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PART I

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N/A

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N/A

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A. Selected Financial Data

SUMMARY OF SELECTED FINANCIAL DATA

The tables below set forth selected consolidated financial data for Sanofi. These financial data are derived from the Sanofi consolidated financial statements. The Sanofi consolidated financial statements for the years ended December 31, 2016, 2015 and 2014 are included in Item 18 of this annual report.

The consolidated financial statements of Sanofi for the years ended December 31, 2016, 2015 and 2014 have been prepared in compliance with IFRS issued by the International Accounting Standards Board (IASB) and with IFRS adopted by the European Union as of December 31, 2016. The term “IFRS” refers collectively to international accounting and financial reporting standards (IAS and IFRS) and to interpretations of the interpretations committees (SIC and IFRIC) mandatorily applicable as of December 31, 2016. Sanofi reports its financial results in euros.

SELECTED CONDENSED FINANCIAL INFORMATION

(€ million, except per share data)	As of and for the year ended December 31, 2016	2015	2014	2013	2012[a]
IFRS Income statement data					
Net sales[b]	33,821	34,060	31,380	30,693	34,743
Gross profit	24,006	23,942	21,769	20,989	24,859
Operating income	6,534	5,624	6,064	4,982	6,430
Net income excluding the held-for-exchange Animal Health business	4,486	4,512	4,392	3,797	-
Net income attributable to equity holders of Sanofi	4,709	4,287	4,390	3,716	4,888
Basic earnings per share (€)[c] :					
Net income excluding the held-for-exchange Animal Health business	3.42	3.38	3.25	2.75	-[a]
Net income attributable to equity holders of Sanofi	3.66	3.28	3.34	2.81	3.70
Diluted earnings per share (€)[d] :					
Net income attributable to equity holders of Sanofi	3.63	3.25	3.30	2.77	3.68
IFRS Balance sheet data					
Goodwill and other intangible assets	51,166[e]	51,583[e]	53,740	52,529	58,265
Total assets	104,672	102,321	97,392	96,055	100,399
Outstanding share capital	2,544	2,603	2,620	2,641	2,646
Equity attributable to equity holders of Sanofi	57,554	58,049	56,120	56,904	57,352
Long term debt	16,815[e]	13,118[e]	13,276	10,414	10,719
Cash dividend paid per share (€)[f]	2.96[g]	2.93	2.85	2.80	2.77
Cash dividend paid per share ($)[f]/[h]	3.12[g]	3.19	3.46	3.86	3.65

*(a) For 2012, the lines **Net sales**, **Gross profit**, and **Operating Income** include the Animal Health business. For the other periods (2013 to 2016), the net results of the Animal Health business are presented in a separate line item, **Net income/(loss) of the held-for-exchange Animal Health business**, in the consolidated income statements.*

*(b) Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards (see Notes A.5. and B.14.). The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly (see Note A.5.).*

(c) Based on the weighted average number of shares outstanding in each period used to compute basic earnings per share, equal to 1,286.6 million shares in 2016, 1,306.2 million shares in 2015, 1,315.8 million shares in 2014, 1,323.1 million shares in 2013 and 1,319.5 million shares in 2012.

(d) Based on the weighted average in each period of the number of shares outstanding plus stock options and restricted shares with a potentially dilutive effect; i.e., 1,296.0 million shares in 2016, 1,320.7 million shares in 2015, 1,331.1 million shares in 2014, 1,339.1 million shares in 2013 and 1,329.6 million shares in 2012.

*(e) As reported, excluding the Animal Health business clarified in the line item, **Assets held for sale or exchange and liabilities related to assets held for sale or exchange** as of December 31, 2015 and December 31, 2016.*

(f) Each American Depositary Share, or ADS, represents one half of one share.

(g) Dividends for 2016 will be proposed for approval at the annual general meeting scheduled for May 10, 2017.

(h) Based on the relevant year-end exchange rate.

SELECTED EXCHANGE RATE INFORMATION

The following table sets forth, for the periods and dates indicated, certain information concerning the exchange rates for the euro from 2011 through March 2017 expressed in US dollars per euro. The information concerning the US dollar exchange rate is based on the noon buying rate in New York City for cable transfers in foreign currencies as certified for customs purposes by the Federal Reserve Bank of New York (the "Noon Buying Rate"). We provide the exchange rates below solely for your convenience. We do not represent that euros were, could have been, or could be, converted into US dollars at these rates or at any other rate. For information regarding the effect of currency fluctuations on our results of operations, see "Item 5. Operating and Financial Review and Prospects" and "Item 11. Quantitative and Qualitative Disclosures about Market Risk."

(U.S. dollar per euro)	Period-end Rate	Average Rate[a]	High	Low
2011	1.30	1.40	1.49	1.29
2012	1.32	1.29	1.35	1.21
2013	1.38	1.33	1.38	1.28
2014	1.21	1.32	1.39	1.21
2015	1.09	1.10	1.20	1.05
2016	1.06	1.10	1.15	1.04
Last 6 months				
2016				
September	1.12	1.12	1.13	1.12
October	1.10	1.10	1.12	1.09
November	1.06	1.08	1.11	1.09
December	1.06	1.05	1.08	1.04
2017				
January	1.08	1.06	1.08	1.04
February	1.06	1.07	1.08	1.06
March[b]	1.05	1.05	1.05	1.05

(a) The average of the Noon Buying Rates on the last business day of each month during the relevant period for the full year average, and on each business day of the month for the monthly average. The latest available Noon Buying Rate being February 24, 2017, we have used European Central Bank Rates for the period from February 27, 2017 through March 2, 2017.

(b) In each case, measured through March 2, 2017.

On March 2, 2017 the European Central Bank Rate was 1.05 per euro.

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 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

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.

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 from product to product and country to country. This protection may not be sufficient to maintain effective product exclusivity because of local differences in the patents, in national laws or applicable legal systems, or developments in law or jurisprudence, which may give rise to inconsistent judgments when we assert or defend our patents.

Moreover, patent and other proprietary rights do not always provide effective protection for our products. 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 patents, for example, through design innovation, and we may not hold sufficient evidence of infringement to bring suit.

In addition, if we lose patent protection in patent litigation 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 payed 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 obtained against the sale of generic clopidogrel during the course of the litigation.

In certain cases, to terminate or avoid patent litigation, we or our partners may be required to obtain licenses from the holders of third-party intellectual property rights that cover aspects of our existing and future products in order to manufacture, use and/or sell them. 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. We have increased the proportion of biological therapeutics in our pipeline relative to traditional small molecule pharmaceutical products. Typically, biological therapeutics face third party intellectual property rights, otherwise known as freedom to operate (FTO) issues, more than 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. Certain countries have laws that provide stronger bases for challenging third party patent rights compared to the laws that are available to challenge patents in other countries. Therefore, we may be able to invalidate a certain third party patent in one country but not invalidate counterpart patents in other countries. 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 and Item 8 B. of this annual report for more information). If third parties obtain a preliminary or permanent injunction from a court of law or if we fail to obtain a required license for a country where the valid third-party intellectual property right, as confirmed by a court of law, exists 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.

Also, 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 are involved in litigation worldwide to enforce certain of our patent rights against generics, proposed generics and biosimilars of our small molecule and biological pharmaceutical products (see "Item 8. Financial Information – A. Consolidated Financial Statements and Other Financial Information – Information on Legal or Arbitration Proceedings" for additional information). 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. A competitor may launch a generic or a biosimilar product "at risk" before the initiation or completion of the court proceedings, and the court may decline to grant us a preliminary injunction to halt

further “at risk” sales and order removal of the infringing product from the market. Additionally, while we would be entitled to obtain damages in such a case, the amount that we may ultimately be awarded and able to collect may be insufficient to compensate all harm caused to us. 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.

We have increased the proportion of biological therapeutics in our pipeline relative to traditional small molecule pharmaceutical products. 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. Governments may adopt more permissive approval frameworks (for example, shortening the duration of data exclusivity, or narrowing the scope of new products receiving data exclusivity) which could allow competitors to obtain broader marketing approval for biosimilars including as a substitutable product, increasing competition for our products (see also “– Changes in the laws or regulations that apply to us could affect our business, results of operations and financial condition” below). If a biosimilar version of one of our products were approved, it could reduce our sales and/or profitability of that product.

However, with our presence as a manufacturer of generics and biosimilars, we will utilize patent challenge strategies against other innovators’ patents, similar to those of long-established generic companies, but there is no assurance that these strategies will be successful.

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

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 regards to their nature, scope and level, from the types of product liability claims that we have handled in the past. Substantial damage awards and/or settlements have been handed down – 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 the Company will be successful in defending against these claims or 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 surveillance and clinical trials provide additional information – for example, potential evidence of rare, population-specific or long-term adverse reactions or of drug interactions that were not observed in preapproval clinical studies – and 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.”).

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 pharmaceutical 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 to be paid to claimants could have a negative impact on our financial condition.

Due to insurance conditions, even when the Company has insurance coverage, recoveries from insurers may not be totally successful. 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.

Our products and manufacturing facilities 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 and/or maintain the required approvals.

Obtaining marketing authorization is a long and highly regulated process requiring us to present extensive documentation and data to the regulatory authorities. Regulatory processes differ from one authority to another. 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, including requiring local clinical studies, and it may delay or refuse to grant approval, even though a product has already been approved in another country. For example, in August 2016, Sanofi submitted at the FDA's request updated information on the pen delivery device of Soliqua™ 100/33, based on feedback received from the FDA during its review of the New Drug Application for this product. This resulted in a three-month delay of the approval date.

Health authorities are increasingly focusing on product safety and on the risk/benefit profile of pharmaceutical products. In particular, the FDA and the EMA have increased their requirements, particularly in terms of the volume of data needed to demonstrate a product's efficacy and safety. Even after regulatory approval, marketed products are subject to continual review, risk evaluations or comparative effectiveness studies including post-marketing studies to which at times we have committed as a condition of approval. In addition, following the implementation of European pharmacovigilance legislation in 2012, the Company and the European Regulatory Agencies (under the supervision of the PRAC (Pharmacovigilance Risk Assessment Committee)) have reinforced their systematic and intensive safety signal detection systems, which may detect safety issues even with mature products that have been on the market for a considerable time. This system may result in additional market authorization suspensions or withdrawals. All of these requirements have increased the costs associated with maintaining regulatory approvals and achieving reimbursement for our products. Post-regulatory approval reviews and data analyses can lead to the issuance of recommendations by government agencies, health professional and patient or other specialized organizations regarding the use of products; for example, a recommendation to limit the patient population of a drug's indication, impose marketing restrictions, or suspend or withdraw the product can result in a reduction in sales volume, as well as an increased risk of litigation.

Moreover, to monitor our compliance with applicable regulations, the FDA, the EMA and comparable agencies in other jurisdictions routinely conduct inspections of our facilities and may identify potential deficiencies. We have received FDA Warning Letters in the past following the inspection of some of our facilities and may receive such letters in the future. In 2016, manufacturing deficiencies were observed by the FDA at our "fill and finish" facility specialized in biologics in Le Trait, France, during a routine CGMP inspection, and the FDA issued a form 483 ("Inspectional Observations") listing manufacturing deficiencies. These CGMP deficiencies led the FDA to issue a Complete Response Letter in October 2016, delaying the approval of sarilumab (Kevzara™). More generally, if we fail to adequately respond to warning letters identifying a deficiency following 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, the EMA or other regulatory authorities. In addition, in order to comply with our duty to report adverse 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, 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.

To the extent that new regulations raise the costs of obtaining and maintaining product authorizations, or limit the economic value of a new product to its originator, the growth prospects of our industry and of Sanofi would be diminished. Approximately 60% of our current development portfolio consists of biological products that may in the future bring new therapeutic responses to current unmet medical needs, but that may also lead to more regulatory and technical constraints and/or costly investments from an industrial standpoint as biological products are complex to produce. These constraints and costs could adversely affect our business, results of operations and financial condition.

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

The marketing of our products is heavily regulated. Sanofi's business covers an extremely wide range of activities worldwide and involves numerous partners. We have adopted a Code of Ethics that calls for employees to comply with applicable legislation and regulations, as well as with the specific principles and rules of conduct set forth in that Code. We also have policies and procedures designed to help ensure that we, our employees, officers, 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 and other anti-bribery laws and regulations).

Notwithstanding these efforts, deviations may occur and there can be no assurance that we, our officers and/or our

directors will not face liability under laws and regulations for actions taken with respect to our business.

Any failure to comply directly or indirectly (including as a result of a business partner's breach) with the laws and regulations applicable to us, including new regulations, could lead to substantial liabilities and harm the Company's reputation. 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 data privacy legislation. Sanofi and certain of its subsidiaries are under investigation or could become the subject of additional investigations by various government entities and the Company is defending a number of lawsuits relating to pricing and marketing practices (including, for example, "whistleblower" litigation in the United States). The Company also faces 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. 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. Responding to such investigations is costly and distracts management's attention from our business.

Unfavorable outcomes in any of these matters, or in similar matters to be faced in the future, could preclude the commercialization of products, harm our reputation, negatively affect the profitability of existing products and subject us to substantial fines (including treble damages and fines based on our sales), 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 this could have a material adverse effect on our business, results of operations or financial condition.

These risks may encourage us to enter into settlement agreements and those settlements may involve significant monetary payments and/or criminal penalties and may include admissions of wrongdoing. Settlement of healthcare fraud cases in the United States may require companies to enter into a Corporate Integrity Agreement, which is intended to regulate company behavior for a specified period of years. For example in 2015 we entered into such an agreement as part of settlements relating to the Seprafilm® and Hyalgan® products.

Changes in the laws or regulations that apply to us could affect our business, results of operations and financial condition.

All aspects of our business, including research and development, manufacturing, marketing, pricing and sales, are subject to extensive legislation and governmental regulation. Changes in applicable laws, or in their application, could have a material adverse effect on our business.

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 (see "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" above).

This new competitive environment and the potential regulatory changes may further limit the exclusivity enjoyed by innovative products on the market and directly impact pricing, access and reimbursement levels, which may adversely affect our business and future results. See "Item 4. Information on the Company – B. Business Overview – B.6. Markets – B.6.2. Competition" and "– B.6.3. Regulatory framework".

In addition to international tax law and regulatory changes such as the OECD BEPS initiatives and EU directives still to be adopted, changes in tax frameworks, tax reforms and other changes to the way existing tax laws are applied in jurisdictions and major countries where Sanofi and its subsidiaries and affiliates operate could affect our income, our effective tax rate, and consequently our future net income. These changes may cover matters such as taxable income, tax rates, indirect taxation, transfer pricing, dividend taxation, controlled companies or a restriction in certain forms of tax relief. Any of these changes could have a material adverse effect on our business and future results. Additionally, due to the complexity of the fiscal environment, the ultimate resolution of any tax matters may result in payments greater or lesser than amounts accrued.

For information regarding risks related to changes in environmental rules and regulations, see "– Environmental liabilities and costs related to compliance with applicable regulations may have a significant adverse effect on our results of operations" below.

Risks Relating to Our Business

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 the decreasing sales of our products facing expiry of patents and regulatory data exclusivity or competition from new products of

competitors that are perceived as being superior or equivalent. In 2016, we spent €5,172 million on research and development (excluding Animal Health), amounting to 15.3% of our net sales.

Our industry is driven by the need for constant innovation, but we may spread ourselves across too many areas of inquiry to be successful and may not be able to improve internal research productivity sufficiently to sustain our pipeline. We may also fail to invest in the right technology platforms, therapeutic areas, and product classes to build a robust pipeline and fulfill unmet medical needs. Fields of discovery, particularly biotechnology, are highly competitive and characterized by significant and rapid technological changes. Numerous companies are working on the same targets and a product considered as promising at the very beginning of its development may become less attractive if a competitor addressing the same unmet need reaches the market earlier.

The research and development process can take up to 15 years from discovery to commercial product launch. This process is conducted in various stages in order to test, along with other features, the efficacy, effectiveness and safety of a product. There can be no assurance that any of these product candidates will be proven safe or effective. See “Item 4. Information on the Company – B. Business Overview – B.5. Global Research & Development”. Accordingly, there is a substantial risk at each stage of development – including clinical studies – 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, even in late stage development (Phase III). 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 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 health authorities for approval. Our ongoing investments in new product launches and research and development for future products could therefore result in increased costs without a proportionate increase in revenues, which would negatively affect our operating results and profitability.

In 2015 we announced that we had up to 18 new medicines and vaccines on track to arrive on the market between 2014-2020, including six key launches. As of the end of 2016, four of those six key products have already been approved or launched: Toujeo®, Praluent®, Dengvaxia® and Soliqua™ 100/33 / Suliqua™. However, there can be no assurance that all (or any) of the other products will be approved, or with the targeted indications, and/or within the expected timeline, or that all the products approved will achieve commercial success.

Following each product marketing approval, the medical need served by the product and the corresponding reimbursement are evaluated by governmental agencies and/or third party payers, requiring in some cases additional studies, including comparative studies, which may effectively delay marketing, change the population which the new product treats, and add to its development costs.

After marketing approval of our products, other companies or investigators, whether independently or with our authorization, may conduct studies or analysis beyond our control that may ultimately report results negatively affecting our sales either permanently or temporarily and it may take time for Sanofi to address the reported findings, leading among other things to a material adverse impact on sales.

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 particularly price increases, limiting our ability to set the price, or to manage or increase the price of our products based upon their value;
- removal of a number of drugs from government reimbursement schemes (for example products determined to be less cost-effective than alternatives);
- partial reimbursement of patient populations within a labelled indication;
- increased difficulty in obtaining and maintaining satisfactory drug reimbursement rates;
- increase in 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; and
- aggressive pricing strategies by some of our competitors.

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 authorisations and step edits) or otherwise discouraging physicians from prescribing our products (see also "– The concentration of the US payer market exposes us to greater pricing pressure" below).

In the United States, the federal Affordable Care Act has increased the government's role with respect to price, reimbursement, and coverage levels for healthcare services and products within the large government healthcare sector. This law also imposed rebates and fees on pharmaceutical companies. Some US states are also considering legislation that could affect transparency practices, the marketing and prices of, and access to, drugs. US federal and state officials will continue to focus on healthcare reform in the future, creating multiple risks for the sector.

Government price reporting obligations are complex, and we face risks related to the reporting of pricing data that could affect the reimbursement of and discount provided for our products to US government healthcare programs.

We encounter similar 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. See also below "– Global economic conditions and an unfavorable financial environment could have negative consequences for our business".

We are also unable to predict the availability or level of reimbursement and related restrictions for our product candidates.

Price negotiations in a country may result in a price that is incompatible with the global price positioning of our products, which may lead us not to launch the product in that country, damaging our image and resulting in a decrease in initially anticipated sales.

Finally, our operating results may also be affected by parallel imports, particularly within the European Union, whereby distributors engage in arbitrage based on national price differences to buy products in low cost markets for resale in higher cost markets.

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), and as the MCOs/PBMs grow in size following market consolidation, pharmaceutical companies have faced increased pressure in pricing and usage negotiations, and competition among pharmaceutical companies to have their products included in the care providers' formulary 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 example, since 2014, we have increased the level of rebates granted for Lantus® in order to maintain favorable formulary positions with key payers in the US. Despite these efforts, in 2016, CVS and UnitedHealthcare (a PBM and MCO, respectively) decided that effective January 1, 2017 and April 1, 2017, respectively, Lantus®/Toujeo® will be excluded from the formulary across the commercial and MMC (Medicaid Managed Care) template formularies covering several million people, thus reducing the potential patient populations to whom Lantus® may be prescribed.

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 Medicare patients.

In addition, distributors have increased their capacity to negotiate price and other terms as a consequence of the growing number of mergers of retail chains and distributors, resulting in consolidation of the distribution channel.

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

We may lose market share to competing therapeutic options, biosimilar or generic products.

We are faced with intense competition from generic products, biosimilars and brand-name drugs including from retail chains and distributors.

Doctors or patients may choose competitors' products over ours or alternative therapeutic options such as surgery if they perceive them to be safer, more reliable, more effective, easier to administer or less expensive, which could cause our revenues to decline and adversely affect our results of operations.

The success of any product also depends on our ability to educate patients when permissible and promote our products to healthcare providers by providing them with innovative data about the product and its uses including through the use of digital tools. If these education efforts are not effective, we may not be able to increase the sales of our products or realize the full value of our investment in their development.

We may not be able to anticipate precisely the date of market entry of generics or biosimilars or the potential impact on our sales, both of which depend on numerous parameters. The introduction of a generic version of a

branded medicine typically results in a significant and rapid reduction in net sales for the branded product because generic manufacturers typically offer their unbranded versions at significantly lower prices, resulting in adverse price and volume effects for our genericized products. Also mandatory price regulations apply in certain countries to off-patent products and classes of products, and generics prices are taken into account for international reference pricing and tenders. Substitution is often permitted for generic products that are considered to be interchangeable or clinically identical. With respect to biosimilars, in the United States only biosimilars that refer to an innovator drug that was approved under a Biologics License Application may be designated as interchangeable with the original biologic and only in circumstances where specific criteria are met. In many European countries, automatic substitution of biologics is officially prohibited or not recommended. Nevertheless, competition including from non-substitutable biosimilars would likely result in a decrease in prices, additional rebates, increased promotion efforts and lower margins.

Approval of a generic or biosimilar that is substitutable for one of our products would increase the risk of accelerated market penetration by that generic or biosimilar to a greater extent than would be the case for a non-substitutable product.

These trends are exacerbated by applicable legislation which encourages the use of generic products to reduce spending on prescription drugs in many countries such as the United States, France and Germany. Therefore, the market for our products could also be affected if a competitor's innovative drug in the same market were to become available as a generic because a certain number of patients can be expected to switch to a lower-cost alternative therapy. We expect this generic competition to continue and to affect more of our products, including those with relatively modest sales.

A substantial share of the revenue and income of Sanofi continues to depend on the performance of certain flagship products.

We 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, 2016 compared with year ended December 31, 2015 – Net Sales – Pharmaceuticals segment"). Lantus® is particularly important; it was Sanofi's leading product with revenues of €5,714 million in 2016, representing 16.9% of Sanofi's net sales for the year. Lantus® is a flagship product of the Diabetes franchise. Accounting for market trends, we announced in October 2015 that we project global diabetes sales over the period from 2015 to 2018 to decline at an average annualized rate of between 4% and 8% at constant exchange rate (CER). Nevertheless our actual sales may differ from these expectations given the numerous underlying assumptions (for example the outlook for insulin glargine sales, the introduction of one or several biosimilar glargines and their penetration of the market or the market uptake of our new products).

Furthermore, the launch of new medicines and vaccines in other therapeutic areas and the performance of our other businesses may not be sufficient to reduce the relative contribution of Lantus® to our overall performance.

Our flagship products benefit from certain intellectual property protections such as patents and exclusivity periods but patent and proprietary rights, even if they are not challenged, are subject to expiration dates. Expiration of effective intellectual property protections for our products typically results in the entry of one or more lower-priced generic competitors, often leading to a rapid and severe decline in revenues on those products (for information on the expected impact of biosimilar entry on the market see "– We may lose market share to competing therapeutic options, biosimilar or generic products" above).

Furthermore, in general, if one or more of our flagship products were to encounter problems such as material product liability litigation, unexpected side effects, recall, regulatory proceedings, publicity affecting doctor or patient confidence, pressure from existing competitive products, changes in labeling, or if a new, more effective treatment were introduced, or if there were a reduction in sales of one or more of our flagship products or in their growth, the adverse impact on our business, results of operations and financial condition could be significant.

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, highly specific raw materials and other production constraints. Third parties supply us with a substantial 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 to Sanofi quality standards or if they experience financial difficulties. Further, some raw materials essential to the manufacture of our products are not widely available from sources we consider reliable; for example, we have approved only a limited number of suppliers of heparins for use in the manufacture of Lovenox®. 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.

Our products are also increasingly reliant on the use of product-specific devices for administration which may result in technical issues. For example in October 2015, we voluntary recalled all Auvi-Q® (epinephrine injection, USP) marketed in the US and Canada as the product was found to potentially have inaccurate dosage delivery, which may include failure to deliver the drug. Sanofi ultimately decided to return all US and Canadian rights to the developer of Auvi-Q®. One of our newly launched products, Praluent®, is administered with an auto-injector manufactured by a third party. The success of this product will depend partially on the performance of this device.

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. 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. Effective insurance coverage for biological products in the event of contaminated batches may also be difficult to obtain as the cause of the contamination can be difficult to ascertain (for the impact on our financial statements see "– Impairment charges or write downs in our books and changes in accounting standards could have a significant adverse effect on the Company's results of operations and financial results." below)

For example, in the US we have encountered production issues for several years which caused delays in the supply of Pentacel® vaccine starting from 2013. While the supply conditions have been improving since the end of 2016, there can be no guarantee that we will not face similar issues in the future or that we will successfully manage such issues when they arise.

Additionally, specific conditions must be respected both by Sanofi and our customers for the storage and distribution of many of our biological products. For example, cold storage for certain vaccines and insulin-based products is required. Failure to adhere to these requirements may result in lost product inventory.

The complexity of these processes, as well as strict internal and health authority standards 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, which 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").

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. 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 require significant time.

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 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. Government authorities and regulators in the United States, in the European Union and other agencies worldwide are also considering measures to reduce these risks, such as Supply Risk Management Plans for some products with high medical need (e.g. the French decree of July 2016 concerning the preparation of shortage management plans ("*plans de gestion des pénuries*"). It cannot be ruled out that these ongoing initiatives may generate additional costs for Sanofi if they result in a requirement to establish backup supply channels or to increase inventory levels to avoid shortages.

We are sometimes required to use animals to test our products in the development phase and our vaccines before distributing them. Animal testing activities have been the subject of controversy and adverse publicity. Testing on animals can be vital for the development or commercialization of a product. If applicable regulations were to ban this practice, or if, due to pressure from animal welfare groups, we were no longer able to source animals to perform such tests, it would be difficult and in some cases impossible to develop or distribute our products in certain jurisdictions under the applicable marketing authorizations. In addition, negative publicity regarding our use, or the industry's use, of animal subjects could harm our reputation.

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

Our industry is highly collaborative, 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.

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 for the discovery, development, commercialization and manufacturing of therapies based on monoclonal antibodies. With Alnylam, we have an agreement to develop and commercialize treatments for rare genetic diseases (See “Item 4. Information on the Company – B. Business Overview – B.2. Main pharmaceutical products”). In addition we may also rely on partners to design and manufacture medical devices, notably for the administration of our products.

If disruptions or quality concerns were to arise in the third-party supply of raw materials, active ingredients or medical devices or if our partners were unable to manufacture a product, this could also adversely affect our ability to sell our products in the quantities demanded by the market and could damage our reputation and relationships with our customers. See also “– 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.

When we research and market our products through collaboration arrangements, the performance of certain key tasks or functions are the responsibility of our collaboration partners. We are therefore subject to the risk that they do not perform effectively. We are also subject to the risk that decisions may be under the control of or subject to the approval of our collaboration partners, and we may have differing views. Failures in the development process or differing priorities may adversely affect the activities conducted through the collaboration arrangements. Any conflicts or difficulties that we may have with our partners during the course of these agreements or at the time of their renewal or renegotiation or any disruption in the relationships with our partners, 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 and 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 12%, 7% and 6% of our consolidated net sales in 2016. We are also exposed to large wholesalers in other markets, particularly in Europe. An inability of one or more of these wholesalers to honor their debts to us would 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 the coming 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 less effective treatments to reduce their costs. In the United States there has been an increase in the number of patients 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, as a result of the insurance coverage mandate that came into effect in the United States in 2015, some employers may seek to reduce costs by reducing or eliminating employer group healthcare plans or transferring a greater portion of healthcare costs to their employees.

(1) *Information in this section is supplementary to Notes B.8.8. (with respect to information required by IFRS 7), D.10 and D.34 to our consolidated financial statements included at Item 18 of this annual report.*

(2) *Information in this section is supplementary to Note B.8.8. to our consolidated financial statements included at Item 18 of this annual report, with respect to information required by IFRS 7.*

In certain emerging markets countries where the economy is highly dependent on oil, a decline in oil prices may impact the ability of those countries to sustain healthcare spending, which could adversely affect our sales in those countries.

Our Consumer HealthCare (CHC) 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, the financial situation of the Company, its results of operations and the distribution channels of its products may be adversely affected. See also “We are subject to the risk of non-payment by our customers” above.

Economic and financial difficulties may have an adverse impact on third parties who are important to our business, including collaboration partners and suppliers, which could cause such third parties to delay or disrupt performance of their obligations to us and could materially adversely affect our business or results of operations. See “– We rely on third parties for the discovery, manufacture and marketing of some of our products” above. For more information see “Item 5. Operating and Financial Review and Prospects – Liquidity and Capital Resources – Liquidity.”

Counterfeit versions of our products harm our business.

Counterfeiting activities and the presence of counterfeit products in a number of markets and over the Internet continue to be a challenge for maintaining a safe drug supply. Counterfeit products are frequently unsafe or ineffective, and can be life-threatening. To distributors and users, counterfeit products may be visually indistinguishable from the authentic version. Reports of adverse reactions to counterfeit drugs along with increased levels of counterfeiting could be mistakenly attributed to the authentic product, affect patient confidence in the authentic product and harm the business of companies such as Sanofi. If one of our products were to be the subject of counterfeits, we could incur substantial reputational and financial harm. See “Item 4. Information on the Company – B. Business Overview – B.6. Markets – B.6.2. Competition.”

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 information technologies. 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 or sensitive information. We and our third-party service providers are implementing secure information technology systems for the protection of data and threat detection. However, there can be no assurance that our efforts or those of our third-party service providers to implement adequate security and control measures would be sufficient to protect against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyber-attack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm.

We commercialize a number of devices using new information technologies which, if they malfunction or are compromised could lead to a risk of harm to patients (see “– Product liability claims could adversely affect our business, results of operations and financial condition” above), including the unavailability of our products.

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

We increasingly rely on social media and new technologies 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. For example, patients may use these channels to comment on the effectiveness of a product and to report an alleged adverse event. When such questions arise, the nature of evidence-based health care and restrictions on what pharmaceutical manufacturers may say about their products are not always well suited to rapidly defending Sanofi or the public’s legitimate interests in the face of the political and market pressures generated by social media and rapid news cycles, and 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 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 the Company, or which could lead to breaches of data security, loss of trade secrets or other intellectual property or public disclosure of sensitive information, including information about our employees, clinical trials or customers. Such uses of social media and mobile technologies could have a material adverse effect on our reputation, business, financial condition and results of operations.

Impairment charges or write downs in our books and changes in accounting standards could have a significant adverse effect on Sanofi's results of operations and financial results.

Substantial value is allocated to intangible assets and goodwill resulting from business combinations, as disclosed at Note D.4. to our consolidated financial statements included in this annual report at Item 18, which could be substantially written down in value upon indications of impairment (primarily relating to pharmacovigilance, discontinued research and development projects, patent litigation and the launch of competing products), with adverse effects on our financial condition and the value of our assets.

If any of our strategic equity investments decline in value and remain below cost for an extended period, we may be required to write down our investment. We own a significant stake in Regeneron Pharmaceuticals, Inc. (22.1% of its share capital as of December 31, 2016), which is listed on the NASDAQ and has been accounted for using the equity method since 2014. Any material deterioration in Regeneron's share price or financial performance would be an indicator that the value of our investment might have become impaired. This would require us to perform an impairment test, which could have a negative impact on our financial statements.

In addition, the inherent variability of biologics manufacturing increases the risk of write-offs of these products. Due to the value of the materials used, the carrying amount of biological products is much higher than that of small-molecule products.

The financial environment and in particular the economic difficulties affecting Russia, Venezuela, Brazil, China and the Middle East could also negatively affect the value of our assets (see "– Global economic conditions and an unfavorable financial environment could have negative consequences for our business" above and "– Fluctuations in currency exchange rates could adversely affect our results of operations and financial condition" below).

Any new or revised accounting standards, rules and interpretations issued by the IASB (International Accounting Standards Board) could also result in changes to the recognition of income and expense that may materially and adversely affect Sanofi's financial results.

Our pension liabilities are affected by factors such as the performance of plan assets, interest rates, actuarial data and experience and changes in laws and regulations.

Our future funding obligations for our main defined-benefit pension plans depend on changes in the future performance of assets held in trust for these plans, the interest rates used to determine funding levels (or company liabilities), actuarial data and experience, inflation trends, the level of benefits provided for by the plans, as well as changes in laws and regulations. Adverse changes in those factors could increase our unfunded obligations under such plans, which would require more funds to be contributed and hence negatively affect our cash flow and results (see Note D.19.1. to our consolidated financial statements included at Item 18 of this annual report).

Risks Relating to Sanofi's Structure and Strategy

Our strategic objectives for long-term growth may not be fully realized.

In November 2015, we outlined our strategic roadmap for the period 2015-2020. Our long term strategy rests on four pillars: reshape our portfolio, deliver outstanding launches, sustain innovation in R&D and simplify our organization.

We may not be able to fully realize our strategic objectives and, even if we are able to do so, these strategic objectives may not deliver the expected benefits or within the expected timeline.

We will look to reshape our portfolio through acquisitions and divestitures and may not reach this objective if we are unable to identify opportunities, or enter into agreements in a timely manner or on sufficiently attractive terms. In addition, we may fail to (i) adopt the best strategy for our acquisitions/ divestitures or (ii) compete in an intensively competitive, increasingly focused market environment (see "– We may fail to successfully identify external business opportunities or realize the anticipated benefits from our strategic investments" below and "Our research and development efforts may not succeed in adequately renewing our product portfolio" above). We may also not have the necessary flexibility to appropriately reallocate resources towards our priority businesses.

The successful launch of a new pharmaceutical product involves substantial investment in sales and marketing activities. In 2015 we announced that we have up to 18 new medicines and vaccines on track to arrive on the market between 2014-2020. As of the end of 2016, four of those six key products have already been approved or launched: Toujeo®, Praluent®, Dengvaxia® and Soliqua™ 100/33 / Suliqua™. However there can be no assurance that all of these products will be approved, or with the targeted indications, and/or within the expected timeline or that, if approved, they will achieve commercial success. For example, we announced in July 2016 that the overall uptake of Dengvaxia® had been delayed by recent political changes and economic volatility in Latin America. Also, the level of Praluent® sales reflects the implementation of management restrictions by payers in the United States and limited market access in Europe. The launch strategy we develop (in terms of timing, pricing, market access, marketing efforts and dedicated sales forces) may not deliver the benefits that we expect. 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 the expected launch of some of our products.

Sustaining innovation in R&D is inherently risky due to the high rate of failure and we may not be able to allocate our resources to obtain optimal results (see also "– Our research and development efforts may not succeed in adequately renewing our product portfolio" above).

Our ongoing simplification of our global organization through the implementation, starting from January 2016, of five global business units (GBUs) to meet significant growth objectives requires substantial attention from our management. There is no guarantee that this new organization will enable Sanofi to concentrate its efforts around the businesses most likely to deliver growth, or that these GBUs will grow in line with anticipated growth rates or deliver the expected benefits.

Failure to successfully implement and meet our strategic objectives would have an adverse impact on our business, prospects and results of operations.

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

We pursue a strategy of selective acquisitions, in-licensing and collaborations in order to reinforce our pipeline and portfolio. The implementation of this strategy depends on our ability to identify business development opportunities and execute them at reasonable cost and on acceptable financing 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;
- integration takes longer than expected;
- key employees leave; or
- we have higher than anticipated integration costs.

In January 2017, we completed the acquisition of Boehringer Ingelheim's consumer healthcare (CHC) business in exchange for our animal health business (Merial), but we cannot guarantee that Boehringer Ingelheim's CHC business will be successfully integrated with ours and that we will be able to retain key personnel. Also, the expected benefits of the transaction may never be fully realized or may take longer to realize than expected.

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 regards 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.

We continue to focus on emerging markets. However, difficulties in operating in emerging markets, a significant decline in the anticipated growth rate in these regions or an unfavorable movement of the exchange rates of these countries' currencies against the euro could impair our ability to take advantage of these growth opportunities and could affect our business, results of operations or financial condition (see also "– Global economic conditions and an unfavorable financial environment could have negative consequences for our business" above).

The expansion of our activities in emerging markets also exposes us to more volatile economic conditions, political instability, 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 (see "– Counterfeit versions of our products harm our business" above)), and compliance issues including corruption and fraud (see "– Claims and investigations relating to compliance, competition law, marketing practices, pricing and other legal matters could adversely affect our business, results of operations and financial condition" above). We may also face compliance and internal control systems issues in mature markets due to increased competition and more complex and stringent regulations.

As a global healthcare leader, we are exposed to a number of risks inherent in sectors in which we were previously less active such as generics and consumer healthcare, whose business models and trade channels are different from our traditional pharmaceutical business, in particular regarding promotional efforts and trade terms.

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 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. In addition, 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 impact our business or results of operations.

Environmental 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 wastes, expose us to various risks, including:

- fires and/or explosions;
- storage tank leaks and ruptures; or
- discharges or releases of toxic or pathogen substances.

These operating risks 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 any of these events 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.

Environmental liabilities and costs related to compliance with applicable regulations 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 significantly 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 a material adverse effect on our results of operations and financial condition.

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.e) 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 significant capital expenditures as well as other costs and liabilities, thereby adversely affecting our business, results of operations or 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)."

Natural disasters prevalent in certain regions in which we do business could affect our operations.

Some of our production sites are located in areas exposed to natural disasters, such as earthquakes, floods and hurricanes. In the event of a major disaster we could experience severe destruction or interruption of our operations and production capacity. As a result, our operations and our employees could suffer serious harm which could have a material adverse effect on our business, financial condition and results of operations.

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, and to currencies in emerging markets. In 2016, 36.6% of our net sales were realized in the United States, 28.4% in Emerging Markets (including countries that are, or may in future become, subject to exchange controls or hyper-inflation), and 5% 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 New York Stock Exchange (NYSE), 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 portion of them, the depositary is allowed, at its own discretion, to sell for their benefit that right to subscribe for new shares instead of making it available to ADS holders. Also, holders of ADSs must instruct the depositary how to vote their shares. Because of this extra 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.

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

As of December 31, 2016, L'Oréal held approximately 9.15% of our issued share capital, accounting for approximately 16.7% 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] *Information in this section is supplementary to Note B.8.8. to our consolidated financial statements included at Item 18 of this annual report with respect to information required by IFRS 7.*

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.

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 trends to date, product sales milestone #1 has not been met. There can be no assurance that the other product sales milestones will be achieved. Failure to achieve the sales milestones would have an adverse effect on the value, if any, of the CVRs (see also Note D.22.d) to the consolidated financial statements included at Item 18 of the annual report regarding the ongoing CVR Trustee Claim).