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 it 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. Following any of these events, pharmaceutical companies can face significant product liability claims.

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 product liability financial risk of 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 indemnifications damage award 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 insurance market 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. We are obligated to comply with the laws of all countries in which we operate. However, legal requirements may vary from country to country and new requirements are imposed on us 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, respect of 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") and 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 our activities relying on personal data processing. Furthermore, some uncertainty remains with respect to the legal and regulatory environment for these evolving privacy and data protection laws.

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, due to the complexity of the fiscal environment, the ultimate resolution of any tax matter may result in payments greater

or lesser than amounts 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 criminal penalties, and may include admissions of wrongdoing and may require the conclusion of a Corporate Integrity Agreement or a Deferred Prosecution Agreement (in the United States), which is intended to regulate company behaviour 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 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.

In addition, 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 Foreign Corrupt Practices Act. Sanofi did not admit any wrongdoing in connection with the settlement but agreed to pay $25 million in penalties and also agreed to a two-year period of self-reporting on the effectiveness of its enhanced internal controls.

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. 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.

In Europe, the implementation of new regulations on Medical Devices and In-Vitro Diagnostics (IVDs) that will apply respectively in May 2020 and May 2022, may cause delays in approvals (for new drug-device combination products and new drug-device combination products and new medical devices/IVDs), product discontinuation (for some legacy medical devices and IVDs), and non-compliance risks, due to increased requirements in terms of approval process, post-marketing surveillance, traceability and transparency.

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 environmental impact of 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. Also 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 to existing products through new regulatory proposals intended to achieve, or resulting in, changes to the scope of patent or data exclusivity rights and 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 is seeking 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.

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 or a permanent 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 currently party to patent infringement proceedings in several countries initiated against us and Regeneron by Amgen relating to Praluent® in which Amgen has 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 laws of national courts. In addition, we expect to face increasing competition from biosimilars in the future. With the accelerated regulatory pathways provided in the US 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. 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 novel coronavirus which has emerged since December 2019 in China, expose us to the risks of a slowdown or temporary suspension in the production of our active pharmaceutical ingredients (API), raw materials and some of our products. A certain number of our API and raw materials are produced in China. We also have a production site for pharmaceutical products in Hangzhou (China) and a production site for API in Singapore. Any prolonged restrictive measures put in place in order to control an outbreak of contagious disease or other adverse public health development, in China or 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).

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. 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 production sites are located in areas exposed to natural disasters such as floods (for example our facility at Le Trait, France), 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, the image of Sanofi and may lead to lower product revenues.

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

The commercial success of our existing products and our product candidates depends in part on their pricing and the conditions under which our products are reimbursed. Our products continue to be subject to increasing price and reimbursement pressure due, inter alia, to:

- price controls imposed by governments in many countries;
- increased public attention to the price of drugs and drug price increases, with growing public calls for us to justify the launch prices of all our products;
- increased use of tendering and grouped purchasing to exert price pressure through competitive access to large parts of the market or markets;
- removal of a number of drugs from government reimbursement schemes (for example products determined to be less cost-effective than alternatives);
- decreased reimbursement rates for drugs, and increased difficulty in obtaining and maintaining satisfactory drug reimbursement rates;
- partial reimbursement of patient populations within a labelled indication;
- increased use of cost containment policies (including budget limitations) related to health expenses;
- governmental and private health care provider policies that favor prescription of generic medicines or substitution of branded products with generic medicines;
- more demanding evaluation criteria applied by Health Technology Assessment (HTA) agencies when considering whether to cover new drugs at a certain price level;
- more governments using international reference pricing to set or manage the price of drugs based on an external benchmark of a product’s price in other countries;
- aggressive pricing strategies by some of our competitors; and
- entry of new consumer healthcare competitors offering online sales.

In addition to the pricing pressures they exert, governmental and private third-party payers and purchasers of pharmaceutical products may reduce volumes of sales by restricting access to formularies (including exclusive formularies), managing prescribing via various conditions (including prior authorizations and step edits) or otherwise discouraging physicians from prescribing our products (see also “- The concentration of the US market exposes us to greater pricing pressure” below).

In the United States, which accounted for 35.3% of our net sales in 2019, the Affordable Care Act (ACA) has increased the government’s role with respect to price, reimbursement, and coverage levels for healthcare services and products. This law also imposed rebates and fees on pharmaceutical companies. In 2018, the Trump Administration published its American Patients First proposal, which indicates its plans to investigate the ACA’s impact on private market drug prices and potentially alter the ACA taxes and rebates for Medicaid and Medicaid managed care organizations. In December 2018, a federal judge for the Northern District of Texas, Fort Worth Division, issued a ruling declaring the ACA unconstitutional. An appeal was filed with the Federal Court of Appeals for the Fifth Circuit. Once a decision is issued, litigation may continue, including possibly a further appeal to the United States Supreme Court. Included in the many parts of the ACA that could potentially be affected by the continued litigation is the Biologics Price Competition and Incentives Act. In addition to further judicial review of the ACA, the Trump Administration and other United States federal and state officials are continuing to focus on the cost of health coverage, health care and pharmaceuticals, although future policy or the timing of any changes remains unclear, creating significant risks for the sector. At the federal level, legislation like the Bipartisan Budget Act of 2018 amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, and also increased in 2019 the percentage by which a drug manufacturer must discount the cost of prescription drugs from 50 percent under current law to 70 percent. Legislation that would affect the price for drugs under the Medicare program has been voted out of committee and is awaiting a vote in the House of Representatives, and different legislation that would require the payment of rebates to Medicare if annual drug price increases exceed overall inflation. Further, federal regulatory reform intended to reduce costs of drugs furnished under Medicare and Medicare Advantage plans through utilization management tools such as step therapy, and to increase price transparency for such drugs, became effective on January 1, 2020. The federal government is evaluating permitting the importation of certain drugs, which would place additional pressure on drug pricing. Since 2017, at least nine states have enacted and an additional 25 states have proposed legislation which will require price transparency and reporting of certain manufacturer information. This trend is

anticipated to continue in 2020, where legislation is expected regarding pricing transparency, marketing, access to drugs and other measures related to pricing.

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, the health authorities continue to develop measures around post loss-of-exclusivity ("LOE") brands including the selection of generics validated through bioequivalence. In September 2019, the health authorities expanded a pilot procurement system (volume-based procurement or "VBP") launched in 2018 - which targeted post LOE brands with generics demonstrating bioequivalence in four municipalities and seven major cities - to a nationwide tender system. With respect to our products, the Plavix® and Aprovel® product families were included in the national tender but due to price adjustments, net sales from the Plavix® and Aprovel® product families are expected to decline by 50% in China for 2020.

In addition, while we are trying to predict the level of reimbursement and related restrictions for our product candidates, external events and unexpected decisions can occur that go against our expectations 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.

In the United States, price is increasingly important to managed care organizations (MCOs) and pharmacy benefit managers (PBMs). As the MCOs/PBMs grow in size following market consolidation, pharmaceutical companies have faced increased pressure in discounting and usage negotiations, and competition among pharmaceutical companies to have their products included in the payers' formularies is robust. This can lead to price discounts or rebates in connection with the placement of products.

Exclusion of one of our drugs from a formulary can significantly reduce sales in the MCO/PBM patient population (for instance, effective 2017 Lantus®/Toujeo® were excluded from certain template formularies covering millions of people).

Also, some payers in the United States have put in place significant restrictions on the usage of Praluent®, which has resulted in significant out-of-pocket expenditures for patients. As a result, in 2018 we reduced the net price of Praluent® for US payers that agreed to reduce burdensome access barriers for patients, which was reflected in 2019 by a sales decrease of 30.5% .

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.

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 2019, we spent €6,018 million on research and development, amounting to 16.7% of our net sales.

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 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 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 - Health Technology Assessment (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) of 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 revenues from the sale of certain key products (see "Item 5. Operating and Financial Review and Prospects - Results of Operations - Year ended December 31, 2019 compared with year ended December 31, 2018 - Net Sales - Pharmaceuticals segment").

Among our flagship products, Lantus®, Lovenox® and Plavix® already face generic competition on the market. Lantus® is particularly important; it was Sanofi's leading product with revenues of €3,012 million in 2019, representing 8.3% of our net sales for the year. Aubagio®, following a settlement agreement entered into in 2017, is expected to face generic competition starting from March 2023.

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 2019 and 2018 for products affected by generic and biosimilar competition shows a loss of €912 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, or product recalls), 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. 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. We have also an immuno-oncology discovery and development agreement with Regeneron on the development of two clinical-stage bispecific antibody programs targeting respectively (i) BCMA and CD3 and (ii) MUC16 and CD3 (see "Item 4. Information on the Company - B. Business Overview"). Dupixent® has been developed and commercialized in collaboration with Regeneron. Also, in December 2019, Sanofi and Regeneron announced their intention to restructure their antibody collaboration related to Kevzara® (sarilumab) and Praluent® (alirocumab) (see "Item 5. Financial Presentation of Alliances - A.1.7.1/ Alliance Arrangements with Regeneron"). 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 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 the performance of certain key tasks or functions is the responsibility of our collaboration partners. 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 these events may affect the development, the launch and/or the 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.

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 8%, 5% and 3% of our consolidated net sales in 2019. 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.

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.

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 move 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, 2019, the United Kingdom represented 1.7% of our consolidated net sales in the 2019 fiscal year and less than 1% of our total assets.

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.

(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.*

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, we had to book a €2.8 billion impairment on Eloctate®, acquired through the Bioverativ acquisition completed in 2018, due to revision of 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.

Emerging markets represented 30.2% of our sales in 2019. 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 7.5% of our net sales in 2019.

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 such as China, it would reduce our sales due to lower healthcare spending on other diseases and fewer promotional activities, and could significantly impact our business operations. Such epidemics or other public health crises could also pose risks to the health and safety of our employees. Furthermore, it is not possible to predict if the current health crisis will impact the Chinese healthcare system, or that of any other affected jurisdiction, or to what extent (see also "- Global economic conditions and an unfavorable financial environment could have negative consequences for our business" 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 Darwin, our 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 digital at an appropriate cost, in a timely manner and/or enter into appropriate collaborations. 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 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 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 2019, there were 2,066 “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 to 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 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 the risks of industrial accidents that may lead to discharges or releases of toxic or pathogen substances or other events that can cause personal injury, property damage and environmental contamination, and may result in 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, 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 environmental impact of 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 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 in France, Germany, Italy, Brazil and elsewhere. As a matter of statutory or contractual obligation, 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 by the Company. An adverse outcome in such disputes might have a significant 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[1]

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 to currencies in emerging markets. In 2019, 35.3% of our net sales were generated in the United States; 22.7% in Emerging Markets other than China (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; 7.5% in China; and 5.3% 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, 2019, L’Oréal held approximately 9.43% 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.

(1) *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.*

Risks relating to our Contingent Value Rights (CVRs)

In addition to the risks relating to our shares, CVR holders are subject to additional risks.

In connection with our acquisition of Genzyme, we issued CVRs under a CVR agreement entered into by and between us and American Stock Transfer & Trust Company, the trustee (see also Note D.18. to the consolidated financial statements included at Item 18 of this annual report). A copy of the form of the CVR agreement is on file with the SEC as Annex B to Amendment No. 2 to the Registration Statement on Form F-4 filed with the Securities and Exchange Commission on March 24, 2011. Pursuant to the CVR agreement, each holder of a CVR is entitled to receive cash payments upon the achievement of certain milestones, if any, based on the achievement of certain cumulative net sales thresholds by Lemtrada® (alemtuzumab for treatment of multiple sclerosis). See “Item 10. Additional Information – C. Material Contracts – The Contingent Value Rights Agreement.”

CVR holders are subject to additional risks, including:

- the public market for the CVRs may not be active or the CVRs may trade at low volumes, both of which could have an adverse effect on the resale price, if any, of the CVRs;
- the market price and trading volume of the CVRs may be volatile;
- no payment will be made on the CVRs without the achievement of certain agreed upon milestones. As such, it may be difficult to value the CVRs and accordingly it may be difficult or impossible to resell the CVRs;
- if net sales do not exceed the thresholds set forth in the CVR agreement for any reason within the time periods specified therein, no payment will be made under the CVRs and the CVRs will expire without value;
- since the US federal income tax treatment of the CVRs is unclear, any part of any CVR payment could be treated as ordinary income and required to be included in income prior to the receipt of the CVR payment;
- any payments in respect of the CVRs rank at parity with our other unsecured unsubordinated indebtedness;
- we are not prohibited from acquiring the CVRs, whether in open market transactions, private transactions or otherwise and we have already purchased CVRs on several occasions (for more information see “Item 5. Operating and Financial Review and Prospects – Liquidity and Capital Resources – Liquidity.”);
- we may, under certain circumstances, purchase and cancel all outstanding CVRs; and
- while we have agreed to use diligent efforts (as defined in the CVR agreement), until the CVR agreement is terminated, to achieve each of the remaining Lemtrada® related CVR milestones set forth in the CVR agreement, we are not required to take all possible actions to achieve these goals. On July 5, 2016 Sanofi disclosed that, based upon actual sales of Lemtrada® in Qualifying Major Markets and in other markets during the respective applicable periods since the Product Launch, Product Sales Milestone #1 had not been met. On February 7, 2018, Sanofi disclosed that, based upon actual sales trends to date, it did not expect that product sales milestones #2, #3 and #4 would be met. Failure to achieve the remaining sales milestones could have an adverse effect on the value of the CVRs (see also Note D.22.c to the consolidated financial statements included at Item 18 of the annual report regarding the settlement of the CVR Trustee Claim pursuant to which, among other things, the CVRs will be delisted from the NASDAQ and extinguished, and the CVR Agreement will be terminated, as was previously disclosed in a Form 6-K filed on October 31, 2019).