation to the drug Zantac® and ranitidine hydrochloride through alleged failure to disclose to the federal government information about the potential presence of NDMA. The notice requests information and documents from Sanofi including applications and communications with FDA.

In November 2020, the Mayor and City Council of Baltimore filed a complaint against Sanofi, the previous marketing authorization holders for branded Zantac®, generic manufacturers, and several retailers. The complaint alleges violations of the Maryland Consumer Protection statute, public nuisance, and negligence.

In January 2021, Sanofi was served with the Center for Environmental Health's Second Amended Complaint alleging Proposition 65 violations. The case, which also names generic manufacturers and retailers, is pending in California Superior Court in Alameda County.

As of December 31, 2020, there were a total of 977 filed personal injury cases (representing 1,607 ingesting plaintiffs) and 25 putative class actions. Additional cases may be filed.

It is not possible, at this stage, to assess reliably the outcome of these lawsuits or the potential financial impact on Sanofi.

Zantac® Litigation in Canada

In October 2019, an application to authorize the bringing of a class action on behalf of all Canadian residents was filed in Quebec Superior Court relating to ranitidine and naming Sanofi Consumer Health Inc. as a defendant. Representative Plaintiffs claim that they suffered personal injury, including cancer, from the ingestion of ranitidine and are seeking general and punitive damages in an unspecified amount.

In October 2019, and April 2020, two proposed class action proceedings were filed in Ontario Superior Court relating to ranitidine and naming Sanofi Consumer Health Inc., Sanofi-Aventis Canada Inc., Chattem (Canada) Inc. and Sanofi Pasteur Limited as Defendants. Representative Plaintiffs claim that they suffered personal injury, including cancer, from the ingestion of ranitidine and are seeking general, special, statutory, punitive and aggravated damages in an unspecified amount. Additionally, they seek restitution for unjust enrichment in an amount equivalent to the purchase price of Zantac®.

In December 2019, a proposed class action proceeding was filed in Alberta Court of Queen's Bench relating to ranitidine and naming Sanofi Consumer Health Inc. as a defendant. The representative plaintiff is claiming on behalf of all Canadian residents damages, including personal injury, arising allegedly from the ingestion of ranitidine. General, special and punitive damages are being claimed in an unspecified amount.

In February 2020, an amended class action proceeding now naming Sanofi Consumer Health Inc. as a Defendant along with 21 other Defendants was filed in the British Columbia Supreme Court. The representative plaintiff is claiming on behalf of all Canadian residents damages, including personal injury, arising allegedly from the ingestion of ranitidine. General, special and punitive damages are being claimed in an unspecified amount.

As a result, as of December 31, 2020, 5 class actions have been filed in the above-mentioned provinces; but additional cases may be filed.

It is not possible, at this stage, to assess reliably the outcome of these lawsuits or the potential financial impact on Sanofi.

Depakine® Product Litigation in France

Civil proceedings

As of December 31, 2020, 75 families brought a civil claim involving 126 people exposed in utero to sodium valproate against a French affiliate of Sanofi seeking indemnification under French law for personal injuries allegedly suffered by children in connection with the use of sodium valproate by their mothers during pregnancy to treat their epilepsy (Depakine®). These actions are held in several jurisdictions in France.

Twenty-three lawsuits are proceedings on the merits, the most advanced has been tried at the French Supreme Court level which issued in November 2019 a ruling quashing partially the November 2017 Orléans Appeal Court decision against Sanofi ordering payment of approximately €2 million to the plaintiff and €1 million to the CPAM (*Caisse Primaire d'Assurance Maladie*). The Supreme Court sent the case back before another Appeal Court to rule on Sanofi's argument on the exoneration cause relating "to compliance of the product with mandatory regulations", as well as on the question of defectiveness of the product and the evaluation of the injuries. There is currently no date set for the hearing of this case.

In a class action lawsuit filed in May 2017 by the APESAC (*Association des Parents d'Enfants souffrant du Syndrome de l'Anti-Convulsivant*) before the Paris Civil Court, the judge denied claimant's motion on interim measures in November 2017. APESAC lodged an appeal which was rejected by the Court of Appeal of Paris in October 2018. No date for trial hearing has been set yet.

In July 2020, a collective redress against the French affiliate was filed by 63 families, seeking indemnification for a prejudice of anxiety.

Criminal investigation

A criminal investigation has been ongoing since May 2015 before the Paris Civil Court. In January 2020, the French affiliate of Sanofi was indicted for aggravated deception and involuntary injuries and in July 2020 for involuntary manslaughter. In July 2020, a judicial supervision of the affiliate was ordered, together with the implementation of financial guarantees. Sanofi has filed several motions including a motion for nullity of its indictment. In November 2020, the Health Authority (ANSM) was indicted for involuntary injuries and involuntary manslaughters.

Public compensation scheme:

The French government has, through the 2017 Finance Law adopted on December 29, 2016, set up a public compensation scheme which is meant to indemnify patients for damages suffered in connection with the prescription of sodium valproate and its derivatives. The scheme entered into force in July 2017 and was further amended through the 2020 Finance Law, with notably the introduction of presumptions of default for lack of information of the mother since 1982 for malformations and since 1984 for neurodevelopment disorders. The scheme was amended again through the 2021 Finance Law in order to increase the maximum premium applicable in case of refusal to make an offer (or insufficient offer) which would be deemed unjustified by a court ruling.

The committee of the compensation scheme has issued final opinions holding the French affiliate liable for damages either in full or in part along with the French State. The French affiliate disagreed with the committee's conclusions and has accordingly not offered indemnification to the claimants who have received compensation from the ONIAM (*Office National d'Indemnisation des Accidents Médicaux*). The ONIAM is now seeking reimbursement from Sanofi who has filed legal actions to oppose ONIAM's payment orders.

It is not possible, at this stage, to assess reliably the outcome of these cases or the potential financial impact on the Company.

Dengvaxia® (Philippines)

Since early 2018 up to present date, several claims were filed in the Philippines by parents of deceased children whose deaths were allegedly due to vaccination with Dengvaxia®. Early March 2019 and 2020, the Philippine Department of Justice (DOJ) prosecution panel announced it had found probable cause to indict six Sanofi employees / former employees and former Government officials for "reckless imprudence" resulting in homicides. Several criminal actions have been filed in court as a result of the DOJ finding probable cause for the cases to proceed. A Motion for Reconsideration (MR) was filed by Sanofi Pasteur Inc. (Philippines) and was dismissed in November 2019 for all respondents who filed the MR except for one. The remaining respondents have filed a further Petition for Review to the DOJ Secretary in December 2019 and the said petition remains pending.

b) Patents

Ramipril Canada Patent Litigation

Sanofi was involved in a number of legal proceedings involving companies which market generic Altace® (ramipril) in Canada. In 2004, Sanofi unsuccessfully brought Notice of Compliance proceedings (NOC proceedings) at the end of which eight manufacturers obtained marketing authorizations from the Canadian Minister of Health for generic versions of ramipril in Canada. Sanofi filed unsuccessful patent infringement actions against all those companies and ultimately Sanofi was liable for damages under Section 8. Sanofi made payment in complete satisfaction of those awards.

In June 2011, while the Section 8 damages action was proceeding in Federal Court, Apotex commenced an action in the Ontario Superior Court of Justice asserting damages under the Ontario Statute of Monopolies, the UK Statute of Monopolies, and the Trade-marks Act (the "Ontario Action"). The Ontario Action was stayed pending exhaustion of appeals in the Section 8 damages action and, despite having received full compensation in the Section 8 action, was reinitiated by Apotex after the conclusion of the appeals.

In June 2017, the Canadian Supreme Court determined that the legal principles applied in the ramipril invalidity decision were unsound and in 2018, Sanofi amended its pleadings to address this development.

In January 2019, the motions judge denied Sanofi's motion to seek summary judgment on the issue of applicability of the Statute of Monopolies in view of the allowed pleadings amendment. In view of the pleadings amendment and denial of summary judgment, the trial for this matter, originally expected for fall 2019, will now likely be delayed significantly.

Praluent® (alirocumab)-related Amgen Patent Litigation in the US

In 2014, Amgen filed four separate complaints against Sanofi and Regeneron in the US District Court for the District of Delaware ("District Court") asserting patent infringement relating to Sanofi and Regeneron's Praluent® product. Together these complaints allege that Praluent® infringes seven patents for antibodies targeting PCSK9 and seek injunctive relief and unspecified damages. In January 2016, Sanofi and Regeneron informed the District Court that they stipulated to infringement. In March 2016, the District Court granted Judgment as a Matter of Law (JMOL) of obviousness in favor of Amgen and JMOL on an aspect of willful infringement in favor of Sanofi and Regeneron. In addition, in 2016, a jury verdict upheld the validity of Amgen's asserted claims of two patents. In January 2017, the District Court denied Sanofi's and Regeneron's motion for a new trial and their motion for JMOL and granted an injunction preventing the marketing, selling or manufacturing of Praluent® in the US during the term of the two Amgen patents starting from February 21, 2017.

In early February 2017, the US Court of Appeals for the Federal Circuit ("Federal Circuit") stayed (suspended) the permanent injunction for Praluent® during Sanofi's and Regeneron's appeal of the validity judgment and injunction ruling in the Federal Circuit.

In October 2017, the Federal Circuit granted a new trial on certain validity issues (lack of written description and enablement), vacated (lifted) the District Court's judgment and found that the District Court improperly granted a permanent injunction.

In February 2019, a jury from the US District Court for the District of Delaware upheld the validity of three of the five asserted claims of two Amgen patents. The jury agreed with Sanofi and Regeneron for two of the five asserted claims, finding they were invalid. On February 8, 2019, the District Court dismissed Amgen's claim for willful infringement.

In August 2019, the Court ruled in favor of Sanofi and Regeneron and found as a matter of law that Amgen's remaining three asserted patent claims are invalid. This means that Sanofi and Regeneron have successfully invalidated all five asserted patent claims in the District Court. Amgen appealed to the Federal Circuit.

Praluent® (alirocumab)-related Amgen Patent Litigation in Europe

Amgen has filed six separate patent infringement lawsuits against Sanofi and Regeneron in Europe based on Amgen's European patent EP2215124. In July 2016, Amgen filed a lawsuit in the UK High Court of Justice, Chancery Division Patents Court against five Sanofi entities and Regeneron alleging that alirocumab infringes its '124 (UK) patent, seeking injunctive relief and unspecified damages; Sanofi has counterclaimed invalidity. In February 2017, the UK action had been stayed (suspended) on terms agreed by the parties. In October 2020, the court issued a judgment in favor of Sanofi and Regeneron to lift the stay of the litigation and awarded Sanofi 50,000 pounds of legal cost. Based on the invalidation of the broad PCSK-9 claims in the European Patent Office (EPO), Amgen has agreed to withdraw its claim of infringement against Sanofi for the sale of Praluent® in the U.K.

In July 2016, Amgen filed a lawsuit in Germany in the Regional Court, Düsseldorf against three Sanofi entities and Regeneron alleging that alirocumab infringes its '124 (DE) patent, seeking injunctive relief and unspecified damages. In July 2019, the Regional Court of Düsseldorf ruled, finding infringement, and issued an injunction which requires Sanofi and Regeneron to stop marketing, selling, and manufacturing Praluent® in Germany. Sanofi and Regeneron appealed. Amgen enforced the injunction and Sanofi and Regeneron complied. Praluent® was no longer commercialized in Germany. The Higher Regional Court of Düsseldorf held a hearing in November 2020 and based on the invalidation of Amgen's broad PCSK-9 claims in the EPO, reversed the lower court's infringement judgement against Sanofi and Regeneron, and also reversed the injunction of the manufacture and sales of Praluent® in Germany. Similarly based on the invalidation of the broad PCSK-9 claims in the EPO, Amgen also has withdrawn or agreed to withdraw its claim of infringement against Sanofi for the sale of Praluent® in France, Italy, the Netherlands and Spain.

Praluent® (alirocumab)-related EPO Patent Oppositions

In February 2016, the European Patent Office (EPO) granted Amgen's European Patent EP2215124. In February 2016, Sanofi filed an opposition with the EPO requesting the revocation of Amgen's '124 patent in its entirety for all contracting states on the grounds that the subject-matter of the opposed patent is not patentable. In November 2016, Sanofi filed a second opposition (in the name of three Sanofi affiliates named as defendants in the German infringement action - see above), and Regeneron filed a separate opposition, requesting revocation of Amgen's '124 patent. In November 2018, the EPO Opposition Division maintained Amgen's patent claims in amended form. Subsequently, Sanofi and Regeneron each filed a notice of appeal. In October 2020, the EPO's Technical Board of Appeals ruled in favor of Sanofi and Regeneron and invalidated all of Amgen's broad claims covering PCSK-9 antibodies, leaving them claims that are narrow and do not cover Praluent®.

Praluent® (alirocumab)-related Amgen Opposition and Patent Litigation in Japan

In May 2017, Amgen filed a lawsuit in the Tokyo District Court (TDC), against Sanofi K.K. for patent infringement of two of its Japanese Patents, JP5705288 and JP5906333. Amgen sought injunctive relief to prevent the infringing manufacture, use and sale of alirocumab, as well as destruction of Praluent® and alirocumab, and the cost of litigation. Sanofi had counterclaimed invalidity and non-infringement.

The validity of these two Japanese patents was separately challenged by Sanofi in the Japanese Patent Office (JPO) by filing invalidation actions in 2016. In August 2017, the JPO upheld the patents' claims in amended form. In December 2017, Sanofi filed an appeal to the Intellectual Property High Court (IPHC) demanding revocation of the JPO decision. In December 2018, the IPHC rendered its decision that Amgen's patents are valid, upholding the JPO's earlier decision. Sanofi filed an appeal to the Supreme Court in February 2019.

In January 2019, the TDC ruled in Amgen's favor, finding its patents valid and infringed. The TDC did not order provisional enforcement of an injunction. Sanofi appealed to the IPHC. In October 2019, the IPHC affirmed the TDC's decision that Amgen's patents are valid and infringed. Sanofi filed an appeal to the Supreme Court in November 2019.

In April 2020, the Supreme Court denied Sanofi's appeal in the invalidation action and the infringement proceeding. The injunction issued by the Tokyo District Court became enforceable and Sanofi complied. Praluent® is no longer commercialized in Japan.

Dupixent® (dupilumab)-related Amgen Patent Opposition and Revocation in Europe

Immunex Corporation, an Amgen affiliate, is the registered proprietor of European Patent EP2292665. The claims of this patent relate to, among other things, human monoclonal antibodies that are capable of inhibiting IL-4 induced biological activity and which compete with one of four reference antibodies for binding to a cell that expresses human IL-4R. In April 2016, Sanofi and Regeneron each filed an opposition in the European Patent Office (EPO) against EP2292665, seeking its revocation on the basis that, inter alia, the claims are invalid for prohibited "added matter", lack of novelty, lack of inventive step and lack of sufficient disclosure. In September 2016, Sanofi also filed a civil action in the UK High Court (Chancery Division/Patents Court) seeking revocation of the UK designation of EP2292665 on similar grounds. In January 2017, at the joint request of Sanofi and Immunex, the UK High Court ordered that the revocation action be stayed pending the final determination of the pending EPO opposition proceedings.

The EPO rendered its decision in November 2017 and revoked the patent in its entirety. The decision revoking the patent was issued in January 2018. In early 2018, Immunex appealed the decision of the EPO.

In September 2017, Sanofi and Regeneron filed oppositions in the EPO against Amgen's European Patent EP2990420, which is a divisional of the EP2292665 Patent discussed above. The issues in this opposition were similar to those made in the oppositions against EP2292665.

In February 2019, the EPO revoked the patent EP2990420 in its entirety, finding the claims invalid for lack of sufficiency. Immunex filed a notice of appeal in May 2019. A hearing date for the appeal has not been scheduled yet.

Dupixent® (dupilumab)-related Amgen Inter Partes Reviews and Patent Litigation in the US

In March and July 2017, Sanofi and Regeneron filed collectively three petitions for *Inter Partes* Review (IPR) for US Patent No. 8,679,487 with the United States Patent and Trademark Office (USPTO). In these petitions, Sanofi and Regeneron collectively attack the validity of all the claims of this patent. The USPTO declined to institute an IPR on the first petition but granted Sanofi and Regeneron's second and third petitions and instituted *Inter Partes* Reviews of all challenged claims in the '487 Patent.

In April 2017, Immunex filed a complaint in the US District Court for the Central District of California against Sanofi and Regeneron asserting that the commercialization of Dupixent® infringes US Patent No. 8,679,487. In response, among other things, Sanofi and Regeneron asserted affirmative defenses of non-infringement, invalidity, and unenforceability.

In February 2019, the USPTO issued final written decisions on the two IPR petitions and declined to hold the challenged claims of the US patent No. 8,679,487 invalid for anticipation but found all claims on the '487 patent invalid for obviousness. In April 2019, Immunex appealed the USPTO's decision invalidating all 17 claims of US Patent No. 8,679,487 to the Federal Circuit. Also in April 2019, Sanofi and Regeneron appealed the USPTO's decision that the challenged claims of the '487 Patent are not invalid as anticipated by Immunex's '132 Publication.

With respect to the Immunex complaint, on February 28, 2019, the US District Court granted parties' joint stipulation seeking to stay (put on-hold) the district court litigation. Accordingly, the litigation is stayed pending final resolution of any rehearings or appeals of the related IPR proceedings.

In October 2020, the Court of Appeals for the Federal Circuit (CAFC) affirmed the USPTO's decision that all claims of US Patent No. 8,679,487 (which Immunex asserted against Dupixent®) are invalid. Immunex has indicated that it plans to appeal the decision to the US Supreme Court.

Jevtana® (cabazitaxel)-related patent litigation in the US

Jevtana® is covered by five Orange Book listed patents U.S. 5,847,170, U.S. 7,241,907, U.S. 8,927,592, U.S. 10,583,110 and U.S. 10,716,777. In May to July 2020, Sanofi filed patent infringement suits under Hatch-Waxman against 12 generic filers asserting the '110 patent and the '777 patent in the U.S. District Court for the District of Delaware. Sanofi has reached settlement agreements with some of the defendants and the suit against the remaining defendants are ongoing. In January 2021, the District Court issued a claim construction decision in favor of the defendants. A trial has been scheduled to start in May 2021.

Mylan filed a petition for *Inter Partes Review* of the '592 patent at the United States Patent and Trademark Office (USPTO). In September 2017, the USPTO issued a Final Written Decision that invalidated all the challenged claims of the '592 patent and denied Sanofi's contingent motion to amend. Sanofi appealed the USPTO's decision and in February 2019, the Federal Circuit vacated the USPTO's decision and remanded it back for reconsideration. In October 2019, the USPTO granted Sanofi's motion to amend and Mylan appealed. In January 2021, the Federal Circuit affirmed the USPTO's decision.

Plavix® Litigation (Commonwealth) in Australia

In August 2007, GenRX (a subsidiary of Apotex) obtained registration of a generic clopidogrel bisulfate product on the Australian Register of Therapeutic Goods. At the same time, GenRX filed a patent invalidation action with the Federal Court of Australia, seeking revocation of Sanofi's Australian enantiomer patent claiming clopidogrel salts (a "nullity action"). In September 2007, Sanofi obtained a preliminary injunction from the Federal Court preventing commercial launch of this generic clopidogrel bisulfate product until judgment on the substantive issues of patent validity and infringement. In February 2008, Spirit Pharmaceuticals Pty. Ltd. also filed a nullity action against Sanofi's Australian enantiomer patent. The Spirit proceeding was consolidated with the Apotex proceeding.

In August 2008, the Australian Federal Court confirmed that the claim in Sanofi's Australian enantiomer patent directed to clopidogrel bisulfate (the salt form in Plavix®) was valid and the patent infringed. On appeal, the Full Federal Court of Australia held in September 2009 that all claims in the patent are invalid. Sanofi's appeal to the Australia High Court was denied in March 2010. The security bond posted by Sanofi in connection with the preliminary injunction obtained in 2007 was subsequently increased from AUD40 million to AUD204 million. Apotex sought damages in the range of AUD20 million to AUD236 million, plus interest for having been subject to an injunction.

In April 2013, the Australian Department of Health and Ageing filed an application before the Federal Court of Australia seeking payment of damages from Sanofi related to the Apotex preliminary injunction of up to AUD449 million (€283 million as of December 31, 2020), plus interest.

Sanofi and BMS settled the patent litigation with Apotex in November 2014. In light of the Apotex settlement, the Commonwealth has requested that the Court consider a set of legal issues separate from trial that could simplify the trial. In April 2020, the Commonwealth's claim was dismissed. In May 2020, the Commonwealth filed a Notice of Appeal to the Full Court of the Federal Court. Appeal hearing took place in February 2021 before the Full Court of the Federal Court.

c) Other litigation

Aubagio® (teriflunomide)-related litigation in Europe

In October 2020, Mylan Ireland Ltd ('Mylan') brought an action before the General Court of the European Union requesting the annulment of the August 18, 2020 decision of the European Medicines Agency ('EMA') refusing to validate Mylan's marketing authorization application for a generic version of Aubagio® (teriflunomide). In January 2021, Sanofi submitted to the General Court an application to intervene in this court case between Mylan and the EMA, in order to defend Aubagio®'s regulatory exclusivity.

Plavix® (clopidogrel) - Attorney General Action in Hawaii

In March 2014, the Hawaii Attorney General (AG) filed a complaint that sets forth allegations related to the sale and marketing of and variability of response to Plavix®. The Hawaii AG specifically alleged that Plavix® had a diminished effect in patients of certain genetic backgrounds and that Sanofi and BMS had failed to make an earlier disclosure of this information. A four week bench trial concluded in November 2020.

Plavix® (clopidogrel)-related litigation in France

In France, in the claim concerning allegations that Sanofi's communication and promotional practices inhibited the entry on the market of generics of clopidogrel (the active ingredient of Plavix®), the French Antitrust Authority issued its decision on May 14, 2013, imposing on Sanofi a fine of €40.6 million. In December 2014, the Paris Court of Appeals rejected Sanofi's appeal and confirmed in totality the decision. Sanofi filed a "*pourvoi*" with the French Supreme Court (*Cour de cassation*) in January 2015. As a consequence of the May 2013 ruling, claims were filed by Sandoz and by Teva in 2014 before the Commercial Court of Paris for compensation of their alleged damages: loss of margin and other ancillary damages (legal fees to external counsel, image and reputation). In June and November 2016 respectively, settlement agreements were entered into with Sandoz and Teva. Consequently, they subsequently withdrew their civil claims, jointly and severally. On October 18, 2016, the Supreme Court confirmed the Court of Appeals' decision. Therefore, the Court of Appeals' decision became definitive. In September 2017, Sanofi and Sanofi-Aventis France received a summons before the Paris Commercial Court from the *French Caisse Nationale d'Assurance Maladie - CNAM* (French Social Security) claiming €115.8 million for their alleged damages. On October 1, 2019, the Paris Commercial Court dismissed the CNAM's action as time barred. In November 2019, the CNAM lodged an appeal. The CNAM appeal hearing is planned for October 2021.

d) Contingencies arising from certain Business Divestitures

Sanofi and its subsidiaries, Hoechst and Aventis Agriculture, divested a variety of mostly chemical, including agro-chemical, businesses as well as certain health product businesses. As a result of these divestitures, the Company is subject to a number of ongoing contractual and legal obligations regarding the state of the sold businesses, their assets, and their liabilities.

Aventis Behring Retained Liabilities

The divestment of Aventis Behring and related protein therapies assets became effective on March 31, 2004. The purchase agreement contained customary representations and warranties running from Sanofi as seller to CSL Limited as purchaser. Sanofi has indemnification obligations that generally expired on March 31, 2006 (the second anniversary of the closing date). However, some indemnification obligations, having a longer duration, remain in effect. For example, indemnification obligations relating to the due organization, capital stock and ownership of Aventis Behring Companies ran through March 31, 2014, and product liability indemnification ran through March 31, 2019, subject to an extension for claims related to certain types of product liability notified before such date. Furthermore, for tax-related issues, the indemnification obligation of Sanofi covers all taxable periods that end on or before the closing date and expires thirty days after the expiration of the applicable statute of limitations. In addition, the indemnification obligations relating to certain specified liabilities, including HIV liability, survive indefinitely.

Under the indemnification agreement, Sanofi is generally obligated to indemnify CSL Limited, only to the extent indemnifiable, losses exceeding $10 million and up to a maximum aggregate amount of $300 million. For environmental claims, the indemnification due by Sanofi equals 90% of the indemnifiable losses. Product liability claims are generally treated separately, and the aggregate indemnification is capped at $500 million. Certain indemnification obligations, including those related to HIV liability, as well as tax claims, are not capped in amount.

Aventis CropScience Retained Liabilities

The sale by Aventis Agriculture S.A. and Hoechst GmbH (both legacy companies of Sanofi) of their aggregate 76% participation in Aventis CropScience Holding (ACS) to Bayer and Bayer CropScience AG (BCS), the wholly owned subsidiary of Bayer which holds the ACS shares, was effective on June 3, 2002. The Stock Purchase Agreement (SPA) dated October 2, 2001, contained customary representations and warranties with respect to the sold business, as well as a number of indemnifications, in particular with respect to: environmental liabilities (the representations and warranties and the indemnification are subject to a cap of €836 million, except for certain legal representations and warranties and specific environmental liabilities); taxes; certain legal proceedings; claims related to StarLink® corn; and certain pre-closing liabilities, in particular, product liability cases (which are subject to a cap of €418 million within the above global cap of €836 million). There are various periods of limitation depending upon the nature or subject of the indemnification claim. Further, Bayer and BCS are subject to a number of obligations regarding mitigation and cooperation.

Since December 2005, Aventis Agriculture and Hoechst GmbH have concluded several settlement agreements to resolve a substantial number of disputes with Bayer and BCS, including the termination of arbitration proceedings initiated in August 2003 for an alleged breach of a financial statement-related representation contained in the SPA, and numerous other warranty and indemnification claims, including certain environmental and product liabilities claims. A number of other outstanding claims remain unresolved.

Aventis Animal Nutrition Retained Liabilities

Aventis Animal Nutrition S.A. and Aventis (both legacy companies of Sanofi) signed an agreement for the sale to Drakkar Holdings S.A. of the Aventis Animal Nutrition business effective in April 2002. The sale agreement contained customary representations and warranties. Sanofi's indemnification obligations ran through April 2004, except for environmental indemnification obligations (which ran through April 2012), tax indemnification obligations (which run through the expiration of the applicable statutory limitation period), and antitrust indemnification obligations (which extend indefinitely). The indemnification undertakings are subject to an overall cap of €223 million, with a lower cap for certain environmental claims. Indemnification obligations for antitrust and tax claims are not capped.

Celanese AG Retained Liabilities

The demerger of the specialty chemicals business from Hoechst to Celanese AG (now trading as "Celanese GmbH") became effective on October 22, 1999. Under the demerger agreement between Hoechst and Celanese, Hoechst expressly excluded any representations and warranties regarding the shares and assets demerged to Celanese. Celanese subsequently contributed rights and obligations relating to

environmental liabilities resulting from the demerger agreement to a subsidiary CCC Environmental Management and Solutions GmbH & Co. KG ("CCC"). The following obligations of Hoechst are ongoing:

- While all obligations of Hoechst (i) resulting from public law or (ii) pursuant to current or future environmental laws or (iii) vis-à-vis third parties pursuant to private or public law related to contamination (as defined) were transferred to Celanese under the demerger agreement in full, after the subsequent contribution CCC can request indemnification from Hoechst for two thirds of any such cost incurred under these obligations.
- To the extent Hoechst is liable to purchasers of certain of its divested businesses (as listed in the demerger agreement), CCC is liable to indemnify Hoechst, as far as environmental damages are concerned, for aggregate liabilities up to €250 million, liabilities exceeding such amount will be borne by Hoechst alone up to €750 million, and amounts exceeding €750 million will be borne 2/3 by Hoechst and 1/3 by CCC without any further caps. Subsequent to the contribution of rights and obligations relating to environmental liabilities by Celanese, Celanese was jointly liable with CCC until November 2016. Thereafter, Celanese remains liable for known environmental claims specified in 2013.

Rhodia Shareholder Litigation

In January 2004, two minority shareholders of Rhodia and their respective investment vehicles filed two claims before the Commercial Court of Paris (*Tribunal de Commerce de Paris*) against Aventis, to which Sanofi is successor in interest, together with other defendants including former directors and statutory auditors of Rhodia from the time of the alleged events. The claimants seek a judgment holding the defendants collectively liable for alleged management errors and for alleged publication of misstatements between 1999 and 2002, and inter alia regarding Rhodia's acquisition of the companies Albright & Wilson and ChiRex. These shareholders seek a finding of joint and several liability for damages to be awarded to Rhodia in an amount of €925 million for alleged harm to it (a derivative action), as well as personal claims of €4.3 million and €125.4 million for their own alleged individual losses. Sanofi contests both the substance and the admissibility of these claims.

Sanofi is also aware of three criminal complaints filed in France by the same plaintiffs and of a criminal investigation order issued by the Paris public prosecutor following the submission of the report issued by the AMF regarding Rhodia's financial communications. In 2006, the Commercial Court of Paris accepted Sanofi's and the other defendants' motion to stay the civil litigation pending the conclusion of the criminal proceedings.

In December 2016, the Court of Appeals of Paris dismissed the appeal lodged by the same plaintiffs against the order of the investigating judge dated October 2015, dismissing all criminal charges in this case. The plaintiffs appealed the December 2016 decision before the French Supreme Court (*Cour de cassation*). Following this decision, the plaintiffs may also petition the Commercial Court of Paris and seek the reopening of the commercial cases mentioned above on the basis that the criminal proceedings have now concluded.

Clariant Retained Liabilities - Specialty Chemicals Business

Hoechst conveyed its specialty chemicals business to Clariant AG (Clariant) pursuant to a 1997 agreement. Clariant has undertaken to indemnify Hoechst for all costs incurred for environmental matters relating to purchased sites. However, certain indemnification obligations of Hoechst for environmental matters in favor of Clariant remain with Hoechst.

Hoechst must indemnify Clariant indefinitely (i) with respect to sites taken over by Clariant, for costs which relate to environmental pollutions attributable to certain activities of Hoechst or of third parties, (ii) for costs attributable to four defined waste deposit sites in Germany which are located outside the sites taken over by Clariant (to the extent exceeding an indexed amount of approximately €20.5 million), (iii) for costs from certain locally concentrated pollutions in the sites taken over by Clariant but not caused by specialty chemicals activities in the past, and (iv) for 75% of the costs relating to a specific waste deposit site in Frankfurt, Germany.

Infraserv Hoechst Retained Liabilities

By the Asset Contribution Agreement dated December 19/20, 1996, as amended in 1997, Hoechst contributed all lands, buildings, and related assets of the Hoechst site at Frankfurt Hoechst to Infraserv GmbH & Co. Hoechst KG. Infraserv Hoechst undertook to indemnify Hoechst against environmental liabilities at the Hoechst site and with respect to certain landfills. As consideration for the indemnification undertaking, Hoechst transferred to Infraserv Hoechst approximately €57 million to fund reserves. In 1997, Hoechst also agreed it would reimburse current and future Infraserv Hoechst environmental expenses up to €143 million. As a former operator of the land and as a former user of the landfills, Hoechst may ultimately be liable for costs of remedial action in excess of this amount.

Boehringer Ingelheim (BI) Retained Liabilities

Sanofi and Boehringer Ingelheim (BI) are involved in arbitrations regarding their respective indemnification obligations for liabilities connected to ongoing US court proceedings in which it is alleged that some drug products with the API ranitidine, including Zantac® manufactured by BI, contain a nitrosamine impurity (NDMA) that is classified as a probable human carcinogen. The dispute arises from indemnification obligations agreed between Sanofi and BI as part of the swap of Sanofi's Animal Health (AH) business for BI's Consumer Health Care (CHC) business in January 2017 and under a Global Settlement Agreement concluded in September 2019 regarding notably the offset of respective AH and CHC claims notified under the SPAs.

In February 2020, BI initiated an arbitration against Sanofi seeking indemnification for losses it could incur as a result of Zantac® litigation in the US. Sanofi is disputing BI's claim for indemnification and has asserted several counterclaims under relevant agreements, including a counterclaim for indemnification of losses Sanofi and its affiliates have incurred and may incur in connection with the same US court proceedings involving Zantac®. The arbitrations are ongoing.

D.23. Provisions for discounts, rebates and sales returns

Adjustments between gross sales and net sales, as described in Note B.13., are recognized either as provisions or as reductions in accounts receivable, depending on their nature.

The table below shows movements in these items:

(€ million)	Government and State programs[a]	Managed care and GPO programs[b]	Chargeback incentives	Rebates and discounts	Sales returns	Other deductions	Total
Balance at January 1, 2018	**2,086**	**663**	**377**	**1,067**	**547**	**6**	**4,746**
Changes in scope of consolidation	37	2	—	(123)	—	2	(82)
Provision related to current period sales	4,624	2,038	3,620	5,942	465	56	16,745
Net change in provision related to prior period sales	(2)	(4)	(1)	(11)	(35)	3	(50)
Payments made	(4,673)	(2,055)	(3,714)	(5,732)	(448)	(54)	(16,676)
Currency translation differences	76	30	12	(3)	17	—	132
Balance at December 31, 2018 [c]	**2,148**	**674**	**294**	**1,140**	**546**	**13**	**4,815**
Provision related to current period sales	5,542	2,563	4,649	5,888	554	96	19,292
Net change in provision related to prior period sales	(27)	—	(1)	(6)	(27)	14	(47)
Payments made	(5,529)	(2,528)	(4,637)	(5,719)	(465)	(72)	(18,950)
Currency translation differences	44	17	7	27	13	—	108
Balance at December 31, 2019 [c]	**2,178**	**726**	**312**	**1,330**	**621**	**51**	**5,218**
Provision related to current period sales	5,970	2,752	4,633	6,221	628	110	20,314
Net change in provision related to prior period sales	(54)	—	—	(113)	(34)	—	(201)
Payments made	(5,552)	(2,556)	(4,604)	(5,838)	(512)	(112)	(19,174)
Currency translation differences	(35)	(14)	(8)	(43)	(15)	(3)	(118)
Balance at December 31, 2020 [c]	**2,507**	**908**	**333**	**1,557**	**688**	**46**	**6,039**

(a) Primarily US government programs: Medicaid (€1,015 million in 2020, €1,017 million in 2019, €1,033 million in 2018) and Medicare (€726 million in 2020, €810 million in 2019 and €829 million in 2018).

(b) Mainly rebates and other price reductions granted to healthcare authorities in the United States (including Managed Care: €692 million in 2020, €649 million in 2019 and €604 million in 2018).

(c) Provisions related to US net sales amounted to €3,982 million as of December 31, 2020, €3,585 million as of December 31, 2019 and €3,509 million as of December 31, 2018.

D.24. Personnel costs

Total personnel costs (other than termination benefits, presented in Note D.27.) include the following items:

(€ million)	2020	2019	2018
Salaries	6,508	6,590	6,547
Social security charges (including defined-contribution pension plans)	1,874	1,949	1,954
Stock options and other share-based payment expense	274	252	282
Defined-benefit plans	159	119	261
Other employee benefits	261	229	225
Total	**9,076**	**9,139**	**9,269**

The total number of registered employees was 99,412 as of December 31, 2020, compared with 100,409 as of December 31, 2019 and 104,226 as of December 31, 2018.

D.25. Other operating income

Other operating income totaled €696 million in 2020, versus €825 million in 2019 and €484 million in 2018.

Other operating income includes (i) gains from disposals relating to ongoing operations, including in particular disposals of intangible rights, amounting to €307 million in 2020 (versus €296 million in 2019 and €326 million in 2018); and (ii) income from Sanofi's pharmaceutical partners, amounting to €199 million in 2020 (including €164 million from Regeneron, see Note D.26. below), compared with €103 million in 2019 and €32 million in 2018. This line item also includes (i) for 2019, the favorable impact of top-up pension plan amendments following the application of the Pacte law in France; and (ii) for 2018, a €112 million gain related to a data transfer agreement.

D.26. Other operating expenses

Other operating expenses totaled €1,415 million in 2020, compared with €1,207 million in 2019 and €548 million in 2018.

For 2020, this line item includes €1,090 million of expenses relating to the alliance with Regeneron (see Note C.1.), versus €715 million for 2019 and €225 million in 2018 (as shown in the table below):

(€ million)	2020	2019	2018
Income & expense related to profit/loss sharing under the Monoclonal Antibody Alliance	(727)	(253)	177
Additional share of profit paid by Regeneron towards development costs	75	21	—
Reimbursement to Regeneron of selling expenses incurred	(349)	(449)	(388)
Total - Monoclonal Antibody Alliance	**(1,001)**	**(681)**	**(211)**
Immuno-Oncology Alliance	**89**	**62**	**4**
Other (mainly Zaltrap®)	**(14)**	**(14)**	**(14)**
Other operating income/(expenses), net related to the Regeneron Alliance	**(926)**	**(633)**	**(221)**
*of which amount presented in **Other operating income** (Note D.25.)*	*164*	*82*	*4*

Other operating expenses included acquisition-related costs of €29 million in 2020, and of €56 million in 2018. Charges to provisions for litigation and environmental risks are also recorded within this line item.

Finally, ***Other operating expenses*** also includes shares of profits due to alliance partners (other than BMS and the alliance partner under the Actonel® agreement) under product marketing agreements (€16 million in 2020, versus €28 million in 2019 and €50 million in 2018).

D.27. Restructuring costs and similar items

Restructuring costs and similar items amounted to €1,064 million in 2020, €1,062 million in 2019 and €1,480 million in 2018, and comprise the following items:

(€ million)	2020	2019	2018
Employee-related expenses	690	791	517
Charges, gains or losses on assets[(a)]	149	106	162
Compensation for early termination of contracts (other than contracts of employment)	40	49	352
Decontamination costs	(2)	27	5
Other restructuring costs	187	89	444
Total	**1,064**	**1,062**	**1,480**

(a) This line consists of accelerated depreciation charges related to site closures (including leased sites), and gains or losses on divestments of assets arising from reorganization decisions made by Sanofi.

In 2020, employee-related expenses amounted to €690 million, and consisted of termination benefits further to the announcement of plans to adapt Sanofi's organization (primarily in Europe) in line with the new "Play to Win" strategy announced in December 2019.

In 2019, restructuring costs mainly comprised termination benefits of €791 million (primarily in Europe, the United States and Asia), plus asset write-downs and accelerated depreciation charges of €106 million.

Costs relating to Sanofi transformation programs included within the "Other restructuring costs" line, as defined in Note B.19., amounted to €173 million in 2020 compared with €109 million in 2019 and €145 million in 2018.

In 2018, restructuring costs mainly comprised (i) termination benefits of €517 million, including provisions associated with headcount adjustments in Europe announced in December 2018; (ii) a provision of €283 million booked as of December 31, 2018 for penalties arising from the restructuring of the Immuno-Oncology Discovery and Development agreement with Regeneron to end the collaboration on research programs included in the initial July 2015 agreement (see Note C.1.); (iii) the costs of transferring the infectious diseases early stage R&D pipeline and research unit, amounting to €252 million and mainly comprising payments to Evotec over a five-year period, including an upfront payment of €60 million in 2018: and (iv) €162 million of losses on property, plant and equipment due to site closures or divestments under transformation or reorganization programs.

D.28. Other gains and losses, and litigation

Other gains and losses, and litigation for 2020 comprise a net gain of €136 million, mainly relating to the sale of Seprafilm®.

For 2019, this line item comprises a net gain of €327 million, mainly relating to a gain on settlement of litigation.

For 2018, this line item consists of the €502 million pre-tax gain arising on the divestment of the European Generics business (completed September 30, 2018), net of separation costs (see Note D.2.).

D.29. Financial expenses and income

An analysis of ***Financial expenses*** and ***Financial income*** is set forth below:

(€ million)	2020	2019	2018
Cost of debt[a]	(328)	(318)	(396)
Interest income[b]	103	146	123
Cost of net debt	**(225)**	**(172)**	**(273)**
Non-operating foreign exchange gains/(losses)	(6)	1	6
Unwinding of discounting of provisions[c]	(11)	(25)	(24)
Net interest cost related to employee benefits	(59)	(87)	(75)
Gains/(losses) on disposals of financial assets	6	—	63
Net interest expense on lease liabilities[d]	(38)	(39)	—
Other	(4)	19	32
Net financial income/(expenses)	**(337)**	**(303)**	**(271)**
comprising: Financial expenses	**(390)**	**(444)**	**(435)**
Financial income	**53**	**141**	**164**

(a) Includes net gains on interest rate and currency derivatives used to manage debt: €93 million in 2020, €187 million in 2019 and €75 million in 2018.
(b) Includes net gains on interest rate and currency derivatives used to manage cash and cash equivalents: €66 million in 2020, €55 million in 2019 and €51 million in 2018.
(c) Primarily on provisions for environmental risks, restructuring provisions, and provisions for product-related risks (see Note D.19.).
(d) Impact of the application of IFRS 16.

In 2020, 2019 and 2018, the impact of the ineffective portion of hedging relationships was not material.

D.30. Income tax expense

Sanofi has elected for tax consolidations in a number of countries, principally France, Germany, the United Kingdom and the United States.

The table below shows the allocation of income tax expense between current and deferred taxes:

(€ million)	2020	2019	2018
Current taxes	(1,912)	(1,892)	(1,212)
Deferred taxes	99	1,753	731
Total	**(1,813)**	**(139)**	**(481)**
Income before tax and investments accounted for using the equity method	**13,804**	**2,822**	**4,405**

The difference between the effective tax rate and the standard corporate income tax rate applicable in France is explained as follows:

(as a percentage)	2020	2019	2018
Standard tax rate applicable in France	32.0	34.4	34.4
Difference between the standard French tax rate and the rates applicable to Sanofi[a]	(18.2)	(22.9)	(17.4)
Revisions to tax exposures and settlements of tax disputes	0.5	4.8	(1.4)
Impact of US tax reform[b]	—	—	(4.3)
Impact of past acquisitions and divestitures	—	(6.2)	—
Fair value remeasurement of contingent consideration[c]	—	(2.6)	0.2
Other items[d]	(1.2)	(2.6)	(0.6)
Effective tax rate	**13.1**	**4.9**	**10.9**

(a) The difference between the French tax rate and tax rates applicable to foreign subsidiaries reflects the fact that Sanofi has operations in many countries, most of which have lower tax rates than France. For 2020, this line includes the difference between the standard French tax rate and the tax rate applicable to the gain on divestment of Regeneron shares.
(b) For 2018, this line reflects an adjustment of €188 million to the estimated tax charge on deemed repatriation attributable to the accumulated earnings of non-US operations.
(c) For 2019, this line includes impacts related to the MSD contingent consideration and to the CVRs issued in connection with the acquisition of Genzyme.
(d) In determining the amount of the deferred tax liability for 2020, 2019 and 2018, Sanofi took into account changes in the ownership structure of certain subsidiaries. For 2018, "Other items" also includes the net tax effect of taxable temporary differences associated with holdings in Sanofi subsidiaries.

For the periods presented, the amount of deferred tax assets recognized in profit or loss that were initially subject to impairment losses at the time of a business combination is immaterial.

D.31. Share of profit/loss from investments accounted for using the equity method

The line item ***Share of profit/(loss) from investments accounted for using the equity method*** comprises:

(€ million)	2020	2019	2018
Regeneron[(a)]	343	245	484
BMS co-promotion entities[(b)]	1	5	12
Other investments accounted for using the equity method	15	5	3
Total	**359**	**255**	**499**

(a) Following the transaction of May 29, 2020 as described in Note D.1., which resulted in the divestment of 22.8 million Regeneron shares, Sanofi no longer exercises significant influence over Regeneron. The 2020 figure presented represents Sanofi's equity-accounted share of Regeneron's net profits up to and including that date.

(b) On February 28, 2020, Sanofi acquired from Bristol-Myers Squibb the remaining 50.1% equity interest not yet held by Sanofi in the three partnerships that organize the commercialization of Plavix® in the United States and Puerto Rico, for a total consideration of $12 million. This acquisition was accounted for in accordance with IFRS 3 (Business Combinations).

D.32. Net income attributable to non-controlling interests

The table below shows ***Net income attributable to non-controlling interests*** for the reporting periods presented:

(€ million)	2020	2019	2018
Share of co-promotion profits attributable to BMS[(a)]	—	—	83
Share of net income attributable to other non-controlling interests	36	31	21
Total	**36**	**31**	**104**

(a) For 2018: share of co-promotion profits attributable to BMS for territories covered by entities majority owned by Sanofi; there was no tax effect on these amounts because BMS received its share before tax. The payment to buy out the BMS non-controlling interests was made on December 31, 2018 (see Note C.2.).

D.33. Related party transactions

The principal related parties are companies over which Sanofi has control or significant influence, joint ventures, key management personnel, and principal shareholders.

Sanofi has not entered into any material transactions with any key management personnel. Financial relations with Sanofi's principal shareholders fall within the ordinary course of business and were immaterial in the years ended December 31, 2020, 2019 and 2018.

Note F.1. lists the principal companies controlled by Sanofi; those companies are fully consolidated, as described in Note B.1. Transactions between those companies, and between the parent company and its subsidiaries, are eliminated when preparing the consolidated financial statements.

Transactions with companies over which Sanofi has significant influence, and with joint ventures, are presented in Note D.6.

Key management personnel include corporate officers and the members of the Executive Committee (an average of 11 members in 2020, 15 members in 2019 and 15 members in 2018).

The table below shows, by type, the compensation paid to key management personnel:

(€ million)	2020	2019	2018
Short-term benefits[(a)]	36	31	38
Post-employment benefits[(b)]	3	(8)	9
Share-based payment	18	30	33
Total recognized in profit or loss	**57**	**53**	**80**

(a) Compensation, employer's social security contributions, directors' attendance fees, and any termination benefits (net of reversals of termination benefit obligations).

(b) This line item includes in 2019 the favorable impact of top-up pension plan amendments following the application of the Pacte law in France.

The table below shows (i) the aggregate top-up pension obligation in favor of certain corporate officers who hold or have held executive positions within Sanofi and of Executive Committee members, and (ii) the aggregate amount of termination benefits and lump-sum retirement benefits payable to key management personnel.

(€ million)	2020	2019	2018
Aggregate top-up pension obligation	28	48	59
Aggregate termination benefits and lump-sum retirement benefits	6	5	10

D.34. Disclosures about major customers and credit risk

Credit risk is the risk that customers (wholesalers, distributors, pharmacies, hospitals, clinics or government agencies) may fail to pay their debts; for Sanofi, that risk is mainly concentrated on amounts receivable from wholesalers in the United States. Sanofi manages credit risk by vetting customers in order to set credit limits and risk levels, and asking for guarantees or insurance where necessary; performing controls; and monitoring qualitative and quantitative indicators of accounts receivable balances, such as the period of credit taken and overdue payments.

Sales generated by Sanofi with its biggest customers, in particular certain wholesalers in the United States, represented 21% of net sales in 2020. The three largest customers respectively accounted for approximately 10%, 6% and 5% of Sanofi's net sales in 2020 (8%, 5% and 3% in 2019; 9%, 6% and 4% in 2018).

D.35. Segment information

As indicated in Note B.26., Sanofi has three operating segments: Pharmaceuticals, Consumer Healthcare and Vaccines.

The Pharmaceuticals segment comprises, for all geographical territories, the commercial operations of the following global franchises: Specialty Care (Dupixent®, Multiple Sclerosis, Neurology, Other Inflammatory Diseases & Immunology, Rare Diseases, Oncology, and Rare Blood Disorders) and General Medicines (Diabetes, Cardiovascular and Established Prescription Products), together with research, development and production activities dedicated to the Pharmaceuticals segment. This segment also includes associates whose activities are related to pharmaceuticals. Following the transaction of May 29, 2020, Regeneron is no longer an associate of Sanofi (see Note D.1.). Consequently, the Pharmaceuticals segment no longer includes Sanofi’s equity-accounted share of Regeneron’s profits for all the periods presented in this note.

The Consumer Healthcare segment comprises, for all geographical territories, the commercial operations for Sanofi's Consumer Healthcare products, together with research, development and production activities dedicated to those products.

The Vaccines segment comprises, for all geographical territories, the commercial operations of Sanofi Pasteur, together with research, development and production activities dedicated to vaccines.

Inter-segment transactions are not material.

The costs of global support functions (External Affairs, Finance, Human Resources, Legal Affairs, Information Solutions & Technologies, Sanofi Business Services, etc.) are managed centrally at group-wide level. The costs of those functions are presented within the “Other” category. That category also includes other reconciling items such as retained commitments in respect of divested activities.

In 2020, Sanofi adapted its management reporting to reflect its new organizational structure. This resulted in cost reallocations between the Pharmaceuticals, Consumer Healthcare and Vaccines segments and the “Other” category, and product reallocations between Pharmaceuticals and Consumer Healthcare. Expenses relating to Global Medical Affairs, allocated to the “Other” category in the old management reporting structure, were reallocated to the Pharmaceuticals segment. Only figures presented for 2019 have been restated, to reflect the new management reporting structure as well as reallocations of some countries between geograophical regions. Due to lack of available data and the over-complex adjustments that would be required (in particular to Sanofi's reporting tools), 2018 figures have not been restated to reflect the changes arising from the new segment reporting model.

D.35.1. Segment results

D.35.1.1. Analysis of net sales

The table below sets forth Sanofi's net sales for the years ended December 31, 2020, 2019 and 2018:

(€ million)		Europe	United States	Other countries	2020	Europe	United States	Other countries	2019 [a]	Europe	United States	Other countries	2018
Pharmaceuticals		**6,819**	**9,635**	**9,220**	**25,674**	**6,797**	**8,918**	**9,985**	**25,700**	**7,303**	**7,897**	**9,485**	**24,685**
General Medicines		**4,505**	**2,869**	**7,346**	**14,720**	**4,809**	**3,386**	**8,342**	**16,537**	**5,299**	**3,510**	**7,607**	**16,416**
of which	Lantus®	537	929	1,195	2,661	599	1,149	1,264	3,012	684	1,614	1,267	3,565
	Toujeo®	374	267	292	933	343	289	251	883	290	344	206	840
	Praluent®	121	106	34	261	112	112	34	258	86	154	21	261
	Multaq®	24	274	14	312	41	295	11	347	43	296	11	350
	Lovenox®	656	30	665	1,351	730	33	596	1,359	870	38	557	1,465
	Plavix®	129	10	777	916	142	—	1,192	1,334	147	—	1,293	1,440
	Generics	100	161	671	932	139	152	783	1,074	568	124	798	1,490
Specialty Care		**2,314**	**6,766**	**1,874**	**10,954**	**1,988**	**5,532**	**1,643**	**9,163**	**2,004**	**4,387**	**1,878**	**8,269**
of which	Aubagio®	473	1,448	124	2,045	414	1,351	114	1,879	385	1,157	105	1,647
	Cerezyme®	249	177	264	690	259	184	265	708	270	174	267	711
	Myozyme®/ Lumizyme®	389	359	200	948	388	331	199	918	374	284	182	840
	Fabrazyme®	200	406	211	817	185	410	218	813	175	383	197	755
	Eloctate®	—	445	193	638	—	517	167	684	—	500	108	608
	Jevtana®	187	246	103	536	170	212	102	484	158	179	85	422
	Dupixent®	386	2,808	340	3,534	204	1,669	201	2,074	75	660	53	788
Consumer Healthcare		**1,359**	**1,071**	**1,964**	**4,394**	**1,434**	**1,105**	**2,156**	**4,695**	**1,403**	**1,066**	**2,191**	**4,660**
of which	Allergy, Cough & Cold	305	361	430	1,096	364	323	502	1,189	347	303	474	1,124
	Pain	539	181	505	1,225	543	185	552	1,280	521	165	568	1,254
	Digestive	319	86	453	858	326	157	502	985	314	195	477	986
	Nutritionals	127	43	441	611	130	38	453	621	125	37	513	675
Vaccines		**973**	**2,759**	**2,241**	**5,973**	**851**	**2,733**	**2,147**	**5,731**	**728**	**2,577**	**1,813**	**5,118**
of which	Polio/Pertussis/ Hib Vaccines	331	412	1,363	2,106	315	380	1,251	1,946	296	397	1,056	1,749
	Influenza Vaccines	441	1,575	456	2,472	230	1,289	372	1,891	177	1,233	298	1,708
Total net sales		**9,151**	**13,465**	**13,425**	**36,041**	**9,082**	**12,756**	**14,288**	**36,126**	**9,434**	**11,540**	**13,489**	**34,463**

(a) The analysis of net sales for 2019 has been restated to align on Sanofi's new management reporting structure, and to reflect the reallocation of certain countries between geographical regions.

D.35.1.2. Business operating income

Sanofi reports segment results on the basis of "Business operating income". This indicator is used internally by Sanofi's chief operating decision maker to measure the performance of each operating segment and to allocate resources.

Following the transaction of May 29, 2020, Regeneron is no longer an associate of Sanofi (see Note D.1.). Consequently, the definition of the "Business operating income" indicator has been adjusted, and no longer includes Sanofi's share of the net income of Regeneron. This means that the ***Share of profit/(loss) from investments accounted for using the equity method*** line in the table reconciling ***Operating income*** (as shown in the income statement) to "Business operating income" no longer includes the equity-accounted share of profits from Regeneron. The comparatives presented for 2019 and 2018 have been restated to reflect that adjustment. In addition, the gain arising on the divestment of the equity investment in Regeneron is not included in "Business operating income", with the exception of the gain on the remeasurement of the 400,000 retained shares at market value at the transaction date.

In addition, with effect from January 1, 2020 "Business operating income" includes depreciation charged against right-of-use assets recognized under IFRS 16 (Leases), applicable since January 1, 2019, and excludes rental expenses previously recognized under IAS 17. In the interests of consistency, the "Business operating income" figures presented for 2019 have been restated to include the effects of (i) IFRS 16, and (ii) certain expenses and income presented differently for segment reporting purposes to align on Sanofi's new 2020 management reporting structure (see Note D.35., "Segment information", above).

"Business operating income" is derived from ***Operating income***, adjusted as follows:

- the amounts reported in the line items ***Restructuring costs and similar items***, ***Fair value remeasurement of contingent consideration*** and ***Other gains and losses, and litigation*** are eliminated;
- amortization and impairment losses charged against intangible assets (other than software and other rights of an industrial or operational nature) are eliminated;
- the share of profits/losses from investments accounted for using the equity method is added;

- net income attributable to non-controlling interests is deducted;
- other acquisition-related effects (primarily the workdown of acquired inventories remeasured at fair value at the acquisition date, and the impact of acquisitions on investments accounted for using the equity method) are eliminated;
- restructuring costs relating to investments accounted for using the equity method are eliminated; and
- the gain on the divestment of Regeneron shares on May 29, 2020 is eliminated (this elimination does not include the gain on the remeasurement of the 400,000 retained shares at market value as of that date).

The table below sets forth Sanofi's segment results for the years ended December 31, 2020, December 31, 2019 and December 31, 2018:

	2020[a]				
(€ million)	Pharmaceuticals	Consumer Healthcare	Vaccines	Other	Total Sanofi
Net sales	**25,674**	**4,394**	**5,973**	**—**	**36,041**
Other revenues	128	59	1,141	—	1,328
Cost of sales	(7,025)	(1,506)	(3,328)	(245)	(12,104)
Research and development expenses	(4,331)	(136)	(692)	(370)	(5,529)
Selling and general expenses	(5,097)	(1,450)	(822)	(2,021)	(9,390)
Other operating income and expenses	(488)	54	2	(130)	(562)
Share of profit/(loss) from investments accounted for using the equity method	5	9	2	—	16
Net income attributable to non-controlling interests	(33)	(5)	—	—	(38)
Business operating income	**8,833**	**1,419**	**2,276**	**(2,766)**	**9,762**

(a) "Business operating income" no longer includes Sanofi's equity-accounted share of Regeneron's net profits (see definition above, and Note D.1.).

	2019[a]				
(€ million)	Pharmaceuticals	Consumer Healthcare	Vaccines	Other	Total Sanofi
Net sales	**25,700**	**4,695**	**5,731**	**—**	**36,126**
Other revenues	173	57	1,275	—	1,505
Cost of sales	(6,750)	(1,599)	(3,372)	(252)	(11,973)
Research and development expenses	(4,850)	(149)	(639)	(380)	(6,018)
Selling and general expenses	(5,442)	(1,529)	(823)	(2,089)	(9,883)
Other operating income and expenses	(625)	193	—	50	(382)
Share of profit/(loss) from investments accounted for using the equity method	5	(5)	9	—	9
Net income attributable to non-controlling interests	(29)	(6)	—	—	(35)
Business operating income	**8,182**	**1,657**	**2,181**	**(2,671)**	**9,349**

(a) In line with the amended management reporting structure adopted in 2020, "Business operating income" no longer includes Sanofi's equity-accounted share of Regeneron's net profits (see definition above, and Note D.1.). It includes the effects of IFRS 16, and the reallocation of some products from Phamaceuticals to Consumer Healthcare (immaterial impact) and the reallocation of costs previously reported in "Other" to operating segments, for a net amount of €291 million).

	2018[a]				
(€ million)	Pharmaceuticals	Consumer Healthcare	Vaccines	Other	Total Sanofi
Net sales	**24,685**	**4,660**	**5,118**	**—**	**34,463**
Other revenues	252	—	962	—	1,214
Cost of sales	(6,738)	(1,539)	(2,854)	(190)	(11,321)
Research and development expenses	(4,572)	(143)	(555)	(624)	(5,894)
Selling and general expenses	(5,431)	(1,534)	(710)	(2,156)	(9,831)
Other operating income and expenses	(37)	101	(4)	(124)	(64)
Share of profit/(loss) from investments accounted for using the equity method	17	1	(3)	—	15
Net income attributable to non-controlling interests	(96)	(10)	—	—	(106)
Business operating income[a]	**8,080**	**1,536**	**1,954**	**(3,094)**	**8,476**

(a) "Business operating income" no longer includes Sanofi's equity-accounted share of Regeneron's net profits (see definition above, and Note D.1.). Due to lack of available data and the over-complex adjustments that would be required (in particular to Sanofi's reporting tools), 2018 figures have not been restated to reflect the changes arising from the new organizational structure.

The table below, presented in compliance with IFRS 8, shows a reconciliation between aggregated "Business operating income" for the segments and ***Income before tax and investments accounted for using the equity method:***

(€ million)	2020	2019	2018
Business operating income[a]	**9,762**	**9,349**	**8,476**
Share of profit/(loss) from investments accounted for using the equity method[b]	(16)	(9)	(15)
Net income attributable to non-controlling interests[c]	38	35	106
Amortization and impairment of intangible assets	(2,011)	(5,750)	(2,888)
Fair value remeasurement of contingent consideration	124	238	117
Expenses arising from the impact of acquisitions on inventories[d]	(53)	(3)	(114)
Restructuring costs and similar items	(1,064)	(1,062)	(1,480)
Other expenses related to business combinations	—	—	(28)
Other gains and losses, and litigation[e]	136	327	502
Gain on divestment of Regeneron shares on May 29, 2020[f]	7,225	—	—
Operating income	**14,141**	**3,125**	**4,676**
Financial expenses	(390)	(444)	(435)
Financial income	53	141	164
Income before tax and investments accounted for using the equity method	**13,804**	**2,822**	**4,405**

(a) "Business operating income" as presented for 2019 and 2018 has been restated to exclude Sanofi's equity-accounted share of Regeneron's net profits, which amounted to €411 million in 2019 and €408 million in 2018 (see above). In addition, "Business operating income" for 2019 has been restated to include (i) the effects of IFRS 16 and (ii) the effect of certain expenses and income being presented differently for segment reporting purposes to align on Sanofi's new 2020 management reporting structure.

(b) Excludes restructuring costs relating to investments accounted for using the equity method and expenses arising from the impact of acquisitions on investments accounted for using the equity method. For 2019 and 2018, this line has been restated to exclude any effect of equity method accounting for the investment in Regeneron following the divestment of Sanofi's entire equity interest (with the exception of the 400,000 shares retained by Sanofi) on May 29, 2020.

(c) Excludes (i) restructuring costs and (ii) other adjustments attributable to non-controlling interests.

(d) This line records the impact of the workdown of acquired inventories remeasured at fair value at the acquisition date.

(e) For 2020, this line mainly comprises the gain on the sale of operations related to the Seprafilm® activity to Baxter.
For 2019, this line comprises a net gain, mainly arising from a settlement of litigation.
For 2018, this line includes the gain on the divestment of Sanofi's European Generics business (€510 million).

(f) This line includes the gain on the sale of (i) 13 million shares of Regeneron common stock in the registered public offering and (ii) the 9.8 million shares repurchased by Regeneron, but does not include the gain arising from the remeasurement of the 400,000 retained shares at market value as of May 29, 2020.

D.35.2. Other segment information

The tables below show the split by operating segment of (i) the carrying amount of investments accounted for using the equity method, (ii) acquisitions of property, plant and equipment, and (iii) acquisitions of intangible assets.

The principal investments accounted for using the equity method in the Pharmaceuticals segment are entities majority owned by BMS (up to and including February 29, 2020, see Note C.2.), and Infraserv GmbH & Co. Höchst KG.

Acquisitions of intangible assets and property, plant and equipment correspond to acquisitions paid for during the period.

	2020			
(€ million)	Pharmaceuticals	Consumer Healthcare	Vaccines	Total
Investments accounted for using the equity method	154	—	47	201
Acquisitions of property, plant and equipment	755	95	404	1,254
Acquisitions of other intangible assets	532	6	322	860

	2019			
(€ million)	Pharmaceuticals	Consumer Healthcare	Vaccines	Total
Investments accounted for using the equity method[a]	205	4	40	249
Acquisitions of property, plant and equipment[b]	773	88	462	1,323
Acquisitions of other intangible assets	321	51	121	493

(a) This line has been restated to eliminate Sanofi's equity investment in Regeneron, which had a carrying amount of €3,342 million as of December 31, 2019 (see Note D.35., "Segment Information", above).

(b) Includes the effect of restatements needed to align on Sanofi's new 2020 management reporting structure.

(€ million)	2018 Pharmaceuticals	Consumer Healthcare	Vaccines	Total
Investments accounted for using the equity method[a]	297	20	30	347
Acquisitions of property, plant and equipment[b]	1,046	5	364	1,415
Acquisitions of other intangible assets	434	7	121	562

(a) This line has been restated to eliminate Sanofi's equity investment in Regeneron, which had a carrying amount of €3,055 million as of December 31, 2018 (see Note D.35., "Segment Information", above).

(b) Due to lack of available data and the over-complex adjustments that would be required (in particular to Sanofi's reporting tools), 2018 figures have not been restated to reflect the changes arising from the new segment reporting model.

D.35.3. Information by geographical region

The geographical information on net sales provided below is based on the geographical location of the customer. In accordance with IFRS 8, the non-current assets reported below exclude right-of-use assets relating to leases as determined under IFRS 16, investments accounted for using the equity method, other non-current assets, non-current income tax assets, and deferred tax assets.

(€ million)	2020 Total	Europe	of which France	North America	of which United States	Other countries
Net sales	**36,041**	**9,151**	**2,223**	**14,060**	**13,465**	**12,830**
Non-current assets:						
• property, plant and equipment owned	9,365	5,895	3,189	2,542	1,899	928
• goodwill	44,364	—	—	—	—	—
• other intangible assets	18,421	6,278	—	10,675	—	1,468

(€ million)	2019 [a] Total	Europe	of which France	North America	of which United States	Other countries
Net sales[a]	**36,126**	**9,082**	**2,261**	**13,370**	**12,756**	**13,674**
Non-current assets:						
• property, plant and equipment owned	9,717	5,827	3,141	2,862	2,264	1,028
• goodwill	44,519	—	—	—	—	—
• other intangible assets	16,572	6,941	—	7,825	—	1,806

(a) Net sales and property, plant and equipment owned for 2019 have been restated to align on the new management reporting structure, and to reflect the reallocation of certain countries between geographical regions.

(€ million)	2018 [a] Total	Europe	of which France	North America	of which United States	Other countries
Net sales	**34,463**	**9,434**	**2,319**	**12,193**	**11,540**	**12,836**
Non-current assets:						
• property, plant and equipment owned	9,651	5,871	3,163	2,719	2,238	1,061
• goodwill	44,235	—	—	—	—	—
• other intangible assets	21,889	8,058	—	11,190	—	2,641

(a) Due to lack of available data and the over-complex adjustments that would be required (in particular to Sanofi's reporting tools), 2018 figures have not been restated to reflect the changes arising from the new segment reporting model.

As stated in Note D.5., goodwill is not allocated by geographical region.

E/ Principal accountants' fees and services

PricewaterhouseCoopers Audit and Ernst & Young et Autres served as independent auditors of Sanofi for the year ended December 31, 2020 and for all other reporting periods presented. The table below shows fees charged by those firms and member firms of their networks to Sanofi and consolidated subsidiaries in the years ended December 31, 2020 and 2019.

	Ernst & Young				PricewaterhouseCoopers			
	2020		2019		2020		2019	
(€ million)	Amount	%	Amount	%	Amount	%	Amount	%
Audit:								
Statutory audit of separate and consolidated financial statements[a]	13.9	82%	14.0	90%	15.1	98%	14.6	99%
Services other than statutory audit[b]	3.1	18%	1.6	10%	0.3	2%	0.2	1%
Audit-related services[c]	2.5		0.9		0.2		0.2	
Tax	—		—		—		—	
Other	0.6		0.7		0.1		—	
Total	**17.0**	**100%**	**15.6**	**100%**	**15.4**	**100 %**	**14.8**	**100%**

(a) Includes services provided by the independent auditors of the parent company and French subsidiaries: Ernst & Young €7.4 million in 2020, €7.2 million in 2019; PricewaterhouseCoopers €8.2 million in 2020, €7.3 million in 2019.

(b) Services other than statutory audit provided by Ernst & Young et Autres during 2020 comprised:

- work on share capital transactions and securities issues submitted to the Annual General Meeting (in extraordinary business) for approval;
- additional procedures to enable reports previously signed by the firm to be incorporated by reference;
- agreed-upon and audit procedures in connection with a proposed divestment; and
- issuance of the Independent third party's report on the consolidated statement of extra-financial performance.

Services other than statutory audit provided by PricewaterhouseCoopers Audit during 2020 comprised:

- work on share capital transactions and securities issues submitted to the Annual General Meeting (in extraordinary business) for approval;
- additional procedures to enable reports previously signed by the firm to be incorporated by reference;
- contractual audits, assurance engagements, agreed-upon procedures and thematic studies.

(c) Includes services provided by the independent auditors of the parent company and French subsidiaries: Ernst & Young: €2.4 million in 2020, €0.8 million in 2019; PricewaterhouseCoopers €0.2 million in 2020, €0.1 million in 2019.

Audit Committee pre-approval and procedures

The Audit Committee of Sanofi has adopted a policy and established certain procedures for the approval of audit services and for the pre-approval of other services to be provided by the independent auditors. In 2020, the Audit Committee established a limit for permitted audit-related and other services (i.e. services other than statutory audit) that can be provided by the independent auditors, and the related fees.

F/ List of principal companies included in the scope of consolidation during 2020

F.1. Principal fully consolidated companies

The table below shows the principal subsidiaries and their country of incorporation:

Europe		Financial interest (%) as of December 31, 2020
Hoechst GmbH	Germany	100.0
Sanofi-Aventis Deutschland GmbH	Germany	100.0
A. Nattermann & Cie. GmbH	Germany	100.0
Sanofi-Aventis GmbH	Austria	100.0
Sanofi Belgium	Belgium	100.0
Ablynx N.V.	Belgium	100.0
Genzyme Flanders BVBA	Belgium	100.0
Sanofi A/S	Denmark	100.0
Sanofi-Aventis S.A.	Spain	100.0
Sanofi Oy	Finland	100.0
Sanofi	France	100.0
Sanofi-Aventis France	France	100.0
Sanofi Winthrop Industrie	France	100.0
Sanofi-Aventis Recherche & Développement	France	100.0
Sanofi-Aventis Groupe	France	100.0
Sanofi Chimie	France	100.0
Francopia	France	100.0
Sanofi-Aventis Participations	France	100.0
Genzyme Polyclonals SAS	France	100.0
Sanofi Pasteur	France	100.0
Aventis Pharma S.A.	France	100.0
Sanofi Biotechnology	France	100.0
Sanofi Mature IP	France	100.0
Sanofi Pasteur NVL	France	100.0
Sanofi Vaccine Technologies	France	100.0
Sanofi Pasteur Europe	France	100.0
Sanofi-Aventis A.E.B.E.	Greece	100.0
Sanofi-Aventis Private Co, Ltd	Hungary	99.6
Chinoin Private Co. Ltd	Hungary	99.6
Carraig Insurance DAC	Ireland	100.0
Sanofi-Aventis Ireland Ltd	Ireland	100.0
Genzyme Ireland Limited	Ireland	100.0
Sanofi Finance Ireland limited	Ireland	100.0
Sanofi S.R.L.	Italy	100.0
Genzyme Global Sarl	Luxembourg	100.0
Sanofi-Aventis Norge AS	Norway	100.0
Sanofi-Aventis Netherlands B.V.	Netherlands	100.0
Genzyme Europe B.V.	Netherlands	100.0
Sanofi Foreign Participations B.V.	Netherlands	100.0
Sanofi-Aventis Sp. z.o.o.	Poland	100.0
Sanofi Produtos Farmaceuticos Lda	Portugal	100.0
Sanofi-Aventis, s.r.o.	Czech Republic	100.0
Sanofi Romania SRL	Romania	100.0
Sanofi-Aventis UK Holdings Limited	United Kingdom	100.0
Genzyme Limited	United Kingdom	100.0
Aventis Pharma Limited	United Kingdom	100.0
AO Sanofi Russia	Russia	100.0
sanofi-aventis Slovakia s.r.o.	Slovakia	100.0
Sanofi AB	Sweden	100.0
Sanofi-Aventis (Suisse) SA	Switzerland	100.0
Sanofi Ilac Sanayi ve Ticaret A.S.	Turkey	100.0
Sanofi Pasteur Asi Ticaret A.S.	Turkey	100.0

Europe		Financial interest (%) as of December 31, 2020
Sanofi Saglik Urunleri Limited Sirketi	Turkey	100.0
Limited Liability Company Sanofi-Aventis Ukraine	Ukraine	100.0

United States		Financial interest (%) as of December 31, 2020
Genzyme Therapeutic Products Limited Partnership	United States	100.0
Aventis Inc.	United States	100.0
Sanofi US Corporation	United States	100.0
Synthorx, Inc.	United States	100.0
Sanofi US Services Inc.	United States	100.0
Sanofi-Aventis U.S. LLC	United States	100.0
Chattem, Inc.	United States	100.0
Aventisub LLC	United States	100.0
Genzyme Corporation	United States	100.0
Sanofi Pasteur Inc.	United States	100.0
VaxServe, Inc.	United States	100.0
Bioverativ Inc.	United States	100.0
Bioverativ U.S.LLC	United States	100.0
Bioverativ Therapeutics Inc.	United States	100.0
Sanofi Pharmaceuticals Holding Partnership	United States	100.0
Principia Biopharma Inc.	United States	100.0

Other Countries		Financial interest (%) as of December 31, 2020
Sanofi-Aventis South Africa (Pty) Ltd	South Africa	100.0
Sanofi-Aventis Algérie	Algeria	100.0
Sanofi Arabia Trading Company Limited	Saudi Arabia	75.0
Sanofi-Aventis Argentina S.A.	Argentina	100.0
Genzyme de Argentina S.A.	Argentina	100.0
Sanofi-Aventis Healthcare Pty Ltd	Australia	100.0
Sanofi-Aventis Australia Pty Ltd	Australia	100.0
Sanofi Medley Farmaceutica Ltda	Brazil	100.0
Sanofi-Aventis Canada Inc.	Canada	100.0
Sanofi Pasteur Limited	Canada	100.0
Sanofi (Hangzhou) Pharmaceuticals Co., Ltd	China	100.0
Sanofi (China) Investment Co., Ltd	China	100.0
Sanofi (Beijing) Pharmaceuticals Co.Ltd	China	100.0
Sanofi Pasteur Biologies Co., Ltd	China	100.0
Shenzhen Sanofi pasteur Biological Products Co, Ltd	China	100.0
Genfar S.A.	Colombia	100.0
Sanofi-Aventis de Colombia S.A.	Colombia	100.0
Sanofi-Aventis Korea Co. Ltd	South Korea	100.0
Sanofi Pasteur Ltd	South Korea	100.0
Sanofi-Aventis Gulf FZE	United Arab Emirates	100.0
Sanofi-Aventis del Ecuador S.A.	Ecuador	100.0
Sanofi Egypt	Egypt	99.8
Sanofi-Aventis Hong-Kong Limited	Hong Kong	100.0
Sanofi-Synthelabo (India) Private Ltd	India	100.0
Sanofi India Limited	India	60.4
Sanofi Healthcare India Private Limited	India	99.9
PT Aventis Pharma	Indonesia	80.0
Sanofi-Aventis Israël Ltd	Israel	100.0
Sanofi K.K.	Japan	100.0
SSP Co.,Ltd	Japan	100.0
Sanofi Nichi-Iko K.K.	Japan	51.0
Sanofi-Aventis (Malaysia) SDN. BHD.	Malaysia	100.0
Sanofi-Aventis Maroc	Morocco	100.0
Sanofi-Aventis de Mexico S.A. de C.V.	Mexico	100.0
Sanofi-Aventis Winthrop S.A. de C.V.	Mexico	100.0
Sanofi Pasteur S.A. de C.V.	Mexico	100.0
Sanofi-Aventis Pakistan Limited	Pakistan	52.9
Sanofi-Aventis de Panama S.A.	Panama	100.0
Sanofi-Aventis del Peru S.A.	Peru	100.0
sanofi-aventis Puerto Rico Inc	Puerto Rico	100.0
Sanofi-Aventis Philippines Inc.	Philippines	100.0
Sanofi-Aventis Singapore Pte. Ltd	Singapore	100.0
Aventis Pharma (Manufacturing) Pte. Ltd	Singapore	100.0
Sanofi Taiwan Co., Ltd	Taiwan	100.0
Sanofi-Aventis (Thailand) Ltd	Thailand	100.0
Sanofi-Aventis de Venezuela S.A.	Venezuela	100.0
Sanofi-aventis Vietnam Company Limited	Vietnam	100.0
Shanghai Rongheng Pharmaceutical Co, Ltd	China	100.0
Sanofi Vietnam Shareholding Company Limited	Vietnam	85.0
Azteca Vacunas, S.A. de C.V.	Mexico	100.0

F.2. Principal investments accounted for using the equity method

		Financial interest (%) as of December 31, 2020
GlaxoSmithKline Consumer Healthcare, L.P.	United States	11.7
Infraserv GmbH & Co. Höchst KG	Germany	31.2
Maphar	Morocco	48.3
MCM Vaccine B.V.	Netherlands	50.0
MSP Vaccine Company (formerly MCM company)	United States	50.0

G/ Events subsequent to December 31, 2020

On January 11, 2021, Sanofi entered into an agreement with Kymab, a UK-based clinical-stage biopharmaceutical company developing fully human monoclonal antibodies with a focus on immune-mediated diseases and immuno-oncology therapeutics, under which Sanofi will acquire Kymab for an upfront payment of approximately $1.1 billion plus up to $350 million upon achievement of certain development milestones.

Apart from that event, no other significant events occurred between the end of the reporting period and the date on which the consolidated financial statements were signed off by the Board of Directors.

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