Sanofi
Form 20-F
March 07, 2018
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

(Mark One)

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

or

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

For the fiscal year ended December 31, 2017

Or

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

Or

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

Date of event requiring this shell company report

For the transition period from to

Commission File Number: 001-31368

Sanofi

(Exact name of registrant as specified in its charter)

N/A

(Translation of registrant s name into English)

France

(Jurisdiction of incorporation or organization)

54, Rue La Boétie, 75008 Paris, France

(Address of principal executive offices)

Karen Linehan, Executive Vice President Legal Affairs and General Counsel

54, Rue La Boétie, 75008 Paris, France. Fax: 011 + 33 1 53 77 43 03. Tel: 011 + 33 1 53 77 40 00

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

Title of each class:	**Name of each exchange on which registered:**
American Depositary Shares, each representing one half of one ordinary share, par value 2 per share	New York Stock Exchange
Ordinary shares, par value 2 per share	New York Stock Exchange (for listing purposes only)
Contingent Value Rights	NASDAQ Global Market

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

The number of outstanding shares of each of the issuer s classes of capital or common stock as of December 31, 2017 was:

Ordinary shares: 1,254,019,904

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer Rule 12b-2 of the Exchange Act. (Check one):

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

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

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Presentation of financial and other information

The consolidated financial statements contained in this annual report on Form 20-F have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and with IFRS as adopted by the European Union, as of December 31, 2017.

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

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

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

- trademarks used or that may be or have been used under license by Sanofi and/or its affiliates, such as Actonel®, a trademark of Actavis; Afrezza®, a trademark of Mannkind Corporation; Aldurazyme®, a trademark of the Joint Venture Biomarin/Genzyme LLC; Avilomics®, a trademark of Avila Therapeutics, Inc.; Cialis® OTC, a trademark of Eli Lilly; Copaxone®, a trademark of Teva Pharmaceuticals Industries; Cortizone-10®, a trademark of Johnson & Johnson (except in the United States where it is a Sanofi trademark); Fludara® and Leukine®, trademarks of Alcafleu; Flutiform®, a trademark of Jagotec AG; RetinoStat® and UshStat®, trademarks of Oxford Biomedica; Spedra® and Stendra®, trademarks of Vivus Inc.; and Zaltrap® a trademark of Regeneron in the United States;

- trademarks sold by Sanofi and/or its affiliates to a third party, such as Altace®, a trademark of King Pharmaceuticals in the United States; Hyalgan®, a trademark of Fidia Farmaceutici S.p.A.; Liberty®, Liberty® Herbicide, LibertyLink® Rice 601, LibertyLink® Rice 604 and StarLink®, trademarks of Bayer; Maalox®, a trademark of Novartis in the United States, Canada and Puerto Rico; and Sculptra® a trademark of Valeant; and

- other third party trademarks such as Advantage® and Advantix®, trademarks of Bayer; Atelvia®, a trademark of Actavis in the United States; DDAVP®, a trademark of Ferring (except in the United States where it is a Sanofi trademark); Enbrel®, a trademark of Immunex in the United States and of Wyeth in other geographical areas; GLAAS®, a trademark of Immune Design; Humalog®, Humulin , Mirioper®, Basaglar® and Kwikpen®, trademarks of Eli Lilly; iPhone® and iPod Touch®, trademarks of Apple Inc.; Lactacyd®, a trademark of Omega Pharma NV in the EU and several other European countries; Rituxan®, a trademark of Biogen Idec, Inc. in the United States and Canada, and Genentech in Japan; Squarekids®, a trademark of Kitasato Daiichi Sankyo Vaccine Co., Ltd.; Unisom® a trademark of Johnson & Johnson in certain geographical areas (except in the United States and Israel where it is a Sanofi trademark and
  Canada where it is a trademark of Paladin Labs, Inc.); and Yosprala®, a trademark of Pozen, Inc.

Not all trademarks related to investigational agents have been authorized as of the date of this annual report by the relevant health authorities; for instance, the Lyxumia® trade name has not been approved by the FDA.

The data relating to market shares and ranking information for pharmaceutical products, in particular as presented in Item 4. Information on the Company B. Business Overview B.6. Markets B.6.1. Marketing and distribution, are

based mainly on sales data excluding vaccines and in constant euros (unless otherwise indicated) on a November 2017 MAT (Moving Annual Total) basis. The data are mainly from IQVIA local sales audit, supplemented by country-specific sources.

Data relating to market shares and ranking information presented herein for our Consumer Healthcare products are based on sales data from Nicholas Hall (Q3 2017 MAT).

Data relating to market shares and ranking information presented herein for our vaccines business are based on internal estimates unless stated otherwise.

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

Cautionary statement regarding forward-looking statements

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

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

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

Words such as believe, anticipate, plan, expect, intend, target, estimate, project, predict, forecast,

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should and similar expressions are intended to identify forward-looking statements but are not the exclusive means of identifying such statements.

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

Risk factors which could affect future results and cause actual results to differ materially from those contained in any forward-

looking statements are discussed under Item 3. Key Information D. Risk Factors . Additional risks, not currently known or considered immaterial by the Group, may have the same unfavorable effect and investors may lose all or part of their investment.

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

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ABBREVIATIONS

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

ADR	American Depositary Receipt
ADS	American Depositary Share
AFEP	*Association française des entreprises privées* (French Association of Large Companies)
AMF	*Autorité des marchés financiers* (the French market regulator)
ANDA	Abbreviated New Drug Application
BLA	Biologic License Application
BMS	Bristol-Myers Squibb
CEO	Chief Executive Officer
CER	Constant exchange rates
CGU	Cash generating unit
CHC	Consumer Healthcare
CHMP	Committee for Medicinal Products for Human Use
CVR	Contingent value right
ECB	European Central Bank
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
EU	European Union
FDA	US Food and Drug Administration
GAVI	Global Alliance for Vaccines and Immunisation
GBU	Global Business Unit
GLP-1	Glucagon-like peptide-1
GMP	Good manufacturing practice
Hib	Haemophilus influenzae type b
HSE	Health, Safety and Environment
IASB	International Accounting Standards Board
ICH	International Council for Harmonization
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IFRS	International Financial Reporting Standards
IPV	Inactivated polio vaccine
ISIN	International Securities Identification Number
J-MHLW	Japanese Ministry of Health, Labor and Welfare
LSD	Lysosomal storage disorder
MEDEF	*Mouvement des entreprises de France* (French business confederation)
MS	Multiple sclerosis
NASDAQ	National Association of Securities Dealers Automated Quotations
NDA	New Drug Application
NHI	National Health Insurance (Japan)
NYSE	New York Stock Exchange
OECD	Organisation for Economic Co-operation and Development
OPV	Oral polio vaccine

OTC	Over the counter
PhRMA	Pharmaceutical Research and Manufacturers of America
PMDA	Pharmaceuticals and Medical Devices Agency (Japan)
PRV	Priority Review Voucher
PTE	Patent Term Extension
QIV	Quadrivalent influenza vaccine
R&D	Research and development
ROA	Return on assets
SA	*Société anonyme* (French public limited corporation)
SEC	US Securities and Exchange Commission
SPC	Supplementary Protection Certificate
TSR	Total shareholder return
UNICEF	United Nations Children s Emergency Fund
US	United States of America
WHO	World Health Organization

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PART I

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ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

PART I

Item 1. Identity of Directors, Senior Management and Advisers

N/A

Item 2. Offer Statistics and Expected Timetable

N/A

Item 3. Key Information

A. Selected Financial Data

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, 2017, 2016 and 2015 are included in Item 18 of this annual report.

The consolidated financial statements of Sanofi for the years ended December 31, 2017, 2016 and 2015 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, 2017. 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, 2017.

Sanofi reports its financial results in euros.

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ITEM 3. KEY INFORMATION

SELECTED CONDENSED FINANCIAL INFORMATION

	As of and for the year ended December 31,				
(million, except per share data)	**2017**	**2016**	**2015**	**2014**	**2013**
IFRS Income statement data[a]					
Net sales[b]	35,055	33,821	34,060	31,380	30,693
Gross profit	24,593	24,006	23,942	21,769	20,989
Operating income	5,803	6,534	5,624	6,064	4,982
Net income excluding the exchanged/held-for-exchange Animal Health business	3,912	4,486	4,512	4,392	3,797
Net income attributable to equity holders of Sanofi	8,434	4,709	4,287	4,390	3,716
Basic earnings per share ( ):					
Net income excluding the exchanged/held-for-exchange Animal Health business	3.02	3.42	3.38	3.25	2.75
Net income attributable to equity holders of Sanofi	6.71	3.66	3.28	3.34	2.81
Diluted earnings per share ( ):					
Net income attributable to equity holders of Sanofi	6.66	3.63	3.25	3.30	2.77
IFRS Balance sheet data					
Goodwill and other intangible assets	53,344[e]	51,166[e]	51,583[e]	53,740	52,529
Total assets	99,826	104,672	102,321	97,392	96,055
Outstanding share capital	2,508	2,544	2,603	2,620	2,641
Equity attributable to equity holders of Sanofi	58,089	57,554	58,049	56,120	56,904
Long term debt	14,326[e]	16,815[e]	13,118[e]	13,276	10,414
Cash dividend paid per share ( )	3.03[g]	2.96	2.93	2.85	2.80

Cash dividend paid per share ($)[f][h]	3.63[g]	3.12	3.19	3.46	3.86

(a) The results of the Animal Health business, and the gain on the divestment of that business, are presented separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations); see Notes D.1. and D.36 to our consolidated financial statements.

(b) Following a change in accounting presentation in 2016, VaxServe sales of non-Sanofi products are included in ***Other revenues****. The presentation of prior period* ***Net sales*** *and* ***Other revenues*** *has been amended accordingly (see Note B.13.) to our consolidated financial statements.*

(c) Based on the weighted average number of shares outstanding in each period used to compute basic earnings per share, equal to 1,256.9 million shares in 2017, 1,286.6 million shares in 2016, 1,306.2 million shares in 2015, 1,315.8 million shares in 2014, and 1,323.1 million shares in 2013.

(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. 1,266.8 million shares in 2017, 1,296.0 million shares in 2016, 1,320.7 million shares in 2015, 1,331.1 million shares in 2014, and 1,339.1 million shares in 2013.

(e) As reported, excluding the Animal Health business presented in the line items, ***Assets held for sale or exchange*** and ***Liabilities related to assets held for sale or exchange*** *as of December 31, 2015, December 31, 2016 and December 31, 2017.*

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

(g) Dividends for 2017 will be proposed for approval by the shareholders at the Annual General Meeting scheduled for May 2, 2018.

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

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ITEM 3. KEY INFORMATION

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 2013 through March 2018 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
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
2017	1.20	1.14	1.20	1.04
Last 6 months				
2017				
September	1.18	1.19	1.20	1.17
October	1.16	1.18	1.18	1.16
November	1.19	1.17	1.19	1.16
December	1.20	1.18	1.20	1.17
2018				
January	1.24	1.22	1.25	1.19
February	1.22	1.23	1.25	1.22
March[(b)]	1.24	1.23	1.24	1.22

(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 March 02, 2018, we have used European Central Bank Rates for the period from March 05, 2018 through March 6, 2018.

(b) In each case, measured through March 6, 2018.

On March 6, 2018 the European Central Bank Rate was 1.24 per euro.

B. Capitalization and Indebtedness

N/A

C. Reasons for Offer and Use of Proceeds

N/A

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ITEM 3. KEY INFORMATION

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, invalidated 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 by country. This protection may not be sufficient to maintain effective product exclusivity because of local differences in the patents, in national laws, 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.

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.

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 collaborators may be required to obtain licenses from the holders of third-party intellectual property rights that already 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.

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 a 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.

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 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. 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. 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. 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 to be approved, it could reduce our sales and/or profitability of that product.

However, through our presence as a manufacturer of generics and biosimilars, we will also utilize patent challenge strategies against other innovators patents similar to those of long-established generic companies, though 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 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 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 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 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 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. 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

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ITEM 3. KEY INFORMATION

to the regulatory authorities. Regulatory processes differ from one jurisdiction and regulatory 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. 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 negative risk/benefit assessments and 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, the imposition of marketing restrictions, or the suspension or withdrawal of 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 notices of deficiencies and 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®) until May 2017. 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 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 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.

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 50% 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. Regulations applicable to biologics are often more complex and extensive than the regulations applicable to other pharmaceutical products. Biologics are also 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, data privacy and other legal matters could adversely affect our business, results of operations and financial condition.

Our industry is heavily regulated. Our business covers an extremely wide range of activities worldwide and involves numerous partners. We have adopted a Code of Ethics (the Code) 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 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, the French Anti-Corruption measures law (Sapin II) 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

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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.

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 Base Erosion and Profit Shifting initiatives and EU directives 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. This particularly applies to the recently enacted US tax reform for which IRS comments, guidelines and regulations are still to come. These changes may cover matters such as taxation of our operations, intercompany transactions, internal restructuring and more generally taxable income, tax rates, indirect taxation, transfer pricing, R&D tax credits, taxation of intellectual property, 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 decreasing sales of products facing patent expiry and regulatory data exclusivity, or competition from new products of competitors that are perceived as being superior or equivalent. 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 2017, we spent 5,472 million on research and development, amounting to 15.6% 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, or fail to build a robust pipeline and fulfill unmet medical needs in a timely manner. Fields of discovery, particularly

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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 generally 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 2017, all of those six products have already been approved or launched: Toujeo®, Praluent®, Dengvaxia®, Soliqua 100/33 / Suliqua , Kevzara® and Dupixent®. However, there can be no assurance that all of the products approved will achieve commercial success.

Following (or in some cases contemporaneously with) review of a product for a marketing authorization, 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, it may take time for us 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, i*nter 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;
- 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 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

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considering legislation that could affect transparency practices, the marketing and prices of drugs, and access to drugs. US federal and state officials, including the new administration, are continuing to focus on the cost of health coverage and health care although future policy, including the nature and timing of any changes (including to the Affordable Care Act), remains unclear, creating multiple risks for the sector. Legislation was introduced in over 26 states in 2017 which will require price transparency and reporting of certain manufacturer information. This trend will continue into 2018 where we anticipate legislation to be filed in at least 20 states and more laws to be enacted around the United States.

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 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 example, since 2014, we have increased the level of rebates negotiated 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® would be excluded from commercial and MMC (Medicaid Managed Care) template formularies covering millions of people, thereby increasing the costs of Lantus®/Toujeo® to patients covered by the affected PBM/MCO (absent a co-pay assistance or other applicable program), and thus in turn reducing the patient population likely to purchase Lantus®/Toujeo®.

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

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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.

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 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, 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. These difficulties may also be encountered during testing, which is a mandatory requirement for the products to be released. Effective insurance coverage for biological products may also be difficult to obtain in the event of contaminated batches 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)

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 or products becoming out of specification, which in turn may result in efficacy or safety issues for patients.

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; 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. 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.

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

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agencies worldwide are also considering measures to reduce these risks, such as through 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 to test 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.

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. 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). 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, we are also subject to the risk that we may not

adequately manage our alliance. For instance, 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.

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 or otherwise negatively affect our results of operations.

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, 2017 compared with year ended December 31, 2016 Net Sales Pharmaceuticals segment). Lantus® is particularly important; it was Sanofi s leading product with revenues of 4,622 million in 2017, representing 13.2% of Sanofi s net sales for the year. Lantus® is a flagship product of the Diabetes franchise. Accounting for market trends, we announced in November 2017 that we now project a cumulative annual negative growth rate of 6% to 8% for our global Diabetes franchise for the period from 2015 to 2018. 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 generic glargines and their penetration of the market, or the market uptake of our new products).

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 our Diabetes franchise to our overall performance. As regards products recently launched or under development in our R&D portfolio for which we have an alliance arrangement with a partner, the terms of the alliance agreements 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.

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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, or changes in labeling, or if a new, more effective treatment were introduced, or if there were a reduction in sales or a decline in sales growth of one or more of our flagship products, the adverse impact on our business, results of operations and financial condition could be significant.

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 9%, 5% and 4% of our consolidated net sales in 2017. 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 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 is a consistent 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.

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, 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 ofnon-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.

(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.

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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, sensitive or personal information regarding our patients, clinical trials, vendors, customers, employees, collaborators and others). We and our third-party service providers use 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 Sanofi, 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 or other information. 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. (22.2% of its share capital as of December 31, 2017), which is listed on 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.

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The financial environment and in particular the economic difficulties affecting Russia, Venezuela 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 are looking 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 successfully 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 toward 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 including six key launches. As of the end of 2017, all of those six products have already been approved or launched: Toujeo®, Praluent®, Dengvaxia® and Soliqua 100/33 / Suliqua®, Kevzara® and Dupixent®. However there can be no assurance that all of our new products will achieve commercial success. We may also encounter failures or delays in our launch strategy. For example, Dengvaxia® sales suffer from political changes and economic volatility in Latin America and also from the recommendation to update the label at the end of 2017 following new clinical studies. In the Philippines, this resulted in the suspension of the dengue vaccination campaign in December 2017, and the temporary suspension of the Dengvaxia® license in early 2018, following a decision of the regulatory authority. In addition, the level of Praluent® sales reflects the implementation of utilization management restrictions by payers in the United States and limited market access in Europe which have hampered our launch strategy. 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 support and grow our marketed products, successfully execute the launches of newly approved products, advance our late-stage pipeline or manage the change of our organization 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

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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 the expected benefits of the transaction may never be fully realized or may take longer to realize than expected.

In January 2018, we announced our intent to acquire Bioverativ and Ablynx. Completion of the transactions is subject to a number of risks and uncertainties. These include (but not limitatively): (i) our ability to complete the transactions on the terms proposed or within the expected time-frame; (ii) our ability to obtain the required regulatory clearances; and (iii) the possibility that competing offers may be made.

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.

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 consumer healthcare. The business models and trade channels in consumer healthcare, in particular regarding promotional efforts and trade terms for example, are different from those in our traditional pharmaceuticals business.

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.

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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 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 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.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 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.

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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 2017, 33.8% of our net sales were realized in the United States; 29.3% in Emerging Markets (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 or hyper-inflation; and 5.1% 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 that right

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, 2017, L Oréal held approximately 9.43% of our issued share capital, accounting for approximately 16.88% 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.

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

(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.

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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 has not been met. On February 7, 2018, Sanofi disclosed that, based upon actual sales trends to date, it does not expect that product sales milestones #2, #3 and #4 will 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 ongoing CVR Trustee Claim).

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ITEM 4. INFORMATION ON THE COMPANY

Item 4. Information on the Company

Introduction

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

In the remainder of this section:

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

For our Pharmaceuticals activity, unless otherwise stated, all market share percentages and rankings are calculated based on consolidated national pharmaceutical sales data, excluding vaccines and in constant euros, on a November 2017 MAT (Moving Annual Total) basis. The data are mainly from IQVIA local sales audit supplemented by various other country-specific sources e.g. Knobloch (Mexico), GERS (France hospital channel), HMR (Portugal), Reveal (Sweden). Market share data for the Consumer Healthcare business are from Nicholas Hall, Q3 2017 MAT.

For our Vaccines activity, market share percentages and rankings are based on our own estimates. These estimates have been made from information in the public domain collated from various sources, including statistical data collected by industry associations and information published by our competitors.

Sanofi has three principal activities: Pharmaceuticals, Consumer Healthcare (CHC) and Vaccines via Sanofi Pasteur. These activities are operating segments within the meaning of the IFRS 8 accounting standard (see Note D.35. to our consolidated financial statements included in Item 18 of this annual report). We exited the Animal Health business on January 1, 2017 when we closed a transaction with Boehringer Ingelheim (BI) in most markets to swap our Animal Health business for BI s Consumer Healthcare business.

We invest in the following activities (see B. Business Overview B.1. Strategy below): Rare Diseases, Multiple Sclerosis, Oncology, Immunology, Diabetes, Cardiovascular, Established Prescription Products(1), Consumer Healthcare, Generics, and Vaccines. Unlike our Vaccines and Consumer Healthcare activities, which are operating segments within the meaning of IFRS 8, our Rare Diseases, Multiple Sclerosis, Oncology, Immunology, Diabetes, Cardiovascular, Established Prescription Products and

Generics activities are franchises whose performance is monitored primarily on the basis of net sales; the products sold by each of those franchises are included in our Pharmaceuticals operating segment. We are also active in emerging markets selling products from our three activities; the performance of our Emerging Markets(2) operations is monitored primarily on the basis of net sales.

For a presentation of the net sales of our activities for the year ended December 31, 2017, refer to Item 5 Results of Operations Year Ended December 31, 2017 Compared with Year Ended December 31, 2016 .

The most important pharmaceutical products marketed by us are described below.

Rare Diseases: a portfolio of enzyme replacement therapies including Cerezyme® for Gaucher disease; Myozyme® and Lumizyme® for Pompe disease; and Fabrazyme® for Fabry disease; Cerdelga®, an oral ceramide analog for Gaucher disease and Aldurazyme® for mucopolysaccharidosis Type 1 (MPS 1).

Multiple sclerosis: Aubagio®, a once-daily oral immunomodulator; and Lemtrada®, a monoclonal antibody. Both products were developed to treat patients with relapsing forms of multiple sclerosis.

Oncology: Jevtana®, a taxane derivative, indicated for patients with prostate cancer; Taxotere®, a taxoid representing a cornerstone therapy for several cancer types; Eloxatin®, a platinum agent, which is a key treatment for colorectal cancer; Thymoglobulin®, a broad immunosuppressive and immunomodulating agent; Mozobil®, a hematopoietic stem cell mobilizer for patients with hematologic malignancies; and Zaltrap®, a recombinant fusion protein, indicated for patients with metastatic colorectal cancer that is resistant to or has progressed following an oxaliplatin-containing regimen.

Immunology: Dupixent® (dupilumab), a monoclonal antibody against the Interleukin-4 alpha receptor, indicated for adults with moderate-to-severe atopic dermatitis; and Kevzara® (sarilumab), a monoclonal antibody against the Interleukin-6 receptor, indicated for adults with moderate to severe rheumatoid arthritis.

Diabetes: Lantus® (insulin glargine), a long-acting human insulin analog which is the world-leading brand in the insulin market; Toujeo® (insulin glargine 300 U/mL); Amaryl®, an oral once-daily sulfonylurea; Apidra®, a rapid-acting human insulin analog; Insuman®, a range of rapid-acting or intermediate-acting human

(1) Established Prescription Products comprises mature products including Plavix®, Lovenox®, Aprovel®, Renagel® and Renvela®.

(2) World excluding the US, Canada, Western & Eastern Europe (apart from Russia, Ukraine, Georgia, Belarus, Armenia and Turkey), Japan, South Korea, Australia, New Zealand and Puerto Rico

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insulins; Lyxumia®/Adlyxin® (lixisenatide), a once-daily GLP-1 receptor agonist; Soliqua 100/33 / Suliqua , a once-daily combination of insulin glargine and lixisenatide; and Admelog® / Insulin lispro Sanofi® (insulin lispro), a rapid-acting insulin.

Cardiovascular diseases: Praluent®, a cholesterol-lowering drug that inhibits PCSK9; and Multaq®, an anti-arrhythmic drug in atrial fibrillation.

Established Prescription Products: Plavix®, an anti-platelet agent indicated for a number of atherothrombotic conditions; Lovenox®, a low molecular weight heparin for the prophylaxis and treatment of venous thromboembolism and of acute coronary syndrome; Aprovel® and CoAprovel®, anti-hypertensives; Renagel® and Renvela®, oral phosphate binders for use in patients undergoing dialysis; Synvisc® and Synvisc-One®, viscosupplements used to reduce pain in patients suffering from osteoarthritis of certain joints; Stilnox®, for the short-term treatment of insomnia; and Allegra®, a long-lasting (12- and 24-hour) non-sedating prescription anti-histamine for the treatment of seasonal allergic rhinitis (hay fever) and uncomplicated hives.

Generics: our pharmaceuticals portfolio also includes a wide range of generics. In October 2016, we announced our intention to initiate a carve-out process in order to divest our European Generics business.

Our Consumer Healthcare (CHC) activity is supported by four strategic categories: Allergy Cough & Cold, Pain, Digestive and Nutritionals. On January 1, 2017, we acquired BI s CHC business in most markets.

Our Vaccines activity is operated through Sanofi Pasteur. We sell leading vaccines in five areas: pediatric vaccines, influenza vaccines, adult and adolescent booster vaccines, meningitis vaccines, and travel and endemic vaccines. At the end of December 2016, Sanofi Pasteur and MSD ended their vaccines joint venture in Europe and integrated their respective European vaccines business into their own operations.

We obtained regulatory approval for two new products (Dupixent® and Kevzara®) in the US and in the EU in 2017. We also obtained regulatory approval in the US for Admelog®, a follow-on insulin lispro, which was also approved in the EU as a biosimilar under the proprietary name Insulin lispro Sanofi®.

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

A/ History and Development of the Company

The current Sanofi corporation was incorporated under the laws of France in 1994 as a *société anonyme*, a form of limited liability company, for a term of 99 years. Since May 2011, we have operated under the commercial name Sanofi (formerly known as Sanofi-Aventis). Our registered office is located at 54, rue La Boétie, 75008 Paris, France, and our main telephone number is

+33 1 53 77 40 00. Our principal US subsidiary s office is located at 55 Corporate Drive, Bridgewater, NJ 08807; telephone: +1 (908) 981 5000.

Main changes since 2011

On April 4, 2011, following a tender offer, we acquired control of Genzyme, a US biotechnology company headquartered in Cambridge, Massachusetts.

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

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

B/ Business overview

B.1. Strategy

The market context for Sanofi

A number of fundamental trends point to a positive outlook for the pharmaceutical industry. The global population is growing and aging. Unmet medical needs remain high. The industry has increased R&D productivity, and has returned to consistently launching a high number of innovative medicines. Patients around the world, and a rising middle class in emerging markets, are demanding better care, empowered by access to new information. It is a particularly exciting time scientifically and technologically, with the promise of genomics being realized, immuno-oncology transforming cancer treatments, big data generating new insights into disease, and digital technologies helping to transform care delivery.

At the same time, funding challenges, budget tightening and affordability will continue to put the entire Healthcare value chain under significant pressure. Even though we believe that the pharmaceutical portion will remain a fundamentally attractive business, the bar for innovation will most likely continue to rise. Innovation must have demonstrable benefit to the system. Payers will continue to put scrutiny on prices and reimbursement and will demand demonstration of real life outcomes, coupled with more innovative pricing and contracting practices.

Biosimilars are now firmly part of the competitive landscape in both the US and Europe. More focused competitors are building leadership positions in their priority therapy areas.

Implementing the strategic roadmap

To compete and win in this market, we are implementing our 2020 strategic roadmap, announced in November 2015. We have made significant progress against each of the four pillars of that strategy in 2017: reshape the portfolio,

deliver outstanding launches, sustain innovation in R&D, and simplify the organization.

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Reshape the portfolio

To reshape the portfolio, we segmented our businesses focusing on three targets: to sustain leadership, build competitive positions, and explore strategic options.

Sustain leadership

Diabetes and Cardiovascular Diseases. We remain committed to fighting the global epidemic of diabetes and to treating cardiovascular disease, the leading cause of death globally. Our three priorities over the next few years are to develop the insulin franchise with Lantus®, Toujeo®, and Soliqua 100/33 / Suliqua and other selected insulins; strengthen our pipeline; and lead the market shift to managing diabetes outcomes. In 2017, notable product achievements included continued global momentum behind Toujeo®; the launch of Soliqua 100/33/Suliqua™ in the US and Europe; approval in the US and Europe of our insulin lispro biosimilar; and ongoing development of our future assets (including sotaglifozin in Phase III, efpeglenatide in Phase III, and our co-agonist drug candidates in Phase I and II). We are also committed to lead the market shift to managing diabetes outcomes. In 2016, we established Onduo, our diabetes solutions joint venture with world-class partner Verily. We have also made investments in several Integrated Care solutions across various geographies.

In cardiovascular, we have the opportunity to transform the management of hypercholesterolemia through Praluent®, developed jointly with Regeneron. In a challenging payer environment, we continue to work on securing access for patients to this important medication. We look forward to the results of the ODYSSEY cardiovascular outcomes study of 18,000 patients, which will be released in the first quarter of 2018.

Vaccines. Our growth will be driven by leading products in flu and by pediatric combinations. Demand typically exceeds supply, so a key priority for us is to produce more. We are investing to secure and expand flu and pediatric capacity. In 2017, to expand our vaccine product portfolio we (i) completed the acquisition of Protein Sciences, adding Flublok® (the only recombinant protein-based influenza vaccine approved by the US) to our influenza vaccine portfolio and (ii) agreed a collaboration with Medimmune to develop and commercialize a monoclonal antibody for the prevention of respiratory syncytial virus (RSV). In addition, our European business has been consolidated and simplified with dissolution of the joint venture with MSD.

Rare Diseases. We continue to sustain our market share leadership in rare genetic diseases through the patient-centered approach unique to Sanofi Genzyme, alongside product differentiation and market access. We continue to grow the market through screening expansion. We also expect to advance our strong pipeline, where four of our assets have received breakthrough or fast-track designation from the FDA. In January 2018, we and Alnylam restructured our RNAi therapeutics
alliance: we now have broader rights to fitusiran (in development for the treatment of people with hemophilia A and B), while Alnylam has broader rights to its investigational RNAi therapeutics programs for the treatment of ATTR amyloidosis, including patisiran and ALN-TTRsc02.

Consumer Healthcare. On January 1, 2017, Sanofi and Boehringer Ingelheim (BI) successfully closed in most markets a transaction to swap Sanofi s Animal Health and BI s CHC businesses. With this transaction, we acquired BI s CHC business in most markets and enhanced our position in four strategic categories: Allergy Cough & Cold, Pain, Digestive and Nutritionals. Since then, we have successfully integrated BI s CHC business; rejuvenated management of the Consumer Healthcare business; and defined a growth model and target operating model. We have also launched portfolio complexity reduction programs and identified key areas for internal and external growth.

Emerging Markets. We are the pharmaceutical industry leader in emerging markets and a major multinational player in the BRIC-M countries (Brazil, Russia, India, China and Mexico).

Build competitive positions

Multiple Sclerosis. We already have a competitive position in multiple sclerosis. We will continue to maximize our support to these products through life cycle management in a competitive market and we intend to strengthen our portfolio. Investing for the future, we have signed a licensing agreement with Principia to develop their experimental oral treatment (Bruton s tyrosine kinase inhibitor) that shows promise in multiple sclerosis and, potentially, other central nervous system diseases.

Oncology. We are rebuilding our oncology portfolio. We intend to maximize our clinical assets, particularly isatuximab (an anti-CD38 monoclonal antibody in late stage development for multiple myeloma) and cemiplimab (a PD-1 inhibitor derived from our alliance with Regeneron, in development for first line treatment of non small cell lung cancer, second line treatment of cervical cancer, the treatment of basal cell carcinoma and the treatment of advanced cutaneous squamous cell carcinoma). In January 2018, we announced that we and Regeneron will accelerate and expand investment in the clinical development of cemiplimab in oncology, and dupilumab in Type 2 allergic diseases.

Immunology. We have the cornerstones of an important new franchise in immunology through Kevzara® (for rheumatoid arthritis) and Dupixent® (developed in several indications including atopic dermatitis, asthma and nasal polyposis). Both drugs were developed in collaboration with Regeneron and both were launched in 2017. We aim to lead in atopic dermatitis with Dupixent®, which was the first in class biologic to reach the market. An important milestone was achieved with the dupilumab Phase III study in uncontrolled persistent asthma which met its two primary endpoints; we filed for this indication and we expect to receive a decision from the FDA by October 20, 2018. Also in

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2017 we entered into a research collaboration and global exclusive licensing agreement with Ablynx, focused on Nanobody®-based therapeutics for the treatment of various immune-mediated inflammatory diseases.

Explore strategic options

Animal Health. We have fully exited the Animal Health business through the swap with BI.

Generics in Europe. As announced, we carefully reviewed all options for our European Generics business. We announced the divestment earlier this year and signing of definitive transaction agreements[(1)] on the divestiture of European Generics is expected in the third quarter of 2018.

Deliver outstanding launches

Our second strategic priority is to deliver outstanding launches of new medicines and vaccines. We have focused the organization on six major product launches: Toujeo®, Praluent®, Dengvaxia®, Soliqua 100/33/ Suliqua , Kevzara®, and Dupixent®.

In 2017 we launched Dupixent®, the first and only biologic medicine for the treatment of adults with moderate-to-severe atopic dermatitis. Dupixent® uptake to date is being driven by high patient need, healthcare professional engagement and initial market access. Also in 2017, we launched Kevzara® for the treatment of adult patients with moderately to severely active rheumatoid arthritis.

We continued the global launch and ramp-up of Toujeo® in diabetes; Praluent® for hypercholesterolemia; and Soliqua 100/33/ Suliqua , a combination of lixisenatide and insulin glargine treatment for diabetes, whose market access in the US is progressing.

Dengvaxia® uptake will most likely be impacted by product label updates to reflect new analysis of long-term data, which found differences in Dengvaxia® performance based on prior dengue infection.

Sustain innovation in R&D

Our strategy depends on continued innovation in R&D. We continue to strengthen our R&D pipeline, increasing the number of high-quality projects in the early stage pipeline and replenishing the late development pipeline as products launch. Having delivered real improvements in development productivity, we are now particularly focused on improving research productivity. We have aligned the R&D organization with the new Global Business Unit structure, reorganized research into thematic clusters, continued to build capability in translational science, and recruited important new talent.

We have moved and rebalanced our portfolio towards biologics especially through our collaboration with Regeneron for monoclonal

antibodies. At the same time, we have worked internally to develop our own proprietary platforms such as multi-specific antibodies to go from a mono-targeting to a multi-targeting world.

Our R&D investments will follow our business priorities, focusing on those businesses where we aim to sustain leadership and build competitive positions.

Simplify the organization

We are creating a more agile organization through a strategic cost savings program, which has delivered 1.5 billion from 2015 to 2017:

- Simplification via the implementation in 2016 of a new Global Business Unit structure, integrating global franchises and country-level commercial and medical organizations for each of our major businesses (Sanofi Genzyme; Diabetes and Cardiovascular; General Medicines and Emerging Markets; Sanofi Pasteur and Consumer Healthcare), and via the creation of Global Functions (Finance, Human Resources, Information Technology and Solutions, etc);

- Operational improvement and productivity efforts in Industrial Affairs;

- Product portfolio streamlining in our Established Products franchise; and

- Resizing of sales forces to reflect evolving market dynamics.

In parallel, we have made reinvestment decisions scaled to the needs of the business and have continued to strengthen our Medical Affairs and External Affairs functions. We have also united the different parts of the Company behind a single vision, a common set of values and a shared culture.

B.2. Main pharmaceutical products

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

a) Rare Diseases

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

(1) Following completion of the dialogue with employee representatives.

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Cerezyme®

Cerezyme® (imiglucerase for injection) is an enzyme replacement therapy used to treat Gaucher disease, an inherited, potentially life-threatening LSD. It is estimated that Gaucher disease occurs in approximately one in 120,000 newborns in the general population and one in 850 in the Ashkenazi Jewish population worldwide, but the incidence and patient severity vary among regions.

Cerezyme® is the only therapy with a 25-year history of reducing, relieving and reversing many of the symptoms and risks of Type 1 and Type 3 (in certain markets) Gaucher disease. Cerezyme® is administered by intravenous infusion over one or two hours.

The principal markets for Cerezyme® are the US, Germany, Italy, France and Turkey.

Cerdelga®

Cerdelga® (eliglustat) is the first and only first-line oral therapy for Gaucher disease Type 1. A potent, highly specific ceramide analogue inhibitor of GL-1 synthesis with broad tissue distribution, Cerdelga® has demonstrated efficacy in the treatment of naive Gaucher disease patients and in patients who switch from enzyme replacement therapy (ERT).

Cerdelga® was approved by the FDA in August 2014 and by the European Commission in January 2015; the product is now available in several European countries. It was approved in Japan in March 2015 and launched in the same year. Regulatory submissions are ongoing in other countries.

The largest market for Cerdelga® and for Gaucher disease overall is the US.

Myozyme® and Lumizyme®

Myozyme® and Lumizyme® (alglucosidase alfa) are enzyme replacement therapies used to treat Pompe disease, an inherited, progressive and often fatal LSD. Pompe disease occurs in approximately one in 40,000 newborns worldwide, but the incidence and patient severity vary among regions.

Myozyme® has been marketed since 2006 in the US and the EU and is approved in more than 70 countries. Outside the US, Myozyme® is marketed for patients with both infantile- and late-onset disease. Lumizyme® has been marketed in the US since June 2010. Initially designed specifically to treat patients with late-onset Pompe disease and patients

over eight years of age without evidence of cardiac hypertrophy, on August 1, 2014 it was approved for infantile-onset Pompe disease.

Myozyme® and Lumizyme® are administered by intravenous infusion once every two weeks. Both products are recombinant forms of the same human enzyme.

The principal markets for Myozyme® are the US, Germany, Italy, the Netherlands and the UK.

Fabrazyme®

Fabrazyme® (agalsidase beta) is an enzyme replacement therapy used to treat Fabry disease, an inherited, progressive and potentially life threatening LSD. Fabry disease occurs in approximately one in 35,000 newborns worldwide, but the incidence and patient severity vary among regions.

Fabrazyme® has been marketed in the EU since 2001 and in the US since 2003, and is approved in more than 70 countries. Fabrazyme® is administered by intravenous infusion once every two weeks.

The principal markets for Fabrazyme® are the US, Japan, France, Italy and the UK.

Aldurazyme®

Aldurazyme® (laronidase) is the first and only approved treatment for mucopolysaccharidosis type 1 (MPS 1). A human recombinant enzyme therapy with over 13 years of clinical post-marketing experience, Aldurazyme® has been shown to be safe and effective in symptomatic MPS 1 patients of all phenotypes. MPS 1 occurs in approximately one per 100,000 live births worldwide, but the incidence and patient severity vary among regions. Aldurazyme® is administered once weekly as an intravenous infusion

The principal markets for Aldurazyme® are the US, France, the UK, Japan and Germany.

b) Multiple Sclerosis

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

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

Aubagio®

Aubagio® (teriflunomide), a small molecule immunomodulatory agent with anti-inflammatory properties, reversibly inhibits dihydroorotate dehydrogenase, a mitochondrial enzyme involved in the de novo pyrimidine synthesis required for activated lymphocytes to multiply. The exact mechanism by which teriflunomide exerts its therapeutic effect in MS is unknown but may involve a reduction in the number of activated lymphocytes in the central nervous system. Aubagio® is a once-daily oral therapy. Aubagio® has shown significant efficacy across key measures of MS disease activity, including slowing the progression of physical disability, reducing relapses, and reducing the number of brain lesions as detected by magnetic resonance imaging (MRI).

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Aubagio® is the first and only oral MS therapy to significantly slow the progression of disability in two Phase III trials (TEMSO and TOWER). Consistent with its effect on slowing disability progression, Aubagio® is the only oral therapy shown to prevent or delay a second clinical attack in patients who have experienced initial neurological symptoms suggestive of MS (TOPIC trial).

Ongoing development efforts include the TeriKIDS study to assess the safety and efficacy of teriflunomide in children (10-17 years old) and global post-marketing registries for pregnancy.

Aubagio® was granted marketing authorization by the FDA in September 2012 for the treatment of patients with relapsing forms of MS, and by the European Commission in August 2013 for the treatment of adult patients with relapsing remitting MS. Aubagio® is now approved in more than 70 countries around the world.

In 2017, Sanofi reached settlement with all 20 generic Aubagio® ANDA first filers granting each a royalty-free license to enter the United States market on March 12, 2023. See Item 8. Financial Information A. Consolidated financial statements and other financial information .

The principal markets for Aubagio® in terms of sales are the US, Germany, France, the UK, Canada, Spain and Italy.

Lemtrada®

Lemtrada® (alemtuzumab) is a humanized monoclonal antibody targeting the CD52 antigen. The exact mechanism by which alemtuzumab exerts its therapeutic effect in MS is unknown. Research suggests immunomodulatory effects through the selective depletion and repopulation of T and B lymphocytes, resulting in a resetting of the immune system. Lemtrada® is administered as two short courses 12 months apart; for the majority of patients no further treatment is necessary, making Lemtrada® the only disease-modifying therapy (DMT) that can provide long term durable efficacy in the absence of continuous dosing.

Lemtrada® was able to show statistically significant improvement across many key measurements of MS disease activity including improvement in physical disability, reducing relapses, and reducing the number of brain lesions as detected by MRI. Lemtrada® is the first and only approved DMT to show an improvement in six-month confirmed disability improvement (CDI) against an active comparator (CARE MS II study). Lemtrada® was also able to reduce brain volume loss over six years to levels seen in healthy controls, despite the majority of Lemtrada® patients

receiving no treatment after the initial two treatment courses (extension of CARE MS I and II studies).

In September 2013, Lemtrada® was granted marketing authorization by the European Commission for treatment of adult patients with relapsing forms of MS with active disease defined by clinical or imaging features. In November 2014, the FDA approved Lemtrada® for the treatment of patients with relapsing forms of multiple sclerosis. Because of its safety profile, the FDA approval

limited use of Lemtrada® to patients who have had an inadequate response to two or more drugs indicated for the treatment of MS and included a black-box warning on potential side effects. Lemtrada® is only available in the US through a restricted program called the Lemtrada® Risk Evaluation and Mitigation Strategy (REMS) Program. Lemtrada® is currently approved in more than 60 countries with additional marketing applications under review by regulatory authorities globally.

Alemtuzumab is being evaluated in a Phase III study to assess the safety and efficacy in pediatric patients with relapsing remitting form of multiple sclerosis.

The principal markets for Lemtrada® in terms of sales are the US, the UK, Germany, Spain, Canada and Italy.

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

c) Immunology

Our Immunology franchise consists of Dupixent® (dupilumab), the first and only biologic medicine for the treatment of adults with moderate-to-severe atopic dermatitis (AD), and Kevzara® (sarilumab) for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA).

Dupixent®

Dupixent® (dupilumab), a human monoclonal antibody, binds to the interleukin-4 receptor (IL-4R) and has been shown to specifically inhibit overactive signaling of two key proteins, IL-4 and IL-13, which are believed to be major drivers of the persistent underlying inflammation in atopic dermatitis, and certain other allergic or atopic diseases.

Atopic dermatitis, a form of eczema, is a chronic inflammatory disease with symptoms often appearing as a rash on the skin. Moderate-to-severe atopic dermatitis is characterized by rashes sometimes covering much of the body, and can include intense, persistent itching and skin dryness, cracking, redness, crusting and oozing. Itch is one of the most burdensome symptoms for patients and can be debilitating.

The global LIBERTY AD clinical trial program, which included nearly 3,000 patients, examined the use of Dupixent® either alone or with topical corticosteroids in patients with inadequately controlled moderate-to-severe AD. In all these studies, Dupixent® alone or with topical corticosteroids met the primary and key secondary endpoints.

Dupixent® comes in a pre-filled syringe and can be self-administered as a subcutaneous injection every other week after an initial loading dose. Dupixent® can be used with or without topical corticosteroids.

Dupixent® was granted marketing authorization by the FDA in March 2017 for the treatment of adults with moderate-to-severe atopic

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dermatitis whose disease is not adequately controlled with topical prescription therapies, or when those therapies are not advisable. Dupixent® was evaluated by the FDA with Priority Review. This followed the FDA s 2014 Breakthrough Therapy designation for Dupixent® for inadequately controlled moderate-to-severe AD. In September 2017, the European Commission approved Dupixent® for use in adults with moderate-to-severe AD who are candidates for systemic therapy. Applications for regulatory approval have also been submitted in several other countries and are being reviewed.

Dupixent® is available in the US (since April 2017) and in Germany (since December 2017).

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

Dupilumab is currently being evaluated in a broad range of clinical development programs for diseases that are driven by Type 2 inflammation, including uncontrolled persistent asthma (we filed for this indication and we expect to receive a decision from the FDA by October 20, 2018), adolescent and pediatric atopic dermatitis, pediatric asthma, nasal polyps and eosinophilic esophagitis. See B.5. Global Research & Development

There are ongoing patent infringement proceedings in several countries initiated by Sanofi and Regeneron against Amgen and Immunex relating to Dupixent®. See Note D.22.b) to the consolidated financial statements included at Item 18 of this annual report and Item 8. Financial Information B. Significant changes of this annual report for more information.

Kevzara®

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

Rheumatoid arthritis is a chronic inflammatory autoimmune disease which carries substantial burden. In RA, the immune system attacks the tissues of the joints, causing inflammation, pain, and eventually joint damage and disability. RA most often strikes people between 30 and 60 years old; however, it can occur in adults at any age.

The global SARIL-RA clinical development program, which evaluated Kevzara®, incorporated data from more than 3,300 adults with moderately to severely active RA who had an inadequate response to previous treatment regimens. In two pivotal Phase 3 clinical trials (MOBILITY study in methotrexate inadequate responders and TARGET study in inadequate responders to anti-TNF treatment), Kevzara® plus background disease modifying anti-rheumatic drugs (DMARDs) demonstrated statistically significant, clinically-meaningful improvements.

In May 2017, the FDA approved Kevzara® for the treatment of adult patients with moderately to severely active RA who have had

an inadequate response or intolerance to one or more DMARDs, such as methotrexate. In June 2017, the European Commission granted marketing authorization for Kevzara® in combination with methotrexate for the treatment of moderately to severely active RA in adult patients who have responded inadequately to or who are intolerant to one or more DMARDs, such as methotrexate.

Kevzara® was launched in Canada in February 2017, in the US in June 2017, and in Germany, the Netherlands and the UK during the second half of 2017.

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

Sarilumab is being evaluated in Phase II studies in children and adolescents with polyarticular-course juvenile idiopathic arthritis (JIA) and with systemic JIA.

d) Oncology

Jevtana®

Jevtana® (cabazitaxel), a cytotoxic agent, is a semi-synthetic taxane promoting tubulin assembly and stabilizing microtubules, approved in combination with prednisone for the treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.

Jevtana® was granted marketing authorization by the FDA in June 2010, by the European Commission in March 2011, and in Japan in July 2014. The product is now approved in over 85 countries.

The main countries contributing to sales of Jevtana® in 2017 were the US, France, Germany, Japan, Italy and Spain.

Taxotere®

Taxotere® (docetaxel), a taxoid class derivative, inhibits cancer cell division by essentially freezing the cell s internal skeleton, which is comprised of microtubules. Microtubules assemble and disassemble during a cell-division cycle. Taxotere® promotes their assembly and blocks their disassembly, thereby preventing many cancer cells from dividing, which ultimately results in destroying many cancer cells.

Taxotere® is available in more than 90 countries as an injectable solution. It has been approved for use in 11 indications in five different tumor types (breast, prostate, gastric, lung, and head and neck).

Generics of docetaxel have been launched globally.

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

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Eloxatin®

Eloxatin® (oxaliplatin) is a platinum-based cytotoxic agent. Eloxatin®, in combination with infusional administration of two other chemotherapy drugs, 5-fluorouracil/leucovorin (the FOLFOX regimen), is approved by the FDA for adjuvant treatment of people with stage III colon cancer who have had their primary tumors surgically removed. This approval was based on evidence of an improvement in disease-free survival after four years.

Eloxatin® is in-licensed from Debiopharm and is marketed in more than 70 countries worldwide.

Generics of oxaliplatin have been launched globally.

Thymoglobulin®

Thymoglobulin® (anti-thymocyte Globulin) is a polyclonal anti-human thymocyte antibody preparation that acts as a broad immunosuppressive and immunomodulating agent. The product s primary mechanism of action is T-cell depletion, which is complemented by a host of other immunomodulating effects. Thymoglobulin® is currently marketed in over 65 countries. Depending on the country, Thymoglobulin® is indicated for the treatment and/or prevention of acute rejection in organ transplantation; immunosuppressive therapy in aplastic anemia; and the treatment and/or prevention of Graft-versus-Host Disease (GvHD) after allogeneic hematopoietic stem cell transplantation.

The main countries contributing to Thymoglobulin® sales in 2017 were the US, China, France, Japan and South Korea.

Mozobil®

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

The largest market for Mozobil® is the US.

Zaltrap®

Zaltrap® (aflibercept/ziv-aflibercept) is a recombinant fusion protein which acts as a soluble decoy receptor that binds to Vascular Endothelial Growth Factor-A (VEGF-A), Vascular Endothelial Growth Factor-B (VEGF-B) and placental growth factor (PIGF), preventing the bound VEGF from binding to their native receptors. VEGF-A is one of the mediators contributing to angiogenesis. VEGF-B and PlGF, related growth factors in the VEGF family, may contribute to tumor angiogenesis as well.

The FDA approved Zaltrap® in August 2012 for use in combination with FOLFIRI (chemotherapy regimen made of 5-fluorouracil/leucovorin/irinotecan), in patients with metastatic colorectal cancer (mCRC) that is resistant to or has progressed following an oxaliplatin-containing regimen. To avoid confusion with Eylea®, the

FDA assigned a new name, ziv-aflibercept, to the active ingredient. The European Commission approved Zaltrap® (aflibercept) in February 2013 to treat mCRC that is resistant to or has progressed after an oxaliplatin-containing regimen.

Zaltrap® is now approved in more than 70 countries worldwide. For additional information on Zaltrap® commercialization, see Item 5 Financial Presentation of Alliances Alliance Arrangements with Regeneron .

The principal markets for Zaltrap® are France, Germany, the US, Spain and Italy.

e) Diabetes

The prevalence of diabetes is expected to increase significantly by 2030, reflecting multiple socio-economic factors including sedentary lifestyles, excess weight and obesity, unhealthy diet and an aging population.

Our main diabetes products are Lantus® and Toujeo®, long acting analogs of human insulin; Apidra®, a rapid acting analog of human insulin; Insuman®, a range of human insulin; Adlyxin®/Lyxumia® (lixisenatide), a once-daily injectable prandial GLP-1 receptor agonist; Soliqua 100/33 / Suliqua , an injectable once-daily insulin glargine and lixisenatide combination; and Admelog®/Insulin lispro Sanofi®, follow-on/biosimilar of insulin lispro, a rapid-acting insulin analog.

Lantus®

Lantus® (insulin glargine) is a long-acting analog of human insulin, indicated for once-daily subcutaneous administration in the treatment of adult patients with type 2 diabetes who require basal insulin for the control of hyperglycemia, and for adult and pediatric patients (label extension for pediatric use was granted in the EU in 2012) aged two years and over with type 1 diabetes.

Lantus® is the most-studied basal insulin, with 16 years of clinical evidence in diabetes treatment and a well-established safety profile.

Lantus® can be administered subcutaneously using syringes or specific pens including:

- Lantus® SoloSTAR®, a pre-filled disposable pen available in over 120 countries worldwide, that combines a low injection force of up to 80 units per injection with ease of use; and

AllSTAR®, a reusable insulin pen developed specially for people with diabetes in emerging markets, indicated for use with Sanofi s insulin portfolio. AllSTAR® is currently available in a dozen countries, mostly in emerging markets.

Lantus® is available in over 130 countries worldwide. The leading countries for sales of Lantus® in 2017 were the US, China, France and Germany.

A biosimilar of Lantus® from Eli Lilly and Company (Lilly) was launched in most European markets under the name Abasaglar® in

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2015; the same product was launched in the US in December 2016 as Basaglar®. It has also been launched in Japan and in several other countries worldwide. The FDA has granted tentative approval for Merck s follow-on glargine insulin, it was approved by the EMA in January 2017 but has not launched as of yet. Mylan s application for its follow-on glargine insulin is under FDA regulatory review and received a CHMP positive opinion in January 2018.

There are ongoing patent infringement proceedings in the US against Merck and Mylan. See Note D.22.b) to the consolidated financial statements included at Item 18 of this annual report and Item 8. Financial Information B. Significant changes of this annual report for more information.

Toujeo®

Toujeo® (insulin glargine 300 units/mL) has been granted marketing authorization by the FDA (February 2015); the European Commission (April 2015); and the Ministry of Health, Labor and Welfare (J-MHLW) in Japan, where its approved brand name is Lantus® XR (June 2015).

Toujeo® is available in Toujeo® SoloSTAR®, a disposable prefilled pen which contains 450 units of insulin glargine and requires one third of the injection volume to deliver the same number of insulin units as Lantus® SoloSTAR®. The maximum single injection dose of 80 IU meets the needs of the vast majority of patients on basal insulin in the US, who require 80 IU or less per day.

Toujeo® has now been launched in more than 40 countries. Toujeo® is currently pending marketing authorization with other health authorities around the world. The principal markets for Toujeo® are the US, Germany, Russia, Spain and Japan.

Apidra®

Apidra® (insulin glulisine) is a rapid-acting analog of human insulin, indicated for the treatment of adults with type 1 or type 2 diabetes for supplementary glycemic control. Apidra® has a more rapid onset and shorter duration of action than fast-acting human insulin and can be used in combination with long-acting insulins such as Lantus® for supplementary glycemic control at mealtimes. Apidra® can be administered subcutaneously using syringes or specific pens including the Apidra® SoloSTAR® disposable pen.

Apidra® is available in over 100 countries worldwide. The principal markets are the US, Germany, Japan, Italy and France.

Insuman®

Insuman® (human insulin) is a range of insulin solutions and suspensions for injection and is indicated for diabetes patients when treatment with insulin is required. Human insulin is produced by recombinant DNA technology in Escherichia coli strains. Insuman® is supplied in vials, cartridges, and pre-filled disposable pens (SoloSTAR®). The Insuman® range is comprised of rapid-acting insulin solutions (Insuman® Rapid and Insuman® Infusat)

that contain soluble insulin, an intermediate-acting insulin suspension (Insuman® Basal) that contains isophane insulin, and combinations of fast-acting and intermediate-acting insulins in various proportions (Insuman® Comb).

Insuman® is principally sold in emerging markets.

Adlyxin®/Lyxumia®

Adlyxin® or Lyxumia® (lixisenatide) is a once-daily injectable prandial GLP-1 receptor agonist and is indicated for the treatment of adults with type 2 diabetes to achieve glycemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycemic control.

In February 2013, the European Commission granted marketing authorization in Europe for Lyxumia®. On completion of pricing and reimbursement discussions, Sanofi initiated a phased launch of Lyxumia® in most EU countries. Lixisenatide was approved by the FDA in July 2016 under the brand name of Adlyxin® after the results of the ELIXA trial demonstrated cardiovascular safety in type 2 diabetes patients with high cardiovascular risk; Adlyxin® was launched in the US in January 2017. Lixisenatide is approved under the proprietary name Lyxumia® in more than 60 countries and marketed in over 40. Lixisenatide was in-licensed from Zealand Pharma A/S.

Soliqua 100/33 / Suliqua

Soliqua 100/33 or Suliqua is a once-daily fixed-ratio combination of insulin glargine 100 Units/mL, a long-acting analog of human insulin, and lixisenatide, a GLP-1 receptor agonist. It has been studied in a Phase III program of more than 1,900 patients.

The FDA approved Soliqua 100/33 in November 2016 for the treatment of adults with type 2 diabetes inadequately controlled on basal insulin (less than 60 units daily) or lixisenatide. Soliqua 100/33 is now available in the US (since January 2017) in a single pre-filled pen for once-daily dosing covering 15 to 60 units of insulin glargine 100 units/mL and 5 to 20 mcg of lixisenatide using SoloSTAR® technology, the most frequently used disposable insulin injection pen platform in the world.

In January 2017, the European Commission granted marketing authorization in Europe for Suliqua (the product s brand name in Europe) for use in combination with metformin for the treatment of adults with type 2 diabetes to improve glycemic control when this has not been provided by metformin alone or metformin combined with another oral glucose-lowering medicinal product or with basal insulin. In Europe, Suliqua is available in two pens providing different dosing options. Within Europe, Suliqua was launched in the Netherlands in May 2017 and in Hungary and Sweden in November 2017.

Applications for regulatory approval have also been submitted in several other countries and are being reviewed.

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Admelog® / Insulin lispro Sanofi®

Admelog® or Insulin lispro Sanofi® is a rapid-acting insulin similar to Humalog®, another insulin lispro 100 Units/mL. Admelog® was approved by the FDA in December 2017, and was also granted marketing authorization as a biosimilar (under the proprietary name Insulin lispro Sanofi®) by the European Commission in July 2017. It is used to improve blood sugar control in adults with Type 2 diabetes and adults and children (3 years and older) with Type 1 diabetes. The Admelog® clinical development program involved more than 1,000 adults living with type 1 or type 2 diabetes.

Admelog® comes in both vials and the SoloStar pen, and was launched in the US in January 2018.

Integrated Care Solutions

Sanofi and Verily Life Sciences LLC (formerly Google Life Sciences), an Alphabet company, announced in September 2016 the launch of Onduo, a joint venture created through Sanofi and Verily s diabetes-focused collaboration. The joint venture is based in Cambridge, Massachusetts (United States). Onduo s mission is to help people with diabetes live full, healthy lives by developing comprehensive solutions that combine devices, software, medicine, and professional care to enable simple and intelligent disease management.

f) Cardiovascular Diseases

Praluent®

Praluent® (alirocumab) is a human monoclonal antibody (mAb) that blocks the interaction of proprotein convertase subtilisin/kexin type 9 (PCSK9) with low-density lipoprotein (LDL) receptors, increasing the recycling of LDL receptors and reducing LDL cholesterol levels.

Praluent® has been extensively studied through the ODYSSEY Phase III program with 16 global trials including more than 23,500 patients in more than 40 countries to evaluate the product s efficacy and safety across various high cardiovascular risk patients (due to but not limited to diabetes, family hypercholesterolemia or previous cardiovascular events) including patients with heterozygous familial hypercholesterolemia (HeFH), patients with primary hypercholesterolemia uncontrolled on statins and/or other lipid-modifying therapies, post acute coronary syndrome

(ACS) patients and as a monotherapy for patients who are unable to tolerate an effective dose of statins.

The effect of Praluent® on cardiovascular morbidity and mortality within the post ACS patient population is being investigated in the ODYSSEY OUTCOMES trial. Results are expected in the first quarter of 2018.

Praluent® has been granted marketing authorization by the FDA (July 2015), the European Commission (September 2015) and the Japanese Ministry of Health, Labor and Welfare (J-MHLW) (July 2016). Praluent® is indicated as an adjunct to diet and

maximally tolerated statin therapy in certain adult patients with uncontrolled LDL cholesterol. Praluent® is available in 75 mg and 150 mg dose injections for self-administration every two weeks.

Praluent® has been approved in more than 50 countries and launched in more than 30 countries including the US, Canada, Japan, Germany, the UK, Spain, Mexico and the UAE.

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

There are ongoing patent infringement proceedings in several countries initiated against us and Regeneron Pharmaceuticals, Inc. by Amgen relating to Praluent® in which Amgen has requested injunctive reliefs. See Note D.22.b) to the consolidated financial statements included at Item 18 of this annual report.

Multaq®

Multaq® (dronedarone) is an oral multichannel blocker with anti-arrhythmic properties for prevention of atrial fibrillation recurrences. Multaq® is among the most extensively studied anti-arrhythmic drugs in atrial fibrillation: it demonstrated a unique cardiovascular outcome benefit in the ATHENA study and effective rhythm control in the EURIDIS and ADONIS studies which was confirmed in real world investigations.

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

g) Established Prescription Products

Plavix® / Iscover®

Plavix® or Iscover® (clopidogrel bisulfate), a platelet adenosine diphosphate (ADP) receptor antagonist with a rapid onset of action that selectively inhibits platelet aggregation induced by ADP, is indicated for the prevention of atherothrombotic events in patients with a history of recent myocardial infarction (MI), recent ischemic stroke or established peripheral arterial disease (PAD).

Plavix® is indicated for patients with acute coronary syndrome (ACS):

For patients with non-ST-segment elevation ACS, including unstable angina/nonQ-wave myocardial infarction, Plavix® has been shown to decrease the rate of a combined endpoint of cardiovascular death, MI or stroke, as well as the rate of a combined endpoint of cardiovascular death, MI, stroke, or refractory ischemia. This applies equally to patients who are to be managed medically, and those who are to be managed with percutaneous coronary intervention (with or without stent) or coronary artery bypass grafting.

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For patients with ST-segment elevation acute myocardial infarction, Plavix® has been shown to reduce the rate of death from any cause and the rate of a combined endpoint of death, re-infarction or stroke.

Plavix® is also indicated in combination with acetylsalicylic acid (ASA) for the prevention of atherothrombotic and thromboembolic events in atrial fibrillation, including stroke.

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

Plavix® or Iscover® are marketed in more than 80 countries. For additional information on the commercialization of these products, see Item 5. Financial Presentation of Alliances Alliance Arrangements with Bristol-Myers Squibb .

A number of generics have been launched in Europe, the US and other markets. In Japan, generics were launched in June 2015 for the stroke indication, in October 2015 for MI and in December 2016 for the PAD indication, the last protected indication.

Plavix® is the leading anti-platelet in the Chinese market. The main countries contributing to sales of Plavix® / Iscover® in 2017 were China and Japan.

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

Lovenox® / Clexane®

Lovenox® or Clexane® (enoxaparin sodium) is registered for a wider range of clinical indications than any other low molecular weight heparin (LMWH). Its comprehensive clinical dossier has demonstrated a favorable risk-benefit ratio, notably in the prophylaxis and treatment of venous thromboembolism and in the treatment of acute coronary syndrome. In the prevention of venous thromboembolism, the use of Lovenox® continues to grow, particularly in prophylaxis of deep vein thrombosis (DVT) in patients hospitalized for an acute medical condition.

In the US, three enoxaparin generics have been approved in addition to our own authorized generic. In the EU, the European Commission granted marketing authorizations to two enoxaparin biosimilars in September 2016. In 2017, two enoxaparin biosimilars were launched in Germany and one in the UK and Italy. One national marketing authorization has been granted in Poland where this biosimilar is available. We expect biosimilars to be launched in

additional countries.

Lovenox® or Clexane® is marketed in more than 100 countries.

Aprovel® / Avapro® / Karvea®

Aprovel® or Avapro ® or Karvea® (irbesartan) is an anti-hypertensive belonging to the class of angiotensin II receptor

antagonists. These highly effective and well tolerated antagonists act by blocking the effect of angiotensin II, the hormone responsible for blood vessel contraction, thereby enabling blood pressure to return to normal. In addition to Aprovel® / Avapro® /Karvea®, we also market CoAprovel® /Avalide® / Karvezide®, a fixed-dose combination of irbesartan and hydrochlorothiazide (HCTZ), a diuretic that increases the excretion of water and sodium by the kidneys and provides an additional blood pressure lowering effect.

Aprovel® and CoAprovel® tablets are available in a wide range of dosages to fit the needs of patients with different levels of hypertension severity.

Aprovel® is indicated as a first-line treatment for hypertension and for the treatment of nephropathy in hypertensive patients with type 2 diabetes. CoAprovel® is indicated for patients whose blood pressure is not adequately controlled with a monotherapy, but also as initial therapy in patients at high risk or with markedly high baseline blood pressure or who are likely to need multiple drugs to achieve their blood pressure goals.

A fixed-dose combination with amlodipine (Aprovasc®) has been launched in several emerging market countries.

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

A number of generics have been launched in Europe, the US and other markets.

The main countries contributing to sales of Aprovel® / Avapro® / Karvea® in 2017 were China and Japan.

Renagel® and Renvela®

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

In the US, there are an estimated 395,000 dialysis patients, approximately 90% of whom receive a phosphate binder. There are an estimated 350,000 dialysis patients in the EU and 65,000 in Brazil. In the EU, Renvela® is also approved to treat CKD patients not on dialysis.

Renagel® and Renvela® are marketed in more than 85 countries. In Japan and several Pacific Rim countries, Renagel® is marketed by Chugai Pharmaceutical Co., Ltd and its sublicensee, Kyowa Hakko Kirin Co., Ltd.

In the US, five sevelamer carbonate tablets generics and one sevelamer carbonate powder generic have been approved. In

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October 2017, Sanofi launched an authorized generic of Renvela® / Renagel® on the US market. Generics of sevelamer carbonate are currently marketed in various European countries. As of December 31, 2017, there are no generics of sevelamer hydrochloride approved in either Europe or in the US. We anticipate the first approvals of generics of sevelamer hydrochloride in the US in 2018.

The main countries contributing to sales of Renagel® and Renvela® in 2017 were the US, France, China, Saudi Arabia and Canada,

Allegra® / Telfast®

Allegra® or Telfast® (fexofenadine hydrochloride) is a long-lasting (12- and 24-hour) non-sedating prescription anti-histamine for the treatment of seasonal allergic rhinitis (hay fever) and uncomplicated hives. It offers patients significant relief from allergy symptoms without causing drowsiness.

We also market Allegra-D® 12 Hour and Allegra-D® 24 Hour, anti-histamine/decongestant combination products with an extended-release decongestant for effective non-drowsy relief of seasonal allergy symptoms, including nasal congestion. This combination is marketed in Japan under the Dellegra® brand name.

Generics of most forms of Allegra® / Telfast® have been approved in our major markets.

In the US, the Allegra® family moved to over-the-counter (OTC) use in adults and children aged two and over in 2011. Allegra® was also launched on the OTC market in Japan in November 2012, though it also remains available on prescription. See B.3. Consumer Healthcare below.

Allegra® / Telfast ® is marketed in approximately 80 countries. The largest market for prescriptions of Allegra® is Japan, where competing generics entered the market in early 2013.

Stilnox® / Ambien® / Myslee®

Stilnox® (zolpidem tartrate) is indicated for the short-term treatment of insomnia. Stilnox® rapidly induces sleep that is qualitatively close to natural sleep and devoid of certain side effects that are characteristic of the benzodiazepine class as a whole. Its action lasts for a minimum of six hours and it is generally well tolerated, allowing the patient to

awaken without notably impaired attention, alertness or memory throughout the day.

Stilnox® is marketed in over 100 countries. It is available under the brand name Ambien® / Ambien®CR in the US and Myslee® in Japan, where it is co-promoted jointly with Astellas.

Stilnox® and Ambien CR® are subject to generic competition in most markets, including the US, Europe and Japan.

In 2017, the main countries contributing to Stilnox® /Ambien® / Myslee® sales were Japan and the US.

Synvisc® / Synvisc-One®

Synvisc® and Synvisc-One® (hylan G-F 20) are viscosupplements used to treat pain associated with osteoarthritis. Synvisc® is indicated for the treatment of pain associated with osteoarthritis of the knee, hip, ankle, and shoulder joint in countries that have adopted CE marking, and for pain due to knee osteoarthritis in the US. Synvisc-One® is approved for use in patients with osteoarthritis of the knee in the US and countries that require CE marking. Currently the main viscosupplementation market is for the treatment of pain associated with osteoarthritis of the knee.

Synvisc® is a triple-injection product and Synvisc-One® a single-injection product. Both are administered directly into the intra-articular space of the joint to temporarily restore synovial fluid.

In 2017, the main countries contributing to Synvisc® and Synvisc-One® sales were the US, Mexico, Brazil and Canada.

Depakine®

Depakine® (sodium valproate) is a broad-spectrum anti-epileptic that has been prescribed for more than 40 years and remains a reference treatment for epilepsy worldwide.

Depakine® is also a mood stabilizer, registered in the treatment of manic episodes associated with bipolar disorder[(1)].

Depakine® is marketed in over 100 countries. We no longer hold any rights to Depakine® in the US, and sodium valproate generics are available in most markets.

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

h) Generics

As announced, we carefully reviewed all options for our European Generics business in 2016. Following that detailed review of the business, we have taken a definitive decision to initiate a carve-out process of our generics business in Europe. Signing of definitive transaction agreements[(2)] on the divestiture of European Generics is expected in the third quarter of 2018. We have also confirmed our commitment to our Generics business in other parts of the world, and will further focus on emerging markets in order to develop this business in those countries.

B.3. Consumer healthcare

With the strategic transaction between Boehringer Ingelheim (BI) and Sanofi, closed in most markets on January 1, 2017, Sanofi acquired BI s CHC business in most markets. The deal enhanced our position in four strategic categories Allergy Cough & Cold, Pain, Digestive and Nutritionals and enabled us to achieve critical scale and strengthen our geographical presence.

(1) In some countries this indication is branded differently (eg Depakote® in France).
(2) Following completion of the dialogue with employee representatives.

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

Allergy Cough & Cold

Allegra® is a range of fexofenadine HCl based products. Fexofenadine is an antihistamine for relief from allergy symptoms including sneezing, runny nose, itchy nose or throat, and itchy, watery eyes. Allegra® OTC is mainly sold in the US, Brazil, Australia, Japan, India and in more than 80 countries across the world.

Xyzal® Allergy 24H is an oral antihistamine (levocetirizine dihydrochloride) for the relief of symptoms associated with seasonal and year-round allergies. Two formulations of Xyzal® are now approved for OTC use: 5 mg tablets for age 6 and older, and 0.5 mg/mL oral solution for age 2 and older. The product was made available in the US in 2017.

Mucosolvan® is a cough brand with many different formulations. The main product is a syrup which can be taken by adults and children in accordance with local dosing recommendations and registrations. It contains the mucoactive agent ambroxol; this stimulates synthesis and release of surfactant. It is sold in Germany, Russia, Philippines and various countries in Europe and Asia.

Pain

Doliprane® offers a range of paracetamol/acetaminophen-based products for pain and fever with a wide range of dosage options and pharmaceutical forms, and is sold mainly in France and various African countries.

The Buscopan® range (hyoscine butylbromide) has an antispasmodic action that specifically targets the source of abdominal pain and discomfort. It is sold across the globe.

Digestive

Dulcolax® products offer a range of constipation solutions from predictable overnight relief to comfortable natural-feeling relief. The products are sold in over 80 countries. Dulcolax® tablets contain the active ingredient bisacodyl, which works directly on the colon to produce a bowel movement.

Enterogermina® is a probiotic in the form of a drinkable suspension in 5 ml bottles or capsules containing two billion Bacillus clausii spores, and also powder sachets (six billion spores). Enterogermina® is indicated for the maintenance and restoration of intestinal flora in the treatment of acute or chronic intestinal disorders. Enterogermina® is sold primarily in Europe and in Latin America and parts of Asia.

Essentiale® is a natural soybean remedy to improve liver health. It is composed of essential phospholipids extracted from highly purified soya and contains a high percentage of phosphatidylcholine, a major component of the cell membrane. Essentiale® is used in fatty liver disease and is sold mainly in
Russia, Eastern Europe, various countries in Southeast Asia, and China.

Zantac® products are for the prevention and relief of heartburn. Zantac® is sold in the US and Canada.

Nutritionals

Pharmaton® is a range of products which contain vitamins, minerals and standardized Ginseng Extract G115. Pharmaton® is sold mainly in Latin America, the Middle East and Southeast Asia.

Other

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

B.4. Vaccine products

Sanofi Pasteur, the vaccines division of Sanofi, is a world leader in the vaccine industry providing more than one billion doses of vaccines each year and making it possible to immunize more than 500 million people worldwide per year against diseases such as polio or influenza.

In Europe, Sanofi Pasteur s vaccine products were historically developed and marketed by Sanofi Pasteur MSD (SPMSD), a joint venture that served 19 countries, created in 1994 and held equally by Sanofi Pasteur and Merck & Co., Inc. (Merck). The vaccines market having undergone significant changes since the creation of SPMSD, Sanofi Pasteur and Merck decided to adjust their strategic priorities and terminated the SPMSD joint venture at the end of December 2016, reintegrating their European vaccine activities into their own operations. We successfully reintegrated our European vaccine portfolios into our company s operations which allowed us to drive significant growth.

Sanofi Pasteur is a key supplier to publicly funded international markets such as UNICEF, the Pan American Health Organization (PAHO) and the Global Alliance for Vaccines and Immunization (GAVI).

The Sanofi Pasteur portfolio includes the following vaccines:

a) Polio, Pertussis and Hib pediatric vaccines

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

Pentaxim®, a pediatric combination vaccine protecting against diphtheria, tetanus, pertussis, polio and *Haemophilus influenzae* type b (Hib), was first marketed in 1997. To date, almost 300 million doses of Pentaxim® have been distributed in over

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100 countries, and the vaccine has been included in the national immunization programs of 24 countries.

Hexaxim® is the only fully liquid, ready-to-use 6-in-1 (hexavalent) pediatric vaccine that provides protection against diphtheria, tetanus, pertussis, polio, Hib and hepatitis B. In 2013, the EMA approved this hexavalent pediatric vaccine in the EU, where it is sold under the brand name Hexyon® in Western Europe and under the brand name Hexacima® in Eastern Europe. The rollout of this new hexavalent vaccine began in July 2013 in Germany and has since ramped up significantly, with 30 countries having launched Hexaxim® in their public or private immunization programs. In December 2014, the WHO granted prequalification status to Hexaxim® in a one-dose vial presentation. Hexaxim® is the only combination vaccine including acellular pertussis (acP) and inactivated polio vaccines (IPV) currently prequalified by the WHO.

In 2017, Sanofi Pasteur in partnership with Merck made its PR5i hexavalent combination vaccine available on the market under the trademark Vaxelis®. The PR5i hexavalent combination vaccine is under regulatory review in the US. PR5i antigens are manufactured by Sanofi Pasteur (diphtheria, tetanus, pertussis (5acP) and polio (IPV)), and by Merck (Hib and hepatitis B).

Pentacel®, a pediatric combination vaccine protecting against five diseases (diphtheria, tetanus, pertussis, polio and Hib), was launched in the US in 2008. Supply limitations have been lifted.

Quadracel®, launched in the US in January 2017, is a combination vaccine against diphtheria, tetanus, pertussis and polio. It is used as a booster to be administered as the fifth dose in the primary series of vaccines, allowing children to complete the entire childhood schedule with as few injections as possible.

Shan5®, developed by Shantha, is a fully-liquid 5-in-1 vaccine protecting against five diseases (diphtheria, tetanus, pertussis, polio and hepatitis B). Following improvements made to key manufacturing steps in the production of the antigen components of the vaccine, Shan5® regained its prequalification from the WHO (which provides access to the product in low-income countries) in May 2014, and was launched in the Indian market in the last quarter of 2014. Shan5® has been retained for the GAVI/UNICEF tender for the 2017-2019 period.

Sanofi Pasteur is the world s leading developer and manufacturer of polio vaccines, with both oral polio vaccines (OPVs) and injectable inactivated polio vaccines (IPVs) in its portfolio. Sanofi Pasteur s polio production capacity and historic commitment have enabled us to serve as an important industrial partner in helping to achieve the goal of

worldwide polio eradication. The combined use of OPVs and IPVs is expected to improve the level of protection in countries threatened by the possible resurgence of polio. In November 2013, GAVI announced its support for the introduction of IPV in the national immunization programs of the world s 71 poorest countries. The WHO expert group on immunization recommended that all countries introduce at least one dose of IPV in their routine immunization schedule by the first half of 2016. In September 2014, Nepal became the first GAVI supported country to introduce IPV. By the end of 2016, all 71 eligible countries had been approved for IPV support and 53

had completed their introductions, with the remaining countries to complete their introductions in the next several years. Sanofi Pasteur continues to partner with public health authorities, supplying much-needed vaccines and making substantial efforts to register Imovax® Polio, Shan IPV Polio and bivalent OPV in an impressive number of countries in record time. As of today, polio remains endemic in three countries: Afghanistan, Pakistan and Nigeria.

b) Influenza Vaccines

Sanofi Pasteur is a world leader in the production and marketing of influenza vaccines, with over 200 million doses delivered in 2017. In recent years, demand for influenza vaccine has experienced strong growth in many countries, particularly in the US, Brazil and Mexico. Sanofi Pasteur expects the global demand for influenza vaccines to continue to grow within the next decade due to increased disease awareness, growth in emerging markets, and expanded recommendations by governmental and advisory bodies to be vaccinated against seasonal influenza.

Sanofi Pasteur has two distinct influenza vaccines that are sold globally: Fluzone® and Vaxigrip®.

Fluzone® High-Dose vaccine, launched in the US in 2010, was specifically designed to generate a more robust immune response against influenza in people aged 65 and older and provide greater protection against influenza. In November 2014, the FDA changed the prescribing information for Fluzone® High-Dose to document its superior clinical benefit compared to the standard Fluzone® dose (the high-dose vaccine was 24% more effective than standard Fluzone® in a large-scale efficacy study).

Fluzone® Quadrivalent is a quadrivalent inactivated influenza vaccine containing two type A antigens and two type B antigens. Compared to the trivalent influenza vaccine, the addition of a second B strain to the vaccine provides increased protection against the most prevalent circulating strains. Fluzone® Quadrivalent/FluQuadri® is available in 24 countries for children aged over six months, adolescents and adults.

Vaxigrip® is a trivalent vaccine licensed in over 150 countries globally for people aged six months and over. A quadrivalent formulation of Vaxigrip® (QIV) for people aged 3 years and over was licensed in 2016 and launched in more than 20 countries in 2017. Vaxigrip® QIV in the 6 to 35 months age group was approved in Europe in December 2017.

In 2017, Sanofi completed the acquisition of Protein Sciences, a vaccines biotechnology company. Through the acquisition, Sanofi Pasteur added to its US portfolio Flublok® (a quadrivalent influenza vaccine for adults age 18 and over), the only recombinant protein-based influenza vaccine approved by the FDA.

c) Adult Booster Vaccines

Many countries now recommend pertussis immunization for adolescents and adults. These recommendations, combined with immunization awareness initiatives, have led to increased pertussis vaccination rates in these populations in recent years.

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Adacel® is the first trivalent adolescent and adult booster offering protection against diphtheria, tetanus and pertussis. It also reduces exposure from infants who are not immunized or only partially immunized.

Repevax® (also marketed under the trademark Adacel-Polio®) is a combination vaccine that provides protection against diphtheria, tetanus, pertussis and polio.

d) Meningitis and Pneumonia Vaccines

Menactra® is the first quadrivalent conjugate vaccine against meningococcal meningitis, which is considered the deadliest form of meningitis in the world. Menactra® is now indicated for people aged nine months through 55 years in the US, Canada, several Middle Eastern countries such as Saudi Arabia, and numerous other countries in all regions of the world. In most markets, a conjugated quadrivalent vaccine like Menactra® offers the best value proposition by protecting against four of the most common serogroups: A, C, Y, and W-135.

e) Travel and Endemic Vaccines

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

In 2009, Shantha launched Shanchol®, the first oral cholera vaccine produced in India for use in children and adults. Shanchol® received WHO prequalification in 2011. In 2013, the first oral cholera vaccine stockpile (which Shanchol® is part of) was created by the WHO, to respond to outbreaks and vaccine needs in areas of heightened risk.

IMOJEV®, a Japanese encephalitis vaccine, was launched in Australia and Thailand in 2012. In 2014, IMOJEV® obtained an extension of indication for use in children aged nine months and over, and obtained WHO prequalification. IMOJEV® has been rolled out in endemic countries throughout Asia.

As regards yellow fever, we shipped a significant part of the outbreak prevention stockpile in record time in 2016 to support our WHO/UNICEF/GAVI partners in their fight against expansion of the ongoing outbreak, confirming our key role in combatting this important public health threat.

f) Dengue

Dengue fever constitutes a major public health and economic burden in the endemic areas of the Asia-Pacific region and in Latin America. More than 100 countries, representing nearly half of the world s population, are at risk. Over the last 50 years, the incidence of the disease has increased 30-fold, an alarming rate given there

was no specific treatment available. In response to this global threat, which can impact children, adolescents and adults, the WHO has set ambitious objectives to reduce the burden of the disease on society. One of these objectives is to reduce morbidity by 25% and mortality by 50% by 2020. Surveillance data from some endemic countries indicate that between 70 and 90 percent of people will have been exposed to dengue at least once by the time they reach adolescence. Following 20 years of innovative research and collaboration with local at-risk communities and dengue scientists around the world, Sanofi Pasteur has developed a dengue vaccine candidate and embarked on a global, multinational clinical development program.

Dengvaxia® has been approved in 19 countries to date: Argentina, Australia, Bangladesh, Bolivia, Brazil, Cambodia, Costa Rica, El Salvador, Guatemala, Honduras, Indonesia, Malaysia, Mexico, Paraguay, Peru, the Philippines (temporarily suspended for one year in December 2017: see below), Singapore, Thailand and Venezuela. Dengvaxia® is currently indicated in most of the countries for individuals aged 9 or older living in a dengue-endemic area. In this indicated population, Dengvaxia® has been shown to prevent 93% of severe disease and 80% of hospitalizations due to dengue over the 25-month phase of the large-scale clinical studies conducted in 10 countries in Latin America and Asia where dengue is widespread.

On November 29, 2017 Sanofi announced results of a new analysis of long-term Dengvaxia® data which found differences in vaccine performance based on prior dengue infection. Sanofi proposed that health authorities update information provided to physicians and patients on its dengue vaccine requesting that healthcare professionals assess the likelihood of prior dengue infection in an individual before vaccinating with Dengvaxia®. For individuals who have not been previously infected by dengue virus, vaccination with Dengvaxia® should not be recommended. This update is being implemented in any relevant countries (excluding the Philippines).

Based on up to six years of clinical data, the new analysis evaluated long-term safety and efficacy of Dengvaxia® in people who had been infected with dengue prior to vaccination and those who had not. The analysis confirmed that Dengvaxia® provides persistent protective benefit against dengue fever in those who had prior infection. For those not previously infected by dengue virus, however, the analysis found that in the longer term, more cases of severe disease could occur following vaccination upon a subsequent dengue infection.

Dengvaxia® had already been launched in two public vaccination programs: one in Parana State (Brazil), and one public program targeting students in public schools in the Philippines. In December 2017, the Philippines put the Dengvaxia® vaccine campaign on hold and temporarily suspended the Dengvaxia license for one year. Brazil s Parana state has continued with the program.

In the Philippines Sanofi has bought back unused doses of Dengvaxia® following the announcement of label update in November.

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B.5. Global research & development

The mission of Sanofi s R&D organization is to discover and develop therapies that prevent, treat or cure diseases. Our day-to-day commitment is to respond to patients needs and to provide them with adapted therapeutic solutions in order to improve their well-being and extend their lives.

Sanofi R&D is a global organization integrating all R&D activities across three major segments: Pharmaceuticals, Vaccines and Consumer Healthcare.

To carry out our mission and maximize its impact, we strive to bring innovation to patients and to build a pipeline of high value projects. Our approach is neutral to the source of innovation, whether it comes from internal research or external partners.

Medical value, scientific quality and operational effectiveness are the three drivers that underpin our strategy. The focus is on projects that have the potential to provide the best added medical value to patients and payers and to reduce healthcare costs for society.

By using a translational medicine approach, ensuring that research hypotheses are validated in humans as early as possible, R&D can translate basic research findings into medical practice more quickly and efficiently and improve the scientific quality of our projects.

B.5.1. Pharmaceuticals

B.5.1.1. Organization

Our Global R&D organization is committed to responding to the real needs of patients by providing them with safe, cost-effective and appropriate therapeutic solutions, improving their access to treatment and delivering better health outcomes. In offering new solutions to patients, it is vital to understand the complexity of human diseases, to sustain innovation and to foster scientific excellence without losing sight of the need for operational efficiency.

To meet these challenges, Sanofi R&D has evolved towards an integrated organization encompassing a wide range of therapeutic areas aligned with the Global Business Units (GBUs), which are dedicated to supporting our commercial

operations and reflect our strengths and expertise as well as the most pressing health issues.

For Pharmaceuticals, six therapeutic areas (TAs) have been rolled out:

- Diabetes, Cardiovascular and Metabolism
- Oncology
- Immunology & Inflammation
- Multiple Sclerosis, Neurology & Gene Therapy
- Infectious Diseases
- Rare Diseases

These TAs drive a portfolio of R&D projects, ensuring a strategically coherent approach and flawless implementation.

Each TA has its own experts who are responsible for analyzing medical needs, defining project strategy and development plans, and leading the Global Project Teams.

Our R&D Operations department handles all operational activities and delivers effective development through integrated, collaborative project teams. Those teams harness high caliber functional expertise and the most appropriate technologies across chemical, biological and pharmaceuticals operations, translational medicine and early development and clinical sciences.

In Research, a dedicated, integrated platform has been introduced that works across multiple disease areas and methods. This platform drives collaboration with internal and external partners to translate human biology research and state-of-the art technologies and processes into novel drug targets and world-class safe and effective drugs.

Sanofi s R&D operations are concentrated in three major hubs: North America, Germany and France. These hubs help build our scientific intelligence network and facilitate connections and knowledge-sharing between in-house scientists, and with external partners and scientific communities, in order to accelerate our research activities.

B.5.1.2. Governance

Global Project Teams (GPTs) are responsible for developing project strategy and driving the execution of projects through functional sub-teams. GPTs are led by a Global Project Head (GPH) who works in collaboration with a Project Manager (PM), and are built around core functional team members representing each department collaborating in the development project.

Various committees assess product and project development across the R&D value chain, carry out in-depth scientific review, make go and no-go decisions and determine portfolio priorities.

Projects are assessed using two key criteria which allow management to rapidly understand how the portfolio is performing in terms of innovation, unmet medical needs, risk and value:

- relative medical value, which encompasses the extent of the unmet need, the market dynamics and the likelihood of getting satisfactory market conditions; and

- science translation, which includes the level of innovation and translatability of the science including likelihood of development success.

The clinical portfolio is the result of decisions taken during these reviews, plus compounds entering the portfolio from the discovery phase or from third parties via acquisition, collaboration or alliances.

As described at Item 3. Key Information D. Risk Factors Risks Relating to Our Business research and development efforts may not succeed in adequately renewing the product portfolio and Risks Relating to the Group Structure and Strategy We may fail to successfully identify external business opportunities or realize the anticipated benefits from our strategic investments , our product development efforts are subject to the risks and uncertainties inherent in any new product development program.

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B.5.1.3. Products

The clinical portfolio for new products as of February 7, 2018 can be summarized as follows; where several indications are being developed for one product, each indication is regarded as a separate project and specified individually in the table below.

For information related to Kevzara®, Praluent®, Aubagio® and Lemtrada®, see Item 4. Information on the Company B. Business Overview B.2. Main Pharmaceutical Products .

	Phase I	**Phase II**	**Phase III /registration**
Diabetes	SAR438335	SAR425899	SAR341402 (T1 & T2 Diabetes)
		sotagliflozin (WHF[a] in Diabetes)	sotagliflozin (T1 & T2 Diabetes)
			efpeglenatide (T2 Diabetes)
Oncology	SAR408701	SAR566658 (TNBC[d])	isatuximab (3L RRMM[f] ICARIA)
	SAR439459	cemiplimab (BCC[e])	isatuximab (1-3L RRMM[g] IKEMA)
	SAR439859		isatuximab (1L NDMM[h] IMROZ)
	SAR439459+cemiplimab		cemiplimab (2L CC[i])
	SAR439859+palbociclib		cemiplimab (1L NSCLC[j])
	isatuximab+cemiplimab (RRMM[b])		cemiplimab (CSCC[k])
	isatuximab+CyBord (NDMM[c])		
Cardiovascular &	SAR247799	mavacamten	Praluent® (post ACS)

Metabolism	SAR440181	SAR407899	
Immunology &	SAR439794	SAR156597	dupilumab (asthma adults, 12+ years)
Inflammation	SAR440340	GZ389988	
			dupilumab (asthma, 6-11 years)
		dupilumab (EE[l])	
			Dupixent® (AD pediatrics[o])
		Kevzara® (pcJiA[m])	
			dupilumab (nasal polyposis)
		Kevzara® (sJiA[n])	
Multiple Sclerosis	SAR442168	venglustat (GPD[p])	Aubagio® (RMS ped.[q])
Neurology	SAR228810	SAR422459	Lemtrada® (RRMS ped.[r])
Ophthalmology	UshStat®		
Infectious diseases		ferroquine (combo OZ439)	
Rare diseases		olipudase alfa	GZ402666
		venglustat (Gaucher type3)	fitusiran
		venglustat (Fabry)	

(a) Worsening Heart Failure

(b) Relapsing and/or Refractory Multiple Myeloma

(c) Newly Diagnosed Multiple Myeloma

(d) Triple Negative Breast Cancer

(e) Basal Cell Carcinoma

(f) 3rd Line Relapsing and/or Refractory Multiple Myeloma

(g) 1st-3rd Line Relapsing and/or Refractory Multiple Myeloma

(h) 1st Line Newly Diagnosed Multiple Myeloma

(i) 2nd Line Cervical Cancer

(j) 1st Line Non-Small Cell Lung Cancer

(k) Cutaneous Squamous Cell Carcinoma

(l) Eosinophilic Esophagitis

(m) Polyarticular Juvenile Idiopathic Arthritis

(n) Systemic Juvenile Idiopathic Arthritis

(o) Atopic Dermatitis

(p) Gaucher related Parkinson s Disease

(q) Relapsing Multiple Sclerosis pediatric

(r) Relapsing Remitting Multiple Sclerosis pediatric

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

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

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

a) Diabetes

Sotagliflozin (SAR439954), an oral dual inhibitor of SGLT1/2, is in-licensed from Lexicon. Results of the Phase III program in type 1 diabetes were released in 2017. We expect to file for approval in the US in type 1 diabetes during the first half of 2018. A large Phase III program is currently ongoing to investigate the use of sotagliflozin for the treatment of type 2 diabetes. A Phase II study in diabetic patients with worsening heart failure is ongoing.

Efpeglenatide (SAR439977) is a long-acting GLP1 receptor agonist derived from our license agreement with Hanmi Pharmaceuticals. A Phase III development program in type 2 diabetes was initiated in December 2017.

Rapid Acting Insulin (SAR341402) is in Phase III for the treatment of type 1 and type 2 diabetes.

Dual GLP-1/glucagon receptor (SAR425899) entered Phase IIb in December 2016 for the treatment of patients with type 2 diabetes. Completion of Phase IIb is expected in the first quarter of 2018.

Dual GLP-1/GIP receptor agonist (SAR438335) is currently in Phase I for the treatment of patients with type 2 diabetes.

b) Cardiovascular & Metabolism

Mavacamten (SAR439152), a myosin inhibitor derived from our partnership with MyoKardia, has achieved proof of concept in treatment of obstructive hypertrophic cardiomyopathy in 2017 and will start a registration Phase IIb/III study in the second quarter of 2018.

SAR407899, a novel Rho-kinase inhibitor, started a Phase IIa Proof of concept study in October 2017 in patients with microvascular angina. Results are expected in January 2019.

SAR440181, an allosteric activator of cardiac myosin ATPase (positive ionotrope) small molecule designed to treat dilated

cardiomyopathy and derived from our partnership with MyoKardia, completed Phase Ia in 2017 and is starting Phase Ib in 2018.

SAR247799, a S1P1 agonist, entered Phase I in August 2016 in the treatment of cardiovascular diseases.

c) Oncology

Products in development

Isatuximab (SAR650984) is a monoclonal antibody which selectively binds to CD38, a cell surface antigen expressed in multiple myeloma cancer cells, and other hematological malignancies. Isatuximab is a collaboration compound derived from the Collaboration and License Agreement with ImmunoGen. Isatuximab kills tumor cells via multiple biological mechanisms including:

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

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

The program is currently in Phase III clinical development.

There are multiple studies ongoing in multiple myeloma (MM), including three pivotal Phase III trials.

The **ICARIA-MM** Phase III trial compares isatuximab in combination with pomalidomide and dexamethasone against pomalidomide and dexamethasone in patients with relapsed and refractory multiple myeloma.

The Phase III **IKEMA** trial is a randomized, open label, multicenter study assessing the clinical benefit of isatuximab combined with carfilzomib (Kyprolis®) and dexamethasone versus carfilzomib with dexamethasone in patients with relapsed and/or refractory multiple myeloma previously treated with one to three prior lines.

The Phase III **IMROZ** trial is a randomized, open-label, multicenter study assessing the clinical benefit of isatuximab in combination with bortezomib (Velcade®), lenalidomide (Revlimid®) and dexamethasone versus bortezomib, lenalidomide and dexamethasone in patients with newly diagnosed multiple myeloma not eligible for transplant.

A Phase I study in combination with cyclophosphamide, bortezomib and dexamethasone is ongoing in the treatment of adult patients newly diagnosed with MM not eligible for transplant.

A Phase I/II study in combination with cemiplimab in the treatment of patients suffering from RRMM should be initiated in the first quarter of 2018.

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Cemiplimab (SAR439684), a PD-1 inhibitor derived from our alliance with Regeneron, is currently in Phase IIb to support registration in the treatment of cutaneous squamous cell carcinoma. The dossier was filed end of February 2018.

A Phase II program in the treatment of basal cell carcinoma was initiated in July 2017.

Additional Phase III studies are also running in different indications:

- in the first-line treatment of patients with advanced or metastatic non-small cell lung cancer (NSCLC) whose tumors express PD-L1, versus Platinum Based Chemotherapy; and

- in the treatment of patients with recurrent or metastatic platinum-refractory cervical cancer. In this study, cemiplimab is assessed versus investigator s choice chemotherapy.

SAR566658 is an antibody drug conjugate (ADC) loaded with a maytansinoid derivative DM4 (huDS6-SPDB-DM4) targeting CA6. CA6 is a tumor specific epitope highly expressed on some solid tumors. The product is currently in Phase II in the treatment of triple-negative breast cancer.

SAR439859 is a potent, orally bioavailable, and selective estrogen receptor (ER) inhibitor that belongs to the SERD class of compounds. SAR439859 antagonizes the binding of estradiol to ER but also promotes the transition of ER to an inactive conformation that leads to receptor degradation (98%) at sub-nanomolar concentrations in tumor cells harboring either wild type or mutant ER. The compound is in Phase I in the treatment of metastatic breast cancer, in monotherapy and in combination with palbociclib.

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

SAR408701 is an antibody drug conjugate (ADC) that binds to CEACAM-5, a membrane glycoprotein originally identified as a surface marker on adenocarcinomas of the human gastrointestinal tract. A study is ongoing to evaluate the activity of the drug in the treatment of non-small-cell lung cancer, colorectal cancer and gastric cancer. In addition, there is an active Phase I trial in Japan.

Product discontinued in 2017

SAR428926, an antibody drug conjugate (ADC) binding to Lysosomal Associated Membrane Protein 1 (LAMP1), was discontinued in November 2017. The product was in Phase I.

Collaborations

Sanofi Oncology has a large number of collaborations and alliances to support its R&D portfolio.

In 2015, we entered into a strategic collaboration and license agreement with Regeneron focusing on cancer immunotherapy. The objective of the collaboration is to generate high value development candidates in the emerging field of immuno-oncology, providing us with an opportunity to expand and accelerate our development pipeline and build a strong position in one of the most attractive segments of the oncology market. To date cemiplimab (SAR439684), a PD-1 inhibitor monoclonal antibody derived from this collaboration, has entered Phase III clinical development.

Also in 2015, we entered into an exclusive strategic collaboration with the German biotech company BioNTech (Mainz) in the field of active immunization. The goal of the alliance is to discover and develop messenger RNA (mRNA) therapeutics for cancer immunotherapy by leveraging the scientific expertise of the two organizations. The first clinical candidate is expected to enter clinical trials in 2018.

These two ambitious alliances have the potential to address some of the unmet medical needs that remain in cancer treatment.

Sanofi Oncology has also established various alliances with leading academic cancer centers such as Institut Gustave Roussy, Institut Curie and the Dana Farber Cancer Institute, and with biotechnology companies like Immunogen and Evotec. We will also be partnering with the Foundation of the US National Institutes of Health (FNIH) in the Partnership for Accelerating Cancer Therapies (PACT).

In 2016, we entered into a collaboration with Innate Pharma to develop innovative bispecific antibody formats engaging natural killer (NK) cells to kill tumor cells, and a collaboration with Warp Drive Bio to develop drugs targeting human oncogenes including RAS. Both these collaborations are in line with our ongoing commitment to the discovery and development of new cancer drugs and therapeutic strategies that will make a difference in the lives of cancer patients.

d) Immunology & Inflammation

Main products in Phase III and in the registration phase

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

Atopic dermatitis: the product was approved by the FDA in March 2017 and by the European Commission in September 2017, and launched under the trade name Dupixent®. Several Phase III pediatric studies (6 months to 5 years, 6 to 11 years and 12-17 years) are currently ongoing.

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Asthma: the Phase III program in adults and children over 12 years was completed in 2017 and the dossier is currently in the submission phase. A Phase III study in children (6-11 years) is ongoing.

Nasal polyposis: the Phase III program consists of two pivotal trials of respectively 24 and 52 weeks. Their objective is to evaluate the efficacy of dupilumab compared to placebo on a background of mometasone furoate nasal spray (MFNS) in reducing nasal congestion/obstruction (NC) severity and endoscopic nasal polyp score (NPS) in patients with bilateral nasal polyposis. In addition the studies will evaluate as key secondary endpoints the reduction in computed tomography (CT) scan opacification of the sinuses, improvement in loss of smell and patient reported quality of life, and reduction in need for steroids or surgery.

Eosinophilic esophagitis: Positive results were obtained in the proof-of-concept study in 2017 and discussions are currently ongoing with the US health authorities regarding the Phase III program.

Main products in early stage

SAR156597 (humanized bi-specific monoclonal antibody targeting the cytokines IL-4 and IL-13) is in Phase IIA for the treatment of diffuse systemic sclerosis. Sanofi decided in 2017 to stop the development of the compound in idiopathic pulmonary fibrosis.

GZ389988 (TrKA) is a small molecule which inhibits binding of nerve growth factor (NGF) to its primary tyrosine receptor kinase A (TrkA), and is being developed as a treatment for symptoms resulting from osteoarthritis. The Phase IIa program initiated in August 2016 was completed in 2017 and the next steps are under discussion.

SAR440340, a human anti-IL33 monoclonal antibody derived from our alliance with Regeneron, has completed Phase I. Several Phase II studies are expected to start in 2018, in moderate-to-severe asthma, in atopic dermatitis and in chronic obstructive pulmonary disease.

SAR439794, a TLR4 agonist, entered Phase I in September 2016 for the treatment of peanut allergy.

Product discontinued in 2017

SAR100842, an LPA1 receptor antagonist, developed in systemic scleroderma, was discontinued in Phase IIa in September 2017.

e) Multiple Sclerosis, Neurology & Ophthalmology

Multiple sclerosis

SAR442168 (PRN2246), an orally administered Bruton s tyrosine kinase (BTK) inhibitor which was designed to access the brain and

spinal cord by crossing the blood-brain barrier and impact immune cell and brain cell signaling, started Phase I development in October 2017 in the treatment of multiple sclerosis.

Neurology

Venglustat (GZ402671), an orally administered brain penetrant glucosylceramide synthase (GCS) inhibitor, has completed Part 1 (dose escalation phase) of a Phase II study in patients with early-stage Parkinson s disease carrying a ß-glucocerebrosidase (GBA) gene mutation (GBA-PD) or other prespecified variant. Part 2 (treatment phase) of the study is due to start in early 2018. The product is also being developed in some rare disease indications described below.

SAR228810, an anti-protofibrillar Abeta monoclonal antibody, has completed the Phase I program in mild cognitive impairment due to Alzheimer s Disease (AD) and in mild AD. The next steps of development are under discussion. Biomarker studies are being performed.

Ophthalmology

SAR422459 is a gene therapy product which uses a lentivector gene delivery technology to introduce a functional ABCR gene into photoreceptors in patients with autosomal recessive Stargardt s disease, an orphan inherited condition that leads to progressive vision loss from childhood. The product is currently in Phase IIA.

UshStat® (SAR421869) is a gene therapy product which uses a lentivector gene delivery technology to introduce a functional MYO7A gene into the photoreceptors and retinal pigment epithelium (RPE) cells in patients with Usher 1B syndrome, an orphan inherited condition that leads to progressive visual field constriction and vision loss from childhood. A Phase I/IIA clinical study is ongoing.

Product discontinued in 2017

GZ402668 (GLD52), an IgG1 monoclonal antibody binding to CD52 (a cell surface antigen present at high levels on T and B lymphocytes) has been discontinued for further development in multiple sclerosis (MS) after Phase I due to strategic reprioritization.

f) Infectious Diseases

Ferroquine (OZ439) is a first in class combination for malaria, developed in collaboration with Medicines for Malaria Venture (MMV). Ferroquine is a new 4 amino quinoline being developed for the treatment of acute uncomplicated malaria, and is active against chloroquine sensitive and chloroquine resistant Plasmodium strains. Due to its long half-life it has the potential to be part of single dose cure regimens for the treatment of both

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P. vivax and P. falciparum malaria. OZ439 is a synthetic peroxide antimalarial drug candidate from MMV designed to provide a single dose oral cure in humans. A Phase IIB clinical study of the combination of the two products, conducted in adults and children with P. falciparum malaria, started in July 2015 in Africa and in October 2017 in Asia.

g) Rare Diseases

Main products in Phase III and in the registration phase

Alnylam collaboration: In October 2012, Genzyme entered into an exclusive license agreement with Alnylam, covering the ALN-TTR programs in the Asia-Pacific-Japan region. ALN-TTR01 and ALN-TTR02 Phase I results were published in the New England Journal of Medicine in August 2013. Results showed that RNAi therapeutics targeting transthyretin (TTR) achieved rapid, dose-dependent, durable, and specific knockdown of TTR, the disease-causing protein in TTR-mediated amyloidosis (ATTR). Genzyme s exclusive territory rights for the ALN-TTR programs were extended to the rest of the world excluding North America and Western Europe on January 14, 2014. The January 2014 agreement also included exclusive rights for Sanofi to opt into future Alnylam rare disease pipeline programs including fitusiran for which we exercised a regional option in September 2015 and then stepped up to a co-development, co-commercialization option on November 14, 2016. On January 6, 2018, the parties executed a strategic restructuring of the alliance to streamline and optimize development and commercialization of certain products. Specifically:

Sanofi will obtain global rights to fitusiran, currently in development for hemophilia A and B. Alnylam will receive royalties based on net sales of fitusiran products.

Alnylam will obtain global rights to its ATTR therapeutics programs, including patisiran and ALN-TTRsc02. Sanofi will receive royalties based on net sales of these ATTR amyloidosis products.

With respect to other products, the material terms of the 2014 Agreement remain unchanged.

Fitusiran (SAR439774 Alnylam (ALN-AT3): This is a program for development of a siRNA therapeutic to treat hemophilia (A and B), using a novel approach targeting antithrombin (AT) with AT

knockdown leading to increase in thrombin generation. The Phase III program (ATLAS) is being initiated with dosing of the first patients expected towards the end of the first quarter of 2018.

GZ402666 (Neo GAA) is a second generation enzyme replacement therapy targeting the treatment of Pompe disease. The Phase III program was launched in November 2016, with the COMET study targeting treatment naïve late onset Pompe disease patients. The Phase II mini-COMET study has enrolled its first patient in October 2017, targeting treatment experienced infantile onset Pompe disease patients.

Main products in early stage

GZ402665 (rhASM) olipudase alfa is an enzyme replacement therapy targeting the treatment of non-neurological manifestations of acid sphingomyelinase deficiency (ASMD), also known as Niemann-Pick B disease. An open label pivotal Phase I/II study in the pediatric population has been expanded to include additional younger patients. The Phase II/III trial to support registration in the adult population started enrolling patients in 2016.

Venglustat/GZ402671 (GCS inhibitor) is in development in Fabry Disease, Gaucher Disease type 3 (GD3) and Autosomal Dominant Polycystic Kidney Disease (ADPKD). The extension study of the Phase II trial for the treatment of Fabry disease is ongoing to understand the long term effects of venglustat therapy in Fabry patients. An observational study for the evaluation of Fabry Disease (PRO - Patient Reported Outcome) started in January 2017 and was fully enrolled by October 2017. A Phase II study in Gaucher disease type 3 (LEAP) is ongoing, and the first patient enrolled is about to reach one-year treatment. A Phase III pivotal study (SAVE-PKD) in rapidly progressive Autosomal Dominant Polycystic Kidney Disease (ADPKD) patients is planned to start in 2018.

B.5.2. Vaccines

Our Vaccines R&D is focused on developing new prophylactic vaccines and improving existing ones.

The Sanofi Pasteur R&D portfolio includes 13 vaccines currently in advanced development as shown in the table below. The portfolio is well balanced, with five vaccine products for novel targets and eight vaccines which are enhancements of existing vaccine products.

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PHASE I	PHASE II	PHASE III	REGISTRATION
Respiratory Syncytial Virus	**Tuberculosis**	**Fluzone® QIV HD**	**VaxiGrip® QIV IM**
RSV infant vaccine	Recombinant subunit vaccine	Quadrivalent inactivated influenza vaccine High dose	Quadrivalent inactivated influenza vaccine (6-35 months)
Herpes Simplex virus Type 2	**HIV**	**Men QuadTT**	**PR5i**
HSV-2 vaccine	Prevention of HIV infections in at-risk adults	Advanced generation meningococcal ACYW conjugate vaccine	DTP-HepB-Polio-Hib[b] Pediatric hexavalent vaccine (US)
	SP0232(8) mAb[a] Respiratory syncytial virus monoclonal antibody	**Pediatric pentavalent vaccine** DTP-Polio-Hib[b] Japan	
	Rabies VRVg Purified vero rabies vaccine		
	Adacel®+		

Tdap booster	
Shan6	
DTP-HepB-Polio-Hib[(b)] Pediatric hexavalent vaccine	

(a) Partnered and/or in collaboration Sanofi may have limited or shared rights on some of these products
(b) D=Diphtheria, T=Tetanus, P=Pertussis, Hib=Haemophilus influenzae b, HepB=Hepatitis B.

Enhancements of Existing Vaccines

Influenza vaccine: To sustain our global leadership in the development of influenza vaccines, our R&D efforts are focused on innovative approaches. In line with our drive to develop quadrivalent flu vaccines (see B.4. Vaccine Products), in August 2017 we completed the acquisition of Protein Sciences, a vaccines biotechnology company that has developed the baculovirus expression system technology (BEST) platform for the production of recombinant proteins. Protein Sciences has used this platform to develop and commercialize Flublok® Quadrivalent, a recombinant influenza vaccine indicated for active immunization of adults aged 18 and older against seasonal influenza.

Meningitis vaccine: *Neisseria meningitidis* bacteria are a leading cause of meningococcal disease in the US, Europe, the African meningitis belt and other endemic regions such as Brazil and Australia. Sanofi Pasteur is developing an advanced generation quadrivalent conjugated meningococcal vaccine. This vaccine uses an alternative technology to diphtheria conjugation as currently used in the commercialized vaccine. Phase II clinical trial results have demonstrated its safety and immunogenicity. The project is currently in Phase III.

Rabies vaccine: VRVg (VerorabVax®) is a next generation human rabies vaccines under development, aiming to replace worldwide both Sanofi Pasteur vaccines currently commercialized (Imovax® Rabies and Verorab). It will offer a purified human rabies vaccine, produced without animal or human material on vero cell. The recent data of the US Phase II clinical trial (VRV11) performed in healthy adults in post-exposure regimen with administration of HRIG, showed a clear dose ranging effect, leading us to consider

the highest dose for the next phase III studies. Overall, VRVg (high dose) shows similar safety profile and at least equivalent immune response to Imovax® Rabies.

Pediatric pentavalent vaccine for the Japanese market: Sanofi Pasteur, in partnership with Kitasato (KDSV) and Daiichi Sankyo (DS), is developing a pediatric pentavalent vaccine for the Japanese market. The vaccine includes diphtheria, tetanus and acellular pertussis (DTaP) from KDSV, and inactivated polio (IPV) and Hib from Sanofi Pasteur. It is anticipated that this product, to be distributed by DS, will be the first pentavalent pediatric combination vaccine in the Japanese market. It would serve as a primary series and booster vaccine for Japanese children up to two years old. The project is currently in Phase III.

PR5i (hexavalent vaccine): Sanofi Pasteur is co-developing with Merck & Co., Inc. (Merck) a hexavalent combination vaccine (PR5i 6-in-1 vaccine) to protect against diphtheria, tetanus, pertussis, polio, Hib and hepatitis B. A license application for this vaccine was submitted to the European Medicines Agency (EMA) by Sanofi Pasteur MSD (SPMSD) in January 2015. On December 17, 2015 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending marketing authorization for the product, to be commercialized as Vaxelis® in the European Union. On February 19, 2016, SPMSD was granted marketing authorization for Vaxelis®, and commercialization began in 2017 through a partnership between Merck and Sanofi Pasteur. A Biologics License

Application was submitted to the US FDA in August 2014, and on November 2, 2015 the FDA issued a Complete Response Letter (CRL) for PR5i which is to be commercialized through a partnership of Merck and Sanofi

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Pasteur. Sanofi Pasteur and Merck are currently reviewing the CRL and plan to further communicate with the FDA. PR5i is expected to be the first hexavalent vaccine in the US market.

Shan 6 is a cost-effective, all-in-one liquid hexavalent combination vaccine being developed for the Indian market and WHO pre-qualification. It comprises a detoxified whole-cell pertussis component as well as diphtheria toxoid, tetanus toxoid, Haemophilus influenza type b PRP-T, inactivated poliovirus types 1, 2, and 3 and hepatitis B virus components. A Phase I/II trial was initiated in India in October 2016, and Phase III preparations are underway.

Adacel+ (Pertussis vaccine): To sustain our global leadership in the development of pertussis vaccines, our R&D efforts are focused on developing an improved Tdap (tetanus toxoid, diphtheria toxoid, and 5-component Acellular pertussis containing formulation), for use in individuals aged 10 and over in the US market. The new formulation is being tested in Phase II trials.

New Vaccine Targets

Tuberculosis: Statens Serum Institute (SSI) of Denmark has granted Sanofi Pasteur a license to its technology for the use of certain fusion proteins in the development of a tuberculosis vaccine. The candidate vaccine is made up of recombinant protein units. Results from a 2008 Phase I trial found that the candidate vaccine was safe when administered to healthy adults living in a region of high endemic tuberculosis. A Phase I/II study in infants was initiated in South Africa in July 2013. A Phase II proof of concept study was initiated in young adolescents in South Africa in March 2014. Results are expected in 2018.

Herpes Simplex Virus: Herpes simplex virus type 2 is a member of the herpes virus family and as such establishes life-long infections, with latent virus established in neural ganglia. Although antivirals currently exist to treat infections, no vaccine exists, greatly limiting options in disease management. Our vaccine candidate is a live attenuated virus and is being assessed as a therapeutic and possibly prophylactic vaccine to reduce recurrence and transmission. In 2014, Sanofi Pasteur signed a contract with Immune Design Corp. to collaborate on the development of a therapeutic herpes simplex virus vaccine by exploring the potential of various combinations of agents.

HIV: Due to the enormity of the disease burden in developing countries and the potential for initial licensing of an efficacious vaccine in the developing world, Sanofi Pasteur is working in a pox-protein public-private partnership (P5) to document efficacy of a pox-protein based HIV prophylactic vaccine in South Africa. Specifically, following the modest success of RV144 (the first trial to show supporting evidence that vaccines could lower the risk of contracting HIV), the P5 partnership adopted a pox-protein based vaccine candidate as potentially providing greater protection for

South Africa and conducted a Phase I/II study (HVTN 100). This study met all pre-specified safety and immunogenicity criteria and supported moving the vaccine regimen to a pivotal efficacy study (HVTN702), which started on October 26, 2016 in South Africa and will continue until 2021. HVTN702 will not only assess the vaccine s

safety and efficacy, it will also help in discovering immune correlates of protection.

RSVi: Respiratory Syncytial Virus (RSV) is the most common cause of bronchiolitis in young children. Globally, RSV accounts for 22%-40% of lower tract respiratory illnesses, 50%-90% of bronchiolitis cases and 19%-40% of pneumonia cases, and causes up to 199,000 deaths each year. It is estimated that in the US alone, about 172,000 RSV hospitalizations occur each year in children under 5 years of age, resulting in significant healthcare costs. Sanofi Pasteur has signed a Cooperative Research and Development Agreement (CRADA) with the US National Institutes of Health (NIH) to develop a live attenuated RSV vaccine for routine immunization in infants aged 4 months and older. The lead candidate(s) are currently under Phase 1 evaluation in healthy infants without previous RSV exposure. In addition, in March 2017 Sanofi Pasteur announced an agreement with MedImmune to develop and commercialize a monoclonal antibody (SP0232, also known as MEDI8897) which has been engineered to have a long half-life so that only one dose would be needed for the entire RSV season. It is currently being investigated in a Phase IIb study in preterm infants. MEDI8897 received fast-track designation from the FDA in 2015.

Zika: Sanofi Pasteur entered into a Cooperative Research and Development Agreement (CRADA) with the Walter Reed Army Institute of Research (WRAIR) on a Zika vaccine project in 2016. The Biomedical Advanced Research and Development Authority (BARDA) of the US Department of Health and Human Services had agreed to provide $43.2 million in funding for the manufacture of the inactivated Zika vaccine and the Phase I-II clinical trials. In August 2017, BARDA informed Sanofi Pasteur that it had decided to limit its funding to a case definition and surveillance study as well as any activities required to advance our vaccine development to a point where development would be indefinitely paused but could be restarted if the epidemic re-emerges. Consequently, Sanofi does not intend to continue development of, or seek a license from WRAIR for, the Zika vaccine candidate at this time. One of the ways Sanofi Pasteur will continue to contribute to the field of knowledge on Zika is by completing, with partial BARDA support, the ongoing case definition and surveillance study; this will provide guidance on Zika epidemiology and diagnosis that can be applicable to any vaccine subsequently developed to prevent the disease.

***Clostridium difficile* (C.diff) Toxoid vaccine:** We announced in December 2017 that we had decided to discontinue clinical development of our experimental C.diff vaccine.

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

Expenditures on research and development amounted to 5,472 million in 2017. Based on our new segment reporting model(1), that comprised 4,056 million in the Pharmaceuticals segment; 123 million in the Consumer Healthcare segment; 557 million in the Vaccines segment; and 736 million allocated to Other , representing R&D support function costs that have been verticalized as part of the reorganization of Sanofi. Research and development expenditures were the equivalent of about 15.6% of net sales in 2017, compared to 15.3% in 2016 and about 14.9% in 2015. The stability in R&D expenditure as a percentage of sales

over the past three years is attributable to active management of the portfolio and close cost control, and has been achieved despite a greater proportion of products being in late stage development. Based on our previous segment reporting model(2), under which we present our comparative analysis, preclinical research in the Pharmaceuticals segment(3) amounted to 1,218 million in 2017 compared to 1,094 million in 2016 and 1,072 million in 2015. Of the remaining 3,617 million relating to clinical development in the Pharmaceuticals segment(3) (3,523 million in 2016 and 3,458 million in 2015), the largest portion was generated by Phase III or post-marketing studies, reflecting the cost of monitoring large scale clinical trials.

Compound	**Entry into Phase III[a] (month/year)**	**Compound Patent Term[b]**			**Comments**
		US	**EU**	**Japan**	
SAR341402	August 2017	N/A	N/A	N/A	Phase III program ongoing in type 1 and 2 diabetes
insulin aspart sotagliflozin (SAR439954)	November 2015	2028	2027	2027	Phase III program ongoing in Type 1 & 2 diabetes. Dossier filing in type 1 diabetes is expected during the first half of 2018
efpeglenatide	December 2017	2028	2028	2028	

(SAR439977)					Phase III program ongoing in Type 2 diabetes
dupilumab (SAR231893)	October 2014	2027	2029	2029	Dossier approved in Atopic Dermatitis (AD) in adults, Phase III program ongoing in AD in children and adolescents. Dossier submitted in Asthma for adults and children over 12 years old, Phase III program ongoing in Asthma for children (six-11 years) Phase III program ongoing in Nasal polyposis
GZ402666	November 2016	2029	2028	2028	Phase III program ongoing in Pompe Disease
isatuximab (SAR650984)	December 2016	2028	2027	2027	Phase Ill program ongoing in relapsing refractory multiple myeloma and in newly diagnosed multiple myeloma. A first filing is expected in 2018
cemiplimab (SAR439684)	May 2017				Phase III program ongoing in non-small cell lung cancer and cervical cancer A biological license application in cutaneous squamous cell carcinoma was filed end of February 2018 in the US
fitusiran (SAR439774)	Expected Q1 2018	2033	2033	2033	Phase III program initiated with dosing of the first patient expected the first quarter of 2018

(a) First entry into Phase III in any indication.

(b) Subject to any future supplementary protection certificates and patent term extensions.

(1) For more information see Item 5 A.1.5 Segment Information below.
(2) For more information see Item 5 A.2.3 Segment Results below.
(3) Includes the Consumer Healthcare business and an allocation of global support function costs. For more information see Item 5 A.2.3 Segment Results below.

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With respect to the compound patent information set out above, investors should bear in mind the following additional factors:

- The listed compound patent expiration dates do not reflect possible extensions of up to five years available in the US, the EU, and Japan for pharmaceutical products. See B.7. Patents, Intellectual Property and Other Rights Patent Protection for a description of supplementary protection certificates and patent term extensions.

- Depending on the circumstances surrounding any final regulatory approval of the compound, there may be other listed patents or patent applications pending that could have relevance to the product as finally approved; the relevance of any such application would depend upon the claims that ultimately may be granted and the nature of the final regulatory approval of the product.

- Regulatory exclusivity tied to the protection of clinical data is complementary to patent protection, and may provide more efficacious or longer lasting marketing exclusivity than a compound s patent estate. See B.7. Patents, Intellectual Property and Other Rights Regulatory Exclusivity for additional information. In the United States the data protection generally runs five years from first marketing approval of a new chemical entity extended to seven years for an orphan drug indication and twelve years from first marketing approval of a biological product. In the EU and Japan the corresponding data protection periods are generally ten years and eight years, respectively.

B.6. MARKETS

A breakdown of revenues by business segment and by geographical region for 2017, 2016, and 2015 can be found at Note D.35. to our consolidated financial statements included at Item 18 of this annual report.

The following market shares and ranking information are based on consolidated national pharmaceutical sales data (excluding vaccines), in constant euros, on a November 2017 MAT (Moving Annual Total) basis. The data are mainly from IQVIA local sales audit supplemented by various other country-specific sources including Knobloch (Mexico), GERS (France hospital channel), HMR (Portugal) and Reveal (Sweden). Market share data for the Consumer Healthcare business are from Nicholas Hall, Q3 2017 MAT. For more information on market shares and rankings see Presentation of Financial and Other Information at the beginning of this Annual Report on Form 20-F.

B.6.1. Marketing and Distribution

We have a commercial presence in approximately 100 countries, and our products are available in more than 170 countries. Our main markets in terms of net sales are respectively:

Emerging Markets (see definition in Information on the Company Introduction above): Sanofi is the leading healthcare company in emerging markets. Sanofi is the fifth largest pharmaceutical company in China.

The US: we rank twelfth with a market share of 3.7%.

Europe: we are the second largest pharmaceutical company in France where our market share is 7.2% and we rank fourth in Germany with a 4.4% market share.

Other countries: our market share in Japan is 1.6%.

A breakdown of our aggregate net sales by geographical region is presented in Item 5. Operating and Financial Review and Prospects Results of Operations Year Ended December 31, 2017 Compared with Year Ended December 31, 2016.

Although specific distribution patterns vary by country, we sell prescription drugs primarily to wholesale drug distributors, independent and chain retail drug outlets, hospitals, clinics, managed-care organizations and government institutions. Rare disease products are also sold directly to physicians. With the exception of Consumer Healthcare products, our drugs are ordinarily dispensed to patients by pharmacies upon presentation of a doctor s prescription.

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

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

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

Our vaccines are sold and distributed through multiple channels including physicians, pharmacies, hospitals, private companies and distributors in the private sector, and governmental entities and non-governmental organizations in the public and international donor markets.

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B.6.2. Competition

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

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

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

We compete with other pharmaceutical companies in all major markets to develop innovative new products. We may develop new technologies and new patented products wholly in-house, but we also enter into collaborative R&D agreements in order to access new technologies. See Note D.21. to our consolidated financial statements included in Item 18 of this annual report.

Sanofi is the fifth largest pharmaceutical company globally by sales. Our prescription drugs compete in all major markets against patented drugs from major pharmaceutical companies. Our competitors in key businesses include: Novo Nordisk, Boehringer Ingelheim and Merck in diabetes; Lilly in diabetes, immunology and oncology; Bristol-Myers Squibb in immunology and oncology; Novartis in diabetes, multiple sclerosis, and oncology; Shire in rare diseases; Pfizer in rare diseases and oncology; Biogen, Teva and Merck Serono in multiple sclerosis; Bayer in multiple sclerosis and oncology; Roche in multiple sclerosis, immunology and oncology; AstraZeneca in diabetes, cardiovascular disease and oncology; and Amgen in cardiovascular disease.

Following our acquisition of Boehringer Ingelheim s consumer healthcare business, our share of the global consumer healthcare market in 2017 was 4.2%. Other key competitors include Johnson & Johnson, Pfizer, GlaxoSmithKline, Bayer and Reckitt Benckiser as well as local players, especially in emerging markets.

Our generics business competes with multinational corporations such as Teva, Sandoz (a division of Novartis), Mylan and local players, especially in emerging markets.

In our Vaccines business we are one of the top four players, competing primarily with large multinational players including Merck, GlaxoSmithKline, and Pfizer.

We also face competition from generic drugs that enter the market when our patent protection or regulatory exclusivity expires, or when we lose a patent infringement lawsuit (see B.7. Patents, Intellectual Property and Other Rights below). Similarly, when a

competing patented drug from another pharmaceutical company faces generic competition, those generic products can also affect the competitive environment of our own patented product. See Item 3. Key Information D. Risk factors Risks relating to our business .

Competition from producers of generics has increased sharply in response to healthcare cost containment measures and to the increased number of products for which patents or regulatory exclusivity have expired.

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

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

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

B.6.3. Regulatory Framework

B.6.3.1. Overview

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

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

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

The International Council for Harmonization (ICH) continues to implement its reform mandate.

The aims are to reinforce the foundations of the ICH; expand harmonization globally beyond the traditional ICH members, i.e. the three founding members (EU, Japan, US) plus Canada and Switzerland as observers; and facilitate the involvement of additional regulators and industry associations around the world. There are now nine regulatory agencies (including China, Brazil and South Korea) and six industry associations as full ICH members and 24 organizations (including nine regulatory authorities from around the world) with observer status.

International collaboration between regulatory authorities continues to develop with the implementation of confidentiality arrangements and memoranda of understanding between both ICH and non-ICH regulatory authorities. Examples include work-sharing on Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP) inspections, as well as regular interactions between the US and the EU in the form of clusters (i.e. pediatrics, oncology, advanced therapy medicinal products, vaccines, pharmacogenomics, orphan drugs, biosimilars, and blood products). In 2017 the United States and the EU completed an exchange of letters to amend the Pharmaceutical Annex to the 1998 US-EU Mutual Recognition Agreement. Under this agreement, US and EU regulators will be able to utilize each other s good manufacturing practice for inspections of pharmaceutical manufacturing facilities.

In addition to the joint efforts listed above, Free Trade Agreements (FTAs) have proven to be one of the best ways to open up foreign markets to exporters and to allow for discussions on harmonization topics for regulatory authorities. Some agreements, such as the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), are international in nature, while others are between specific countries. The requirements of many countries (including Japan and several EU Member States) to negotiate selling prices or reimbursement rates for pharmaceutical products with government regulators significantly extend the time to market

entry beyond the initial marketing approval. While marketing authorizations for new pharmaceutical products in the EU have been largely centralized within the European Commission in collaboration with the EMA, pricing and

reimbursement remain a matter of national competence.

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

The centralized procedure is mandatory for drugs derived from biotechnologies; new active substances designed for human use to treat HIV, viral diseases, cancer, neurodegenerative diseases, diabetes and auto-immune diseases; orphan drugs; and innovative products for veterinary use. When an application is submitted to the EMA, the scientific evaluation of the application is carried out by the Committee for Medicinal Products for Human Use (CHMP) and a scientific opinion is prepared. This opinion is sent to the European Commission which adopts the final decision and grants an EU marketing authorization. Such a marketing authorization is valid throughout the EU and the drug may be marketed within all EU Member States.

If a company is seeking a national marketing authorization in more than one Member State, two procedures are available to facilitate the granting of harmonized national authorizations across member states: the mutual recognition procedure or the decentralized procedure. Both procedures are based on the recognition by national competent authorities of a first assessment performed by the regulatory authority of one Member State.

National authorizations are still possible, but are only for products intended for commercialization in a single EU Member State or for line extensions to existing national product licenses.

Generic products are subject to the same marketing authorization procedures. A generic product must contain the same active medicinal substance as a reference product approved in the EU. Generic applications are abridged: generic manufacturers only need to submit quality data and demonstrate that the generic drug is bioequivalent to the originator product (i.e. performs in the same manner in the patient s body), but do not need to submit safety or efficacy data since regulatory authorities can refer to the reference product s dossier. Generic product applications can be filed and approved in the EU only after the originator product eight-year data exclusivity period has expired. Further, generic manufacturers can only market their generic products after a 10- or 11-year period has elapsed from the date of approval of the originator product. In the case of orphan drugs, generic product applications may not be filed before the expiry of a 10- or 12-year period from the date of approval of the originator product.

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

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In 2017, the EMA recommended 92 medicines for marketing authorization (versus 81 in 2016), including 35 new active substances.

Among the 92 medicines recommended, 19 (21%) had an orphan designation (versus 17 in 2016 and 18 in 2015), providing medicines for patients with rare diseases. Seven medicines were evaluated under accelerated assessment in 2017 (also seven in 2016 and five in 2015); this mechanism is reserved for medicines that have the potential to address unmet medical needs. Three medicines were recommended for a conditional marketing authorization; this is one of the EMA s early access routes to patients, and is intended for medicines that address an unmet medical need and that target seriously debilitating, life-threatening or rare diseases, or are intended for use in emergency situations in response to a public health threat.

Post-authorization safety monitoring of pharmaceutical products is carefully regulated in Europe. EU pharmaceutical legislation for medicinal products describes the respective obligations of the marketing authorization holder (MAH) and of the regulatory authorities to set up a system for pharmacovigilance in order to collect, collate and evaluate information about suspected adverse reactions.

It is possible for the regulatory authorities to withdraw products from the market for safety reasons. Responsibilities for pharmacovigilance rest with the regulatory authorities of all the EU Member States in which the marketing authorizations are held. In accordance with applicable legislation, each EU Member State has a pharmacovigilance system for the collection and evaluation of information relevant to the risk-benefit balance of medicinal products. The regulatory authority regularly monitors the safety profile of the products available in its territory, takes appropriate action where necessary, and monitors the compliance of MAHs with their pharmacovigilance obligations. All relevant information is shared between the regulatory authorities and the MAH, in order to allow all parties involved in pharmacovigilance activities to fulfill their obligations and responsibilities.

The pharmacovigilance legislation was amended in 2012. The amendments aimed to further strengthen the protection of patient health by promoting prompt and appropriate regulatory action on European medicines. In particular, the amendments included major changes to notification requirements: MAHs of human medicines now have to notify EU regulators of any action to withdraw a product from a market, together with the reason for this action. Changes also included the creation of a Pharmacovigilance Risk Assessment Committee (PRAC), a scientific advisory committee at EMA level, with a key role in the assessment of all aspects of risk management relating to the use of medicinal products for human use approved in the European Economic Area (EEA). This includes measures relating to the

detection, assessment, minimization and communication of the risk of adverse reactions, having due regard to the therapeutic effect of the medicinal product. This committee is also responsible for the design and evaluation of post-authorization safety studies (PASS) and pharmacovigilance audits.

In Europe, the PRAC has performed reviews of marketed products (by class or on ad hoc basis) through various procedures. For Sanofi, 182 products underwent PRAC review through signal and referral procedures from July 2012 to December 2017, generating 112 labeling variations (14 new variations in 2017) and five additional risk minimization measures. In only two cases for Sanofi (Myolastan®, and methadone oral solutions containing povidone) did the review lead to the product being withdrawn from the EU market.

The EU pharmacovigilance legislation also strengthens the legal basis for regulators to require post-authorization safety and efficacy studies throughout the life cycle of a medicinal product, with regulatory supervision of protocols and results. Such studies are aimed at collecting data to enable the safety or efficacy of medicinal products to be assessed in everyday medical practice. The granting of marketing authorization is conditional on such studies being performed. Consequently, the pharmaceutical industry now has to build the need for PASS and post-authorization efficacy studies (PAES) into development and life cycle management plans. Sanofi has put in place robust processes to ensure that PASS and PAES can be properly implemented as required, either as part of a Risk Management Plan (RMP) or following a health authority request.

A further requirement introduced by the EU pharmacovigilance legislation is for pharmaceutical companies to prepare Periodic Safety Update Reports (PSURs). These are not limited to safety data, but instead present a critical analysis of the risk-benefit balance of a medicinal product, taking into account new or emerging information in the context of cumulative information on risks and benefits.

There is in addition a legal requirement for an enhanced adverse reaction collection and management system (EudraVigilance) that delivers better health protection through simplified reporting, higher quality data, and improved search, analysis and tracking functionalities. Associated with this is a legal requirement for MAHs to monitor EudraVigilance data, to the extent to which they have access to such data. On November 22, 2017, the EMA launched a new and improved version of EudraVigilance with enhanced functionalities to support the fulfilment of these pharmacovigilance obligations. Alongside the launch, simplified electronic reporting of suspected adverse reactions related to medicines by national Competent Authorities and MAHs to EudraVigilance became mandatory. On February 22, 2018, the legal requirement for MAHs to monitor EudraVigilance data and inform the EMA and national competent authorities of validated signals became applicable for active substances included in the List of medicinal products under additional monitoring , for a one-year pilot period.

The database of medicinal products aims to deliver structured and quality assured information on medicinal products authorized in the EU that incorporates the terminology adopted in the EU for products, substances, and organizations underpinning pharmacovigilance and regulatory systems. Since January 1, 2015,

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MAHs have been required to notify the EMA of any new marketing authorizations within 15 calendar days from the date of authorization, and to notify the EMA of any change in the terms of a marketing authorization as soon as possible within 30 calendar days following the date on which the changes were authorized.

The EMA s medical literature monitoring (MLM) service was launched on September 1, 2015 to monitor selected medical literature for reports of suspected adverse drug reactions containing certain active substances, and to enter reports in the EudraVigilance database.

There is a legal requirement for the EMA to set up a repository for Periodic Safety Update Reports (PSURs) and for EMA assessment reports on PSURs in order to facilitate centralized PSUR reporting and to enhance access to data and information, thereby supporting risk/benefit assessments of medicines. The PSUR Repository achieved full functionality in June 2015 and its use in the EU became mandatory on June 13, 2016.

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

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

The FD&C Act provides another abbreviated option for NDA approved products, which is a hybrid between an NDA and ANDA called the 505(b)(2) pathway. This 505(b)(2) pathway enables a sponsor to rely on the FDA s findings that the reference product is safe and effective, based on the innovator s preclinical and clinical data.

The FDA Center for Drug Evaluation and Research (CDER) approved 46 novel drugs in 2017 (versus 22 in 2016, 45 in 2015, 41 in 2014, and 27 in 2013). Designations and pathways to expedite drug development and review include Fast Track (18/46 = 39%), Breakthrough Therapy (17/46 = 37%), Accelerated approval (6/46 = 13%) and Priority

Review (28/46 = 61%). Of the 46 novel drugs approved in 2017, 61% were designated in one or more expedited categories.

CDER identified 15 of the 46 novel drugs approved in 2017 (33%) as First-in-Class, one indicator of the innovative nature of a drug. Approximately 39% of the novel drugs approved in 2017 were approved to treat rare or orphan diseases that affect 200,000 or fewer Americans.

In Japan, the regulatory authorities can require local clinical studies, though they also accept multi-national studies. In some cases, bridging studies have been conducted to verify that foreign clinical data are applicable to Japanese patients and obtain data to determine the appropriateness of the dosages for Japanese patients. The Japanese Ministry of Health, Labor and Welfare (J-MHLW) has introduced a new National Health Insurance (NHI) pricing system. Reductions in NHI prices of new drugs every two years are compensated by a Premium for a maximum of 15 years. A Premium is granted in exchange for the development of unapproved drugs or off-label indications with high medical needs. Once an official request for development of an unapproved drug or off-label indication has been made, the pharmaceutical companies must file literature-based reports within six months or submit a clinical trial notification for registration within one year after the official development request. For unapproved drugs with high medical needs, clinical trials in Japanese patients are generally required. Otherwise, a fine equivalent to 105% (with 5% representing interest) of sales based on the premium would have to be paid back to the government.

To promote the development of innovative drugs and bring them into early practical use in Japan ahead of the world, the Sakigake (a Japanese term meaning forerunner) review designation program was introduced in April 2015. The Pharmaceuticals and Medical Devices Agency (PMDA) will review designated products on a priority basis with the aim of reducing their review time from the normal 12 months to six months.

Based on the NHI price system, the Premium classification will be restricted to new products from companies which conduct R&D on pharmaceuticals truly conducive to the improvement of healthcare quality, i.e. (i) pediatric/orphan drugs and (ii) drugs to treat diseases that cannot be adequately controlled with existing drugs. From 2019, all prescription product prices will be reviewed annually instead of once every two years, but price cuts will actually be conducted only for a limited number of products with big gaps between their official reimbursement prices and market prices

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(e.g. generic drugs and long-listed original products). On the other hand, prices of products that are rapidly adopted after approvals for new indications may from 2017 be reviewed four times a year.

The PMDA has set a target for 80% (as opposed to the current 50%) of all applications to be reviewed in 12 months for products with standard review status and in nine months for products with priority review status by the end of 2018.

The PMDA also plans to eliminate the review lag between the filing and approval of drugs and medical devices relative to the FDA by the end of 2020.

The Pharmaceuticals and Medical Devices Act was implemented on November 25, 2014. There are three major objectives. The first objective is to strengthen safety measures for drugs and medical devices. In particular, MAHs must prepare a package insert based on the latest knowledge and notify the J-MHLW before placing products on the market or when revisions are made. The second objective is to accelerate the development of medical devices. The third-party accreditation system will be expanded to specially controlled generic medical devices (i.e. Class III devices). Consequently, the PMDA can accelerate the review of innovative medical devices. The third objective is accelerated commercialization of regenerative medicinal products.

The term Regenerative Medicinal Products used in the law includes cellular and tissue-based products and gene therapies. This concept is similar to Advanced Therapy Medicinal Products (ATMPs) in the EU. The law allows for conditional regulatory approval based on confirmation of probable efficacy and safety in small-scale clinical trials, followed up by comprehensive studies to confirm safety and efficacy in a wider population that would then lead to a regular (full) approval.

For new drugs and biosimilar products with approval applications submitted on or after April 2013, Japan has implemented an RMP (Risk Management Plan), similar to the EU Pharmacogivilance system.

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

B.6.3.2. Biosimilars

Products can be referred to as biologics when they are derived from natural sources, including blood products or products manufactured within living cells (such as antibodies). Most biologics are complex molecules or mixtures of molecules which are difficult to characterize and require physico-chemical-biological testing, and an understanding of and control over the manufacturing process.

The concept of generics is not scientifically appropriate for biologics due to their high level of complexity. Consequently the

concept of biosimilar products is more appropriate. A full comparison of the purity, safety and efficacy of the biosimilar product against the reference biological product should be undertaken, including assessment of physical-chemical-biological, non-clinical and clinical similarity.

In the EU, the regulatory framework for developing and evaluating biosimilar products has been in place since 2005. The CHMP has issued several product/disease specific guidelines for biosimilar products including guidance on preclinical and clinical development of biosimilars of Low Molecular Weight Heparin (LMWH) and of insulins. Starting in 2011 and continuing through 2017, the CHMP has been engaged in revising most of the existing biosimilar guidelines (general overarching guidelines, quality, and non-clinical and clinical product-specific guidelines).

While the CHMP has adopted a balanced approach for all biosimilars, allowing evaluation on a case-by-case basis in accordance with relevant biosimilar guidelines, it has also indicated that in specific circumstances, a confirmatory clinical trial may not be necessary. This applies if similar efficacy and safety can clearly be deduced from the similarity of physicochemical characteristics, biological activity/potency, and pharmacokinetic and/or pharmacodynamic profiles of the biosimilar and the reference product. With respect to vaccines, the CHMP currently takes the view that it is at present unlikely that these products can be characterized at the molecular level, and that each vaccine product must be evaluated on a case-by-case basis.

In February 2017, the EMA launched a tailored scientific advice pilot project to support step-by-step development of new biosimilars, based on a review of the quality, analytical and functional data already available. This pilot will encompass six scientific advice requests. The EMA will analyze the outcome after completing the pilot.

In 2017, the EMA and the European Commission published an information guide for healthcare professionals to provide them with reference information on the science and regulation underpinning the use of biosimilar medicines.

In the US, the Patient Protection and Affordable Care Act (Affordable Care Act), signed into law in March 2010, amended the Public Health Service Act to create an abbreviated licensure pathway (351k) for biological products that are demonstrated to be biosimilar to or interchangeable with an FDA-licensed biological product.

In 2017 the FDA published for consultation two biosimilar draft guidance documents: *Considerations in Demonstrating Interchangeability with a Reference Product* and *Statistical Approaches to Evaluate Analytical Similarity.*

As of the date of this annual report nine biosimilar products have been approved by the FDA. Five of those nine products were approved in 2017. To date no biosimilar products have been deemed interchangeable.

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In Japan, guidelines defining the regulatory approval pathway for follow-on biologics were finalized in March 2009. These guidelines set out the requirements on preclinical, clinical and Chemistry, Manufacturing and Control (CMC) data to be considered for the development of the new application category of biosimilars. Unlike the CHMP guidelines, the main scope of the Japanese guidelines includes recombinant proteins and polypeptides, but not polysaccharides such as LMWH.

Many regulatory authorities worldwide have in place, or are in the process of developing, a regulatory framework for biosimilar development and approval. It should be noted that although many emerging markets are basing their regulations and guidance on WHO or EMA documentation, some markets have approved biosimilars under an existing regulatory framework that is not specific to biosimilars.

B.6.3.3 Regenerative Medicine

The US Center for Biologics Evaluation and Research (CBER) has established the Regenerative Medicine Advanced Therapy (RMAT) designation program, as authorized in section 3033 of the 21st Century Cures Act. This program aims to facilitate an efficient development program, expedite review of innovative regenerative medicine therapies, and provide more timely access to potentially life-saving products. Products granted the RMAT designation are eligible for increased early interactions with FDA, including all the benefits available to breakthrough therapies. As of October 31, 2017, FDA had granted 11 RMAT designations.

In 2017, the FDA published two final guidance documents that are part of a comprehensive policy framework to address how the agency plans to support and expedite the development of regenerative medicine products, including human cells, tissues, and cellular and tissue-based products (HCT/Ps). These guidance documents build upon the FDA s risk-based, flexible regulatory framework, and underscore the agency s commitment to help bring new and innovative treatment options to patients. The first guidance (Regulatory Considerations for Human Cell, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use) is intended to provide clarity in the determination of whether HCT/Ps are subject to the FDA s premarket review requirements. The second guidance (Same Surgical Procedure Exception: Questions and Answers Regarding the Scope of the Exception) is intended to provide clarity as to whether an establishment may qualify for an exception from the requirements under Part 1271 of the Code of Federal Regulations (CFR) Title 21 by meeting the exception in 21 CFR 1271.15(b).

Novel regenerative medicine therapies approved by the CBER in 2017 include the first three gene therapies: Novartis AG s chimeric antigen receptor T-cell (CAR-T) therapy Kymriah (tisagenlecleucel) followed by Kite Pharma Inc. s CAR-T therapy Yescarta (axicabtagene ciloleucel), both for oncology indications, and Spark Therapeutics Inc. s Luxturna (voretigene neparvovec-rzyl) for inherited vision loss.

B.6.3.4. Generics

In the EU 20 positive opinions were issued under the centralized procedure for generics in 2017 (versus 16 in 2016 and 21 in 2015). Most of the generics applications for chemical entities use the mutual recognition and decentralized procedures. Pricing systems for generics remain at national level in the EU.

In the US, to help the FDA ensure that participants in the US generic drug system comply with US quality standards and to increase the likelihood that American consumers get timely access to low cost, high quality generic drugs, the FDA and the industry have jointly agreed to a comprehensive program (Generic Drug User Fee Amendments) to supplement traditional appropriated funding, focused on safety, access, and transparency. For the period October 1, 2016 through September 30, 2017 the FDA planned to review and act on 90% of original ANDA submissions within 10 months from the date of submission. For this period, 763 ANDAs were approved, 174 received tentative approval and 1603 complete responses were issued.

In Japan, the 2014 reforms to the NHI price system included a new special price reduction rule for long-listed drugs. The rule was introduced in April 2014. It reduced the NHI prices of long-listed drugs whose generic replacement rates are less than 20% five years after their first generics join the NHI price list. Reductions are 2.0% in the first NHI price revision, 1.75% if the substitution rate is 20% or higher but less than 40%, and 1.5% if the rate is 40% or higher but less than 60%.

Under the new price system, NHI prices of first generics (previously set at 60%) were set at 50% of the price of the originator product. A 40% rule is applied to oral first generics once more than ten products with the same ingredients have obtained listing.

In addition, a maximum Sakigake premium of 20% was introduced in April 2016 for Sakigake-designated products, which have new mechanisms of action and obtain approval in Japan ahead of the rest of the world.

B.6.3.5. Medical Devices

In the EU, there is no pre-market authorization by a regulatory authority. Instead there is a Conformity Assessment Procedure (for medium and high risk devices), possibly involving an independent third party Notified Body (NB) depending on the classification of the device. Once certified, medical devices have to bear the CE-mark, allowing them to circulate freely in the EU/EFTA (European Free Trade Association) countries and Turkey.

To align legal requirements across the EU Member States and to strengthen the protection of public health, two new Regulations came into force in 2017 replacing older EU Directives.

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices came into force on May 26, 2017 with a transition period of three years.

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Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices came into force on May 26, 2017 with a transition period of five years.

In the US, the FDA Center for Devices and Radiological Health (CDRH) is responsible for regulating firms that manufacture, repackage, relabel and/or import medical devices sold in the US. The CDRH also regulates radiation-emitting electronic products (medical and non-medical) such as lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions.

Medical devices are classified into Class I, II, and III based on their risks and the regulatory controls necessary to provide reasonable assurance of safety and effectiveness. Regulatory control increases from Class I to Class III. The device classification regulation defines the regulatory requirements for a general device type. Most Class I devices are exempt from Premarket Notification 510(k); most Class II devices require Premarket Notification 510(k); and most Class III devices require Premarket Approval. Low and moderate risk devices (Class I and II) can also be classified through the de novo pathway if certain conditions are met.

The basic regulatory requirements that manufacturers of medical devices distributed in the US must comply with are: Establishment Registration; Medical Device Listing; Premarket Notification 510(k) (unless exempt) or Premarket Approval; Investigational Device Exemption; Quality System Regulation; Labeling Requirements and Medical Device Reporting.

B.6.3.6. OTC drugs

In the EU, four European centralized prescription to OTC (Rx-to-OTC) switches have occurred since 2009. For nationally authorized products, switches follow national rules for OTC classification. In 2017, a European platform for non-prescription medicines was launched to harmonize non-prescription status and to facilitate the switching environment.

In the US, the FDA approved one prescription to OTC switch in 2017: Sanofi Consumer Healthcare s Xyzal® Allergy 24HR (levocetirizine dihydrochloride).

In Japan, the J-MHLW drug safety committee set new rules in 2013 on the details of safety evaluations for drugs newly switched from prescription to OTC, following the passage of a bill to revise the Pharmaceutical Affairs Law (PAL). The J-MHLW gives the green light for online sales of such OTC drugs if no safety concerns arise during an

initial three-year safety evaluation period. During this three-year evaluation period, drugs that moved from prescription to OTC are categorized as products that require

pharmacist consultations when purchased. Under the new rules, the J-MHLW requires marketing authorization holders to submit interim reports upon completion of their post marketing surveillance (PMS).

The PMS needs to cover 3,000 patients for oral drugs and 1,000 patients for topical drugs. Based on these interim reports and other reports on adverse events, the J-MHLW performs the first evaluation on whether there are any safety concerns three years after the launch. If no safety concerns are identified during this three-year safety evaluation period, the classification of these Rx-to-OTC switches will be downgraded to Category 1 OTC drugs, i.e. drugs which do not require pharmacist consultation and can be sold online. The J-MHLW performs the second safety evaluation one year after the transfer to Category 1 OTC drugs. If no safety concerns are identified, the classification of the Category 1 OTC drugs will be downgraded to Category 2 OTC drugs, i.e. drugs that can be handled by pharmacists but also by registered salespersons.

Generic OTC drugs can be filed after completion of the three-year PMS period and will be approved in seven months**.**

The J-MHLW launched a new panel in April 2016 to pick up Rx-to-OTC switch candidates. Under the new scheme, the MHLW accepts requests for Rx-to-OTC switch candidates from various stakeholders such as medical societies, consumers, and pharmaceutical companies, and then these requests are publicly reviewed by the new panel in order to minimize pressures from medical societies. Based on its deliberations, the panel refers shortlisted requests to the Pharmaceutical Affairs and Food Sanitation Council (PAFSC) committee on nonprescription drugs, which effectively makes decisions on marketing approval for OTCs.

B.6.3.7. Transparency and public access to documents

Transparency regarding regulatory information, clinical trials and associated regulatory decision-making

Over the last several years the pharmaceutical industry has been subject to growing pressure for greater transparency about clinical trials (conduct and results). Regulatory authorities are also being pressed for more openness and transparency, for example by making more comprehensive disclosures about the rationale and basis of regulatory decisions on medicinal products, so as to enhance the credibility of the regulatory process. This is a significant driver of the transparency initiatives undertaken in several countries.

Pharmaceutical manufacturers have committed to publishing protocols, study information and results of clinical studies conducted with their products in publicly accessible registries. In addition, both ICH and non-ICH countries often impose mandatory disclosure of clinical trials information.

From a regulatory perspective, ambitious initiatives have been undertaken by the major regulatory authorities and Sanofi has processes in place to address these initiatives.

EU pharmaceutical legislation for medicinal products requires national regulatory authorities and the EMA to actively publish information concerning authorization and supervision of medicinal

products. The EMA has introduced a series of initiatives aimed at improving the transparency of its activities, such as improving the format of the European Public Assessment Report and web-published product approvals, withdrawals and rejections. In addition, there is an increased focus on comparative efficacy and effectiveness. The new EU pharmacovigilance legislation aims at giving greater transparency, especially with regard to communication of safety issues (e.g. public hearings, specific European web portals with information on medicinal products). Finally, patients and consumers are increasingly involved in the work of the EMA s scientific committees.

The EMA has committed to continuously extend its approach to transparency. A key goal in this process is the proactive publication of clinical trial data for medicines once the decision-making process on an application for an EU-wide marketing authorization is complete.

In 2014, the EMA adopted Policy 70 for publication of clinical trial reports. The policy came into force on January 1, 2015. It applies to clinical reports contained in any new marketing authorization applications for centralized marketing authorizations; to post-authorization procedures for existing centrally authorized medicinal products; and to article 58 applications (medicines that are intended exclusively for markets outside the EU).

For post-authorization procedures for existing centrally authorized medicinal products, the effective date was July 1, 2015 for extension of indication and line extension applications submitted as of that date.

The policy is being implemented in two phases:

- The first phase concerns the publication of clinical reports only, the data from which will be accessible on the EMA website.

- In the second phase, the EMA will endeavor to find the most appropriate way to make Individual Patient Data (IPD) available, in compliance with privacy and data protection laws.

In order to operationalize EMA Policy 70, Sanofi launched an internal project to define, develop, implement and control a sustainable process, supported by associated tools and documents, as well as resourcing, training and communication plans to manage clinical documents and data redaction in compliance with Policy 70. In 2016, the EMA Policy 70 process was fully transitioned to the business operational teams. Awareness communication is ongoing not only for current submissions, but also to streamline the process for ongoing and future studies.

In the US, the FDA launched a Transparency Initiative in June 2009. The objective of the initiative was to render the FDA much more transparent and open to the American public by providing the public with useful, user-friendly information about agency activities and decision making.

The FDA Transparency Initiative has three phases: Phase I Improving the understanding of the FDA basics (completed with ongoing updates); Phase II Improving the FDA s disclosure of information to the public (ongoing); and Phase III Improving the FDA s transparency to regulated industry (ongoing). Proposals to improve transparency and access to information have been released for consultation for both Phase II and Phase III. Some of the less controversial proposals have been implemented; others, such as proactive release of information that the Agency has in its possession, may require revisions to US federal regulations.

In September 2016, the US Department of Health and Human Services, National Institute of Health (NIH) published Final Rule under Section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) on the Dissemination of Clinical Trial Information. The Final Rule requires registration and results submission for applicable clinical trials (ACTs); clarifies and expands registration data elements; expands scope of results reporting requirements to include trials of unapproved products; clarifies and expands results data elements; and revises Quality Control (QC) and posting process.

Additionally, in January 2018, the FDA launched a new pilot program to evaluate whether disclosing certain information included within clinical study reports (CSRs) of approved drugs is beneficial to the public. CSRs are scientific reports prepared by the sponsor to summarily address a drug s efficacy and safety, and include information related to the methods and results of clinical trials supporting the drug. Traditionally, this information has only been released following submission of a Freedom of Information Act (FOIA) request. Under the pilot program, the Agency will continue to protect from disclosure trade secrets and confidential commercial information, as required by law.

In Japan, the J-MHLW/PMDA actively publishes information concerning approvals of medicinal products (ethical drugs, nonprescription drugs, and quasi-drugs) and medical devices. For ethical drugs discussed at the J-MHLW s Pharmaceutical Affairs and Food Sanitation Council, the redacted clinical trials data modules 1 and 2 (except for commercial confidential information and personal data) have been made publicly available on the PMDA website.

Transparency regarding Health Care Professionals

In the EU, there is no harmonized approach regarding transparency for Health Care Professionals (HCPs). For transparency purposes, there is increased external scrutiny of interactions between pharmaceutical companies and HCPs at national level, with legal provisions or healthcare industry voluntary undertakings in some countries (such as the UK, Denmark, France and Portugal).

The European Federation of Pharmaceutical Industries Association (EFPIA) released in mid-2013 a Code on Disclosure of Transfers of Value from Pharmaceutical Companies to HCPs and Healthcare

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Organizations (HCOs), the EFPIA HCP/HCO Disclosure Code . EFPIA members are required to comply with this Code and transpose it into their national codes.

The Code includes stricter rules on hospitality and gifts, with the requirement for member associations to include a threshold on hospitality and the prohibition of gifts in their national codes.

In the US, the Physician Payments Sunshine Act, or Sunshine Act , was passed as part of the Affordable Care Act. The law is designed to bring transparency to financial relationships between physicians, teaching hospitals, and the pharmaceutical industry. Manufacturers and group purchasing organizations (GPOs) must report certain payments or transfers of value including payments for research, publication support, travel, honoraria and speaking fees, meals, educational items like textbooks and journal reprints whether made directly to a physician or teaching hospital or indirectly through a third party. The law also requires manufacturers and GPOs to report physicians or members of their immediate family who have an ownership interest in the company. Reports are made to the Centers for Medicare and Medicaid Services, a government agency.

In Japan, the Japan Pharmaceutical Manufacturers Association (JPMA) member companies started releasing information on their funding of healthcare professionals in 2013 and patient groups in 2014 under the trade group s voluntary guidelines to boost financial transparency. Under the JPMA s transparency guidelines for the relations between companies and medical institutions, its members currently report their payments in five categories: R&D, academic research support, manuscript/writing fees, provision of information, and other expenses.

B.6.3.8. Other new legislation proposed or pending implementation

In the **US**, in August 2017 the Food and Drug Reauthorization Act (FDARA) was signed into law. The law reauthorized user fee collection for the next five years for drugs (PDUFA VI), devices (MDUFA IV), generics (GDUFA II) and biosimilars (BsUFA II) and reflects a move to a more stable funded program. In addition to user fees, FDARA focuses on modifications and improvements of the regulation of drugs, devices and generics.

In China, since the initial programmatic regulatory reform initiative started in 2015, most of the country s regulatory processes have been adapted to bring them into line with other major regulatory agencies. These include establishing predictable pathways and timelines (including conditional approvals); a Marketing Application Holder system; risk-based inspections; and clinical trial processes that allow companies developing innovative drugs to conduct

clinical trials simultaneously with other countries (International Multicenter Clinical Trials). The China Food and Drug Administration (CFDA) has also established a system for intellectual property protection.

Clinical trial regulation in the EU

The Clinical Trial Regulation ((EU) 536/2014) of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, was published in the Official Journal of the EU on May 28, 2014.

Pharmaceutical companies and academic researchers will be required to post the results of all their European clinical trials in a publicly-accessible database.

The legislation streamlines the rules on clinical trials across Europe, facilitating cross-border cooperation to enable larger, more reliable trials, as well as trials of products for rare diseases. It simplifies reporting procedures, and gives the European Commission the authority to perform audits. Once a clinical trial sponsor has submitted an application dossier to a Member State, the Member State will have to respond to it within fixed deadlines.

One of the main objectives of the European Commission in introducing the clinical trial regulation was to simplify the clinical trial approval process. The new legislation was drafted in the more stringent form of a regulation rather than as a directive, so as to achieve better harmonization between countries without interfering with Member States competencies in terms of ethical issues.

The major points are:

The timeline for approving a clinical trial proposal is set at 60 days without questions (and a maximum of 99 with questions and clock stops). This can be seen as a setback for the industry, as the Commission s proposal was based on 41 days without questions and a maximum of 74 days including all possible delays. In the case of advanced therapy medicinal products, the timeline can be extended by another 50 days, making 110 days in total.

To make both the reference state and the relevant Member States comply with the timelines, the legislation includes the concept of tacit approval. The fact that this feature was accepted by all parties can be seen as a positive outcome for the industry.

Selection of reference Member State by the sponsor was maintained.

As regards transparency requirements for clinical trial data submitted through a single EU submission portal and stored in a Union-level database, the new clinical trial regulation allows for protection of personal data of patients and commercially confidential information, which is in line with the industry data sharing laid out in Policy 70 (see previous section). The new regulation cannot be implemented until the single EU submission portal and database is fully operational. Work on the EU database and portal progressed during 2017, but due to technical difficulties with the development of the IT systems the portal s go-live date was postponed. An audit will be carried out in 2018, and the EMA will provide further information on timelines after the audit. According to an EMA assessment report in 2017,

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development remains in line with a schedule that would allow the EU Clinical Trial Regulation to enter into force in the second half of 2019.

Falsified medicines

The EU has reformed the rules for importing active substances for medicinal products for human use into the EU (Directive 2011/62/EU). Since January 2013, all imported active substances must have been manufactured in compliance with GMP standards or standards at least equivalent to GMP. The manufacturing standards in the EU for active substances are those specified in Q7 as issued by the International Council for Harmonization (ICH). With effect from July 2, 2013, such compliance must be confirmed in writing by the competent authority of the exporting country, except for countries with waivers. Written confirmation must also confirm that the plant where the active substance was manufactured is subject to control and enforcement of GMP at least equivalent to that in the EU.

Several implementing measures for the Falsified Medicines Directive have been adopted. A common EU logo for online pharmacies was adopted in June 2014, giving Member States until July 2015 to prepare for its application. Detailed rules for the safety features appearing on the outer packaging of medicinal products for human use have been adopted, meaning that all prescription drugs or reimbursed drugs commercialized on the European market will have to be serialized by February 2019.

Nagoya Protocol

The Nagoya Protocol came into force in October 2014 and is intended to create greater legal certainty and transparency for both providers and users of genetic resources by:

establishing more predictable conditions for access to genetic resources; and

helping to ensure benefit-sharing when genetic resources leave the contracting party providing the genetic resources.

In the EU, the European Commission published the implementation Act in 2015 (Regulation 2015/1866).

It states that the pharmaceutical industry has to implement compliance procedures for non-human biological materials used in the discovery, development, manufacturing and packaging of medicinal products.

The Sanofi Nagoya Ready Project was launched in 2015 to ensure compliance with international treaties on the sustainable use of biodiversity. The Nagoya Ready Project Team has ensured that Sanofi is prepared for compliance with the Nagoya Protocol and ready for full implementation. A Nagoya Expert Group reporting to the Bioethics

Committee will continue to monitor the international implementation of the protocol and provide appropriate support and advice to the relevant Sanofi teams.

In Japan, the relevant ministries are currently considering local measures for the ratification of the Nagoya Protocol. The schedule for ratification has yet to be determined. The details of local measures for the implementation of the Nagoya Protocol cannot be disclosed due to ongoing discussion, but the relevant ministries are considering a framework where terms and conditions can be set for mutual agreement and a consent can be obtained in advance from providers in accordance with laws and regulations in a source country when genetic resources from the source country are used in Japan.

NDA electronic clinical trial data submission (eCTD)

In the EU, electronic submission for marketing authorization and variation applications has already been in place for many years. To

allow secure submission over the Internet for all types of eCTD applications for human medicines, the EMA launched the eSubmission Gateway, which is now mandatory for all eCTD submissions through the centralized procedure, in order to improve efficiency and decrease costs for applicants.

As of July 1, 2015, companies are obliged to use electronic application forms provided by the EMA for all centralized marketing authorization applications for human and veterinary medicines. From January 2016, the use of electronic application forms became mandatory for all other EU marketing authorization procedures (i.e. mutual recognition and decentralized procedures, and national submissions).

In Japan, electronic submission of CDISC-based clinical data will become mandatory after the transition period that runs from October 2016 to March 2020, allowing the authority to efficiently store and analyze the data to improve its efficacy and safety predictions.

Such mandatory electronic submissions are expected to be limited to clinical trial data for new drugs newly filed for regulatory approval. The necessity for electronic submission for Phase I trial data will likely be decided on a case-by-case basis, while pharmaceutical companies will be required to file nonclinical toxicity study data in one of the Standard for the Exchange on Non clinical Data (SEND) formats in due course.

Brexit

The United Kingdom s decision to withdraw from the European Union (Brexit) has triggered a need to adapt regulatory activities in the region. Early in 2017, the EMA established a working group to explore options to (re)distribute across the remaining network the workload related to human (and veterinary) medicines and inspections currently managed by the UK.

The risk-based methodology leverages the diverse expertise in the network and takes into account the workload associated with the regulation of medicines. The EMA will communicate details of the methodology and next steps in early 2018.

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The EMA has conducted Industry Stakeholder meetings to discuss the various issues related to Brexit and is continuing to release regulatory and procedural guidance for pharmaceutical companies in order to facilitate preparation for Brexit.

To safeguard continuity of operations and secure timely execution of its core tasks, the EMA has launched a Business Continuity Plan (BCP). The BCP defines priority levels for EMA activities according to their impact on public health and the ability of the EMA to manage the tasks in light of the human resources available. Some regulatory activities are already temporarily suspended, or output is temporarily reduced, such as for instance work on the Transparency Policy 70 project.

In November 2017, following a predetermined procedure, it was decided that the EMA will relocate to Amsterdam in the Netherlands. The EMA s collaboration with the Netherlands commenced promptly and agreement has been reached on a joint governance structure, with plans to progress activities within five work streams relating to temporary and permanent premises, staff relocation, financial and legal aspects, and external communication.

Sanofi has set up an internal Brexit Task Force to proactively address issues triggered by Brexit.

B.6.4. Pricing & Reimbursement

Rising overall healthcare costs are leading to efforts to curb drug expenditures in most markets in which we operate. Increasingly, these efforts result in pricing and market-access controls for pharmaceuticals. The nature and impact of these controls vary from country to country, but some common themes are reference pricing, systematic price reductions, formularies, volume limitations, patient co-pay requirements, and generic substitution. In addition, governments and third-party payers are increasingly demanding comparative/relative effectiveness data to support their decision-making process. They are also increasing their use of emerging healthcare information technologies such as electronic prescribing and health records to enforce transparency and tight compliance with these regulations and controls. As a result, the environment in which pharmaceutical companies must operate in order to make their products available to patients and providers who need them continues to grow more complex each year.

While a drive to expand healthcare coverage has become a noticeable feature in many regions, providing opportunities for industry, it has also brought pressure on these new budgets, bringing with it a wave of price and volume control measures. Many countries and regions have increased pressure on pricing through joint procurement and negotiation.

National production, whether through a policy of industrialization, through technology transfer agreements or through preferential conditions for local production, is equally a growing issue.

Significant trends:

In the United States there is increased scrutiny on the price of branded pharmaceutical products, and therefore heightened sensitivity to patient exposure to high out-of-pocket expense.

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

- Medicare, which provides health insurance for retirees and for people with permanent disabilities. The basic Medicare scheme (Part A) provides hospital insurance only and the vast majority of retirees purchase additional cover through some or all of three other plans named Part B, Part C and Part D. Part D enables Medicare beneficiaries to obtain outpatient drug subsidies. Almost two-thirds of all Medicare beneficiaries have enrolled in Part D plans.

- Medicaid, which provides health insurance for those on low incomes.

Managed Care Organizations (MCOs) combine the functions of health insurance, delivery of care, and administration. MCOs use specific provider networks and specific services and products. There are three types of managed care plans: Health Maintenance Organizations (HMOs), Preferred Provider Organizations (PPOs), and Point of Service (POS) plans.

Pharmacy benefit managers (PBMs) serve as intermediaries between insurance companies, pharmacies and manufacturers to secure lower drug costs for commercial health plans, self-insured employer plans, Medicare Part D plans, and federal and state government employee plans.

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. Legislation was introduced in over 26 states in 2017 which would require price transparency and reporting of certain manufacturer information. Legislation has been passed in Nevada (requiring detailed reporting to the state on information for all drugs essential for treating diabetes) and in California (requiring advance price notification and detailed information for any drugs with a WAC increase of 16% or more over a two year period). This trend will continue into 2018 where we anticipate legislation to be filed in at least 20 states and more laws to be enacted around the country. US federal and state officials, including the Trump administration, are continuing to focus on the cost of health coverage and health care although the future policy, including the nature and timing of any changes to the Affordable Care Act, remains unclear.

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In October 2017, the President signed an Executive Order directing federal agencies to modify how the ACA is implemented and announced the Administration would no longer fund cost sharing subsidies paid to health insurance exchange plans. However, health insurance exchanges remain a minor percentage of the payor mix using branded pharmaceuticals, and so the impact of these changes appears limited. Currently, while there is the potential for additional disruptions to the ACA exchange markets via administrative or congressional action, full repeal or other wholesale changes to the law appear unlikely in the near term. Drug pricing-related policies continue to be a focus for the government, however, so there is no assurance that additional adverse policy changes could arise.

Affordable access for patients is critical to our industry s success; however, the cost of access via third party intermediaries Pharmaceutical Benefit Managers (PBMs), Health Plans and Government Markets is calling into question the integrity of the healthcare system and the sustainability of our business.

As the US approached the so-called Patent Cliff major market insurers realized the traditional business revenue model was threatened and there was an immediate shift to a model that would increase enrollment and cut costs. In recent years mergers and acquisitions have been the largest source of payer revenue growth, as acquired patients translate to increased demand.

With a decline in generic conversion and no further scope for consolidation, payers are seeking alternative methods to cut costs. As payers consolidate they can leverage their size and market share to demand higher rebates in return for increased access. If a manufacturer is reluctant to offer a higher rebate, the insurer will resort to interventions to enforce formulary controls.

As a soft measure to control access, payers use step therapy (to ensure use of low-cost therapies) and prior authorization (to require proof of medical necessity). For example, some US payers have placed significant restrictions on usage of Praluent®, which has resulted in significant out-of-pocket expenditures for Medicare patients.

A more extreme tactic, initially provoked by pharma coupons, is adding a product to an exclusion list; this means that (i) a patient has to pay out of pocket and (ii) manufacturer coupons are rejected at the pharmacy. 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® and Toujeo® will be excluded from the formulary across the commercial and MMC (Medicaid Managed Care) template formularies covering approximately 34.7 million people, thus reducing the potential patient populations to whom Lantus® may be prescribed.

US insurers have prioritized the need to control costs in specialty categories, and will maximize exclusions and protocols to achieve

savings. There is a particular focus on all chronic disease states, which will limit the ability of new entrants to achieve coverage without demonstration of comparative effectiveness. Finally, US insurers are quick to adopt Follow-On-Biologic (copycat) versions of branded drugs as a good enough alternative to leverage higher rebates as compared with incumbent products.

A new approach to copayments was adopted recently by some plans: the copay accumulator programs do not apply manufacturer copay coupons for specialty drugs to the patient s deductible and out-of-pocket maximum, which may lead to an increase in patients overall costs.

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 consolidation of the distribution channel.

In May 2017, Sanofi adopted pricing principles for the US (for more information, please see https://www.sanofi.com/en/our-responsibility/documents-center/)

The industry in China is going through a transformative period with many proposals on reform from the government. The first update of the NRDL (National Reimbursement Drug List) since 2009 occurred in 2017 and it has been announced that this will be done on a more regular basis going forward, to bring innovative medicines to the Chinese market earlier. The CFDA (China Food and Drugs Administration) has also made clear its intent to clear the backlog of regulatory reviews. Generics manufacturers are incentivized to submit originator bioequivalence data in order to access priority tendering, in a drive to modernize the generics industry and change their image as an affordable alternative to brands. The market itself is also due to transform through a series of smaller measures. For example, a two-invoice policy will simplify the supply chain, and tax reform has reallocated funds to poorer provinces for healthcare. While these can be viewed as positive, there are many uncertainties. Whatever the outcome, we can expect many other measures in the Chinese market following a call to step up the pace of reforms.

Recent trends in European policy have been towards joint procurement and joint negotiations, ignited by the controversy on funding Hepatitis C drugs. At the same time, political uncertainty, especially Brexit negotiations in the UK and tightening evaluation processes (e.g. the dissolution of the pricing committee in favor of an HTA committee in Greece, ultra-orphan drug quality adjusted life-year (QALY) thresholds and budget thresholds in the UK) are ever-present. However, with an increasing number of innovative products on the horizon, some countries have begun to address this, such as a dedicated budget for innovative medicines in Italy and the Accelerated Access Pathway in the UK.

While reforms in Japan were announced, several proposals were delayed until future reviews. However, some significant modifications were made to the Price Maintenance Premium and to the Foreign Price Adjustment. The final details are currently under preparation.

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In South America, inflation continues to have a major effect on the sustainability of the industry in the region. Transparent tendering platforms have begun to appear in Colombia and Brazil while joint procurement actions are widening (brought about for HCV and oncology).

The Eurasian Economic Union (Armenia, Belarus, Kazakhstan, Kyrgyzstan and Russia) has moved forward with its plans for a single pharmaceutical market with a centralized system for product registration under a mutual recognition agreement. This should further streamline processes and also increase the region s negotiating power.

We believe that third-party payers will continue to act to curb the cost of pharmaceutical products. While the impact of those measures cannot be predicted with certainty, we are taking the necessary steps to defend the accessibility and price of our products in order to reflect the value of our innovative product offerings:

- In compliance with local law we actively engage with our key stakeholders to define criteria for assessing the value of our products to them. These stakeholders, including physicians, patient groups, pharmacists, government authorities and third-party payers, can have a significant impact on market access for our products.

- We continue to add flexibility and adaptability to our operations so as to better prepare, diagnose, and address issues in individual markets.

Conscious of the importance of recognizing the value of our products and the high cost of research and development, we continue to analyze innovative pricing and access strategies that balance patient access with appropriate rewards for innovation. Specifically, we are involved in risk-sharing agreements with payers, whereby part of the financial risk related to a treatment s success is carried by the marketing company. Those agreements provide that clinical efficacy be monitored after launch, for a specified period of time and patient population. The price and reimbursement level of the drug is then either confirmed or revised based on the post-marketing results.

We are also actively testing pilot models for affordability and access to healthcare, allowing wider access to therapies for populations that would otherwise be denied this.

B.7. Patents, intellectual property and other rights

Patent Protection

We own a broad portfolio of patents, patent applications and patent licenses worldwide. These patents are of various types and may cover:

- active ingredients;
- pharmaceutical formulations;
- product manufacturing processes;
- intermediate chemical compounds;
- therapeutic indications/methods of use;
- delivery systems; and
- enabling technologies, such as assays.

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

Additionally, the product may benefit from the protection of patents obtained during development or after the product s initial marketing authorization. The protection a patent provides to the related product depends upon the type of patent and its scope of coverage, and may also vary from country to country. In Europe for instance, applications for new patents may be submitted to the European Patent Office (EPO), an intergovernmental organization which centralizes filing and prosecution. As of December 2017, an EPO patent application may cover the 38 European Patent Convention Member States, including all 28 Member States of the EU. The granted European Patent establishes corresponding national patents with uniform patent claims among the Member States. However, some older patents were not approved through this centralized process, resulting in patents having claim terms for the same invention that differ between the countries. Additionally, a number of patents prosecuted through the EPO may pre-date the European Patent Convention accession of some current European

Patent Convention Member States, resulting in different treatment in those countries.

In 2013, EU legislation was adopted to create a European Unitary Patent and a Unified Patent Court. However, it will only enter into force once the agreement on the Unified Patent Court is ratified by at least 13 Member States including France, Germany, and the United Kingdom. As of the date of this document, 14 countries including France have ratified the agreement, but ratification by the United Kingdom and Germany is still outstanding, and the process is impacted by Brexit.

The Unitary Patent will provide unitary protection within the participating states of the EU (when ratified by the Member States with the exception of Croatia, Spain, and Poland, not currently signatories of the agreement). The Unified Patent Court will be a specialized patent court with exclusive jurisdiction for litigation relating to European patents and Unitary Patents. The Court will be

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composed of a central division (headquartered in Paris) and several local and regional divisions in the contracting Member States to the agreement. The Court of Appeal will be located in Luxembourg.

We monitor our competitors and vigorously seek to challenge patent infringements when such infringements would negatively impact our business objectives. See Item 8 A. Consolidated Financial Statements and Other Financial Information A.3. Information on Legal or Arbitration Proceedings Patents of this annual report.

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

Regulatory Exclusivity

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

In the US, the FDA will not grant final marketing authorization to a generic competitor for a New Chemical Entity (NCE) until the expiration of the regulatory exclusivity period (five years) that commences upon the first marketing authorization of the reference product. The FDA will accept the filing of an Abbreviated New Drug Application (ANDA) containing a patent challenge one year before the end of this regulatory exclusivity period (see the descriptions of ANDAs in Product Overview Challenges to Patented Products below). In addition to the regulatory exclusivity granted to NCEs, significant line extensions of existing NCEs may qualify for an additional three years of regulatory exclusivity. Also, under certain limited conditions, it is possible to extend unexpired US regulatory and patent-related exclusivities by a pediatric extension. See Pediatric Extension , below.

In the US, a different regulatory exclusivity period applies to biological drugs. The Biologics Price Competition and Innovation Act of 2009 (BPCIA), was enacted on March 23, 2010 as part of the Affordable Care Act. The BPCIA introduced an approval pathway for biosimilar products. A biosimilar product is a biologic product that is highly

similar to the reference (or innovator) product notwithstanding minor differences in clinically inactive components, and which has no clinically meaningful differences from the reference product in terms of the safety, purity, and potency of the product. The BPCIA provides that an application for a biosimilar product that relies on a reference product may not be submitted to the FDA until four years after the date on which the reference product was first licensed, and that the FDA may not approve a biosimilar application until 12 years after the date on which the reference product was first licensed. US Federal and state officials, including the new Administration, are continuing to focus on the cost of health coverage and health care although the future policy, including the nature and timing of any changes to the Affordable Care Act, remains unclear.

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

In Japan, the regulatory exclusivity period varies from four years for medicinal products with new indications, formulations, dosages, or compositions with related prescriptions, to six years for new drugs

containing a medicinal composition, or requiring a new route of administration, to eight years for drugs containing a new chemical entity, to ten years for orphan drugs or new drugs requiring pharmaco-epidemiological study.

Emerging Markets

One of the main limitations on our operations in emerging market countries is the lack of effective intellectual property protection or enforcement for our products. The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIP) required developing countries to amend their intellectual property laws to provide patent protection for pharmaceutical products since January 1, 2005. However, it also provided a limited number of developing countries with an extended period in which to achieve compliance with TRIP. Additionally, these same countries frequently do not provide non-patent exclusivity for innovative products. While the situation has gradually improved, the lack of protection for intellectual property rights or the lack of robust enforcement of intellectual property

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rights poses difficulties in certain countries. Additionally, in recent years a number of countries facing health crises have waived or threatened to waive intellectual property protection for specific products, for example through compulsory licensing of generics. See Item 3. Key Information D. Risk Factors Risks Relating to Sanofi s Structure and Strategy The globalization of our business exposes us to increased risks in specific areas .

Pediatric Extension

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

In the US, the FDA may ask a company for pediatric studies if it has determined that information related to the use of the drugs in the pediatric population may produce health benefits. The FDA has invited us by written request to provide additional pediatric data on several of our main products. Under the Hatch-Waxman Act, timely provision of data meeting the FDA s requirements (regardless of whether the data supports a pediatric indication) may result in the FDA extending regulatory exclusivity and patent life by six months, to the extent these protections have not already expired (the so-called pediatric exclusivity).

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

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

Orphan Drug Exclusivity

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

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

Orphan drug exclusivity runs from the time of approval and bars approval of another application (ANDA, 505(b)(2), New Drug Application (NDA) or Biologic License Application (BLA)) from a different sponsor for the same drug in the same indication for a seven year period. Whether a subsequent application is for the same drug depends upon the chemical and clinical characteristics. The FDA may approve applications for the same drug for indications not protected by orphan exclusivity.

Orphan drug exclusivities also exist in the EU and Japan.

Product Overview

We summarize below the intellectual property coverage (in some cases through licences) in our major markets of the marketed products described above at B.2. Main Pharmaceutical Products . In the discussion of patents below, we focus on active ingredient patents (compound patents) and for NCEs on any later filed patents listed, as applicable, in the FDA s list of Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book) or in their foreign equivalents. For Biologics the Orange Book listing does not apply. These patents or their foreign equivalents tend to be the most relevant in the event of an application by a competitor to produce a generic or a biosimilar version of one of our products (see Challenges to Patented Products below). In some cases, products may also benefit from pending patent applications or from patents not eligible for Orange Book listing (for NCEs) (e.g. patents claiming industrial processes). In each case below, we specify whether the active ingredient is claimed by an unexpired patent. Where patent terms have been extended to compensate for US Patent and Trademark Office (USPTO) delays in patent prosecution (Patent Term Adjustment PTA) or for other regulatory delays, the extended dates are indicated below. The US patent expirations presented below reflect USPTO dates, and also reflect six month pediatric extensions when applicable. Where patent terms have expired we indicate such information and mention whether generics are on the market.

We do not provide later filed patent information relating to formulations already available as an unlicensed generic. References below to patent protection in Europe indicate the existence of relevant patents in most major markets in the EU. Specific situations may vary by country, most notably with respect to older patents and to countries that have only recently joined the EU.

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

	United States	European Union	Japan
Aldurazyme ® (laronidase)	Compound: November 2019 Later filed patents: ranging through July 2020 with PTA	Compound: November 2020 in some EU countries only Later filed patent: November 2020 in some EU countries only	Compound: November 2020
Allegra® (fexofenadine hydrochloride)	Compound: expired Generics on the market Converted to over-the-counter	Compound: expired Generics on the market	Compound: expired Generics on the market Converted to over-the counter
Amaryl® (glimepiride)	Compound: expired	Compound: expired	Compound: expired
Apidra® (insulin glulisine)	Compound: June 2018 Later filed patents: ranging through September 2027	Compound: September 2019 with SPC in most of the EU countries Later filed patent: March 2022	Compound: May 2022 with PTE Later filed patent: July 2022 Regulatory exclusivity: Expired
Aprovel® (irbesartan)	Compound: expired Generics on the market	Compound: expired Generics on the market	Compound: expired Later filed patent: June 2021 with PTE
Aubagio® (teriflunomide)[a]	Compound: expired Later filed patents: coverage ranging through February 2034 Regulatory exclusivity: September 2017	Compound: expired Later filed patent: coverage ranging through September 2030 Regulatory exclusivity: August 2023	Compound: expired Later filed patent: coverage ranging through March 2024

Cerdelga® (eliglustat)	Compound: April 2022 (2026 with PTE if granted) Later filed patent: November 2030 (pending) Regulatory exclusivity: August 2019 Orphan drug exclusivity: August 2021	Compound: July 2022 (2027 with SPC if granted) Later filed patent: November 2030 Orphan drug exclusivity: January 2025	Compound: July 2022 (March 2025 with PTE) Later filed patent: November 2030 (pending) Regulatory exclusivity: March 2023
Cerezyme® (imiglucerase)	Compound: expired	Compound: N/A	Compound: N/A
Depakine® (sodium valproate)	Compound: N/A[(b)]	Compound: N/A[(b)] Later filed patent: Depakine® Chronosphere formulation: Expired	Compound: N/A[(b)] Later filed patent: Depakine® Chronosphere formulation: Expired

(a) In 2017, Sanofi reached settlement with all 20 generic Aubagio® ANDA first filers granting each a royalty-free license to enter the United States market on March 12, 2023 (see Item 8. Financial Information).
(b) No rights to compounds in the US, EU and Japan.

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	United States	European Union	Japan
Dupixent® (dupilumab)			Compound: October 2029 (PTE to be determined once product is approved)
	Compound: October 2027 (Mar 2031 with PTE if granted)	Compound: October 2029 (September 2032 if SPC granted)	
	Later filed patents: coverage ranging through December 2033 with PTA	Later filed patents: coverage ranging through September 2033 (pending)	Later filed patents: coverage ranging through September 2033 (pending)
	Regulatory exclusivity: March 2029	Regulatory exclusivity: September 2027	Regulatory exclusivity: January 2026
Fabrazyme® (agalsidase beta)	Compound: N/A	Compound: N/A	Compound: N/A
	Later filed patents: expired	Later filed patents: expired	Later filed patents: expired
Insuman® (human insulin)	Compound: N/A	Compound: N/A	Compound: N/A
		Later filed patent: August 2018	
Jevtana® (cabazitaxel)	Compound: September 2021 with PTE and pediatric exclusivity	Compound: expired	Compound: March 2021 with PTE
	Later filed patents: coverage ranging through April 2031 with pediatric exclusivity	Later filed patents: coverage ranging through October 2030 (pending)	Later filed patents: coverage ranging through October 2030 with PTE
		Regulatory exclusivity: March 2021	Regulatory exclusivity: July 2022
Kevzara® (sarilumab)	Compound: January 2028 with PTA	Compound: June 2027	Compound: June 2027
	Later filed patents: coverage ranging through March 2037	Later filed patents: coverage ranging through March 2037	Later filed patents: coverage ranging through March 2037

	(pending) Regulatory exclusivity: May 2029	(pending)	(pending)
Lantus® (insulin glargine)	Compound: expired Later filed patents ranging through March 2028	Compound: Expired Later filed patents ranging through June 2023	Compound: expired Later filed patents ranging through June 2023
Lemtrada® (alemtuzumab)	Compound: expired Later filed patent: August 2029 with PTA	Compound: expired Later filed patent: September 2027 (pending)	Compound: expired Later filed patent: September 2027
Lovenox® (enoxaparin sodium)	Compound: N/A Generics on the market	Compound: expired	Compound: expired
Lumizyme® / Myozyme® (alglucosidase alpha)	Compound: N/A Later filed patents: coverage ranging through February 2023 with PTA Biologics regulatory exclusivity: April 2018	Compound: N/A Later filed patents: July 2021	Compound: N/A Later filed patents: coverage ranging through July 2021 Orphan drug exclusivity: expired
Adlyxin®/Lyxumia® (lixisenatide)	Compound: July 2020 (July 2025 with PTE if granted) Later filed patents: coverage ranging through August 2032 Regulatory exclusivity: July 2021	Compound: July 2020[(b)] (2025 with SPC in most EU countries if granted) Later filed patents: November 2030 (pending) Regulatory exclusivity: February 2023	Compound: July 2024 with PTE Later filed patents: November 2030 Regulatory exclusivity: June 2021

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	United States	European Union	Japan
Mozobil® (plerixafor)	Compound: N/A	Compound: N/A	Compound: N/A
	Later filed patents: coverage ranging through July 2023	Later filed patent: July 2022 (2024 with SPC in some EU countries)	Later filed patent: August 2026 with PTE
		Orphan drug exclusivity: August 2019	Orphan drug exclusivity: December 2026
Multaq® (dronedarone hydrochloride)	Compound: expired Later filed patents: coverage ranging through June 2031	Compound: expired Later filed patent: June 2018 (2023 with SPC in most EU countries) Regulatory exclusivity: December 2019	Compound: expired Later filed patent: June 2018
Soliqua100/33 / Suliqua (lixisenatide + insulin glargine)	Compound: July 2020 (July 2025 with PTE if granted)	Compound: July 2020 (July 2025 with SPC in most EU countries if granted)	Compound: July 2024 with PTE
	Later filed patents: coverage ranging through November 2030 (pending)	Later filed patents: coverage ranging through January 2032 with SPC	Later filed patents: coverage ranging through November 2030
	Regulatory exclusivity: July 2021	Regulatory exclusivity: January 2027	Regulatory exclusivity: to be determined
Plavix® (clopidogrel bisulfate)	Compound: expired Generics on the market	Compound: expired Generics on the market	Compound: expired
Praluent® (alirocumab)	Compound: December 2029	Compound: December 2029 (September 2030 if SPC granted)	Compound: November 2032 with PTE
	Later filed patents: coverage ranging through September 2032 (pending)	Later filed patents: coverage ranging through September 2032 (pending)	Later filed patents: coverage ranging through September 2032
	Biologics regulatory exclusivity: July 2027	Regulatory exclusivity: September 2025	Regulatory exclusivity: July 2024
	Compound: N/A	Compound: N/A	Compound: N/A

Renagel® (sevelamer hydrochloride)	Later filed patent: October 2020	Later filed patent: October 2020	Later filed patent: October 2020
Renvela® (sevelamer carbonate)	Compound: N/A Later filed patents: October 2025 (tablet) and December 2030 (sachet) Generics on the market	Compound: N/A Later filed patent: November 2025 (tablet) and September 2026 (sachet) Generics on the market	Compound: N/A Later filed patents: November 2025 (tablet) and September 2026 (sachet)
Stilnox® (zolpidem tartrate)	Compound: expired Generics on the market	Compound : expired Generics on the market	Compound : expired Later filed patent: Ambien® CR formulation (December 2019) not commercialized
Synvisc® (Hylan G-F 20)	Compound: expired	Compound: N/A	Compound: expired Regulatory exclusivity: July 2018
Synvisc-One® (Hylan G-F 20)	Compound: expired	Compound: N/A Later filed patent: December 2025	Compound: expired Later filed patent: December 2025

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	United States	European Union	Japan
Toujeo® (insulin glargine)	Compound: expired Later filed patents: coverage ranging through May 2031 Regulatory exclusivity: February 2018	Compound: expired Later filed patents: coverage ranging through May 2031 (pending)	Compound: expired Later filed patents: coverage ranging through July 2033 with PTE Regulatory exclusivity: July 2019
Zaltrap® (aflibercept)	Compound: May 2020 (July 2022 with PTE if granted) Later filed patents: coverage ranging through April 2032 (pending) Biologics regulatory exclusivity: November 2023	Compound: May 2020 (May 2025 with SPC in most EU countries, if granted) Later filed patents: coverage ranging through April 2032 (pending) Regulatory exclusivity: February 2023	Compound: May 2020 (May 2025 with PTE if granted) Later filed patents: coverage ranging through April 2032 (pending) Regulatory exclusivity: March 2023

PTE: Patent Term Extension.

SCP: Supplementary Protection Certificate.

PTA: Patent Term Adjustment.

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

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

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

Challenges to Patented Products

Abbreviated New Drug Applications (ANDAs)

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

approved product. ANDAs may not be filed with respect to drugs licensed as a biological. See B.6.3. Regulatory Framework B.6.3.2. Biosimilars above. An ANDA relies on the safety and other technical data of the original approved product, and does not generally require the generic manufacturer to conduct clinical trials (thus the name abbreviated new drug application), presenting a significant benefit in terms of time and cost. As a result of regulatory protection of our safety and other technical data, the ANDA may generally be filed only five years after the initial US original product marketing authorization. See Regulatory Exclusivity above. This period can be reduced to four years if the ANDA includes a challenge to a patent listed in the FDA s Orange Book. However, in such a case if the patent holder or licensee brings suit in response to the patent challenge within the statutory window, then the FDA is barred from granting final approval to an ANDA during the 30 months following the patent challenge (this bar is referred to in our industry as a 30-month stay), unless, before the end of the 30 months, a court decision or settlement has determined either that the ANDA does not infringe the listed patent or that the listed patent is invalid and/or unenforceable.

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

The accelerated ANDA-type procedures are potentially applicable to many, but not all, of the products we manufacture. See B.6.3. Regulatory Framework 6.3.2. Biosimilars and Regulation above. We seek to defend o patent rights vigorously in these cases. Success or failure in the assertion of a given patent against a competing product is not necessarily predictive of the future success or failure in the assertion of the same patent or *a fortiori* the corresponding foreign patent against another competing product due to factors such as possible differences in the

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formulations of the competing products, intervening developments in law or jurisprudence, local variations in the patents and differences in national patent law and legal systems. See Item 3. Key Information D. Risk Factors Risks Relating to Legal and Regulatory Matters We rely on our patents and other proprietary rights to provide exclusive rights to market certain of our products, and if such patents and other rights were limited or circumvented, our financial results could be materially and adversely affected .

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

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

A 505(b)(2) applicant is required to identify the reference drug on which it relies, as well as to certify to the FDA concerning any patents listed for the referenced product in the Orange Book. Specifically, the applicant must certify in the application that, for each patent that claims the drug or a use of the drug for which the applicant is seeking approval:

- there is no patent information listed for the reference drug (paragraph I certification);
- the listed patent has expired for the reference drug (paragraph II certification);
- the listed patent for the reference drug has not expired, but will expire on a particular date and approval is sought after patent expiration (paragraph III certification); or
- the listed patent for the reference drug is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of the product for which the 505(b)(2) NDA is submitted (paragraph IV certification).

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

exclusivity, and the FDA may be prohibited from giving final approval to a 505(b)(2) application until the expiration of all applicable non-patent exclusivity periods.

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

Trademarks

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

It is our policy to protect and register our trademarks with a strategy adapted to each product or service depending on the countries where they are commercialized: on a worldwide basis for worldwide products or services, or on a regional or local basis for regional or local products or services.

The process and degree of trademark protection vary country by country, as each country applies its own trademark laws and regulations. In most countries, trademark rights may only be obtained through formal trademark application and registration. In some countries, trademark protection can be based primarily on use. Registrations are granted for a fixed term (in most cases ten years) and are renewable indefinitely, except in some countries where maintenance of the trademarks is subject to their effective use.

When trademark protection is based on use, it covers the products and services for which the trademark is used. When trademark protection is based on registration, it covers only the products and services designated in the registration certificate. Additionally, in certain cases, we may enter into a coexistence agreement with a third party that owns potentially conflicting rights in order to avoid any risk of confusion and better protect and defend our trademarks.

Our trademarks are monitored and defended based on this policy and in order to prevent counterfeit, infringement and/or unfair competition.

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B.8. Production and Raw Materials

Our policy is to manufacture the majority of our products in-house. There are three principal stages in our production process: the manufacture of pharmaceutical active ingredients, the transformation of those ingredients into drug products, and packaging those products.

Our general policy is to produce the majority of our active ingredients and principal drug products at our own plants in order to reduce our dependence on external suppliers. In some cases, however, we rely on third parties for the manufacture and supply of certain active ingredients, drug products and medical devices. Active ingredients are manufactured using raw materials sourced from suppliers who have been subject to rigorous selection and approval procedures, in accordance with international standards and our own internal directives. We have outsourced some of our production under supply contracts associated with acquisitions of products or businesses or with plant divestitures, or to establish a local presence to capitalize on growth in emerging markets. Our pharmaceutical subcontractors follow our general quality and logistics policies, as well as meeting other criteria. See Item 3. Key Information D. Risk Factors Risks Relating to Our Business .

At the start of 2017 we launched our Global External Manufacturing team, to enhance the way we manage relations with our third-party suppliers.

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

Our pharmaceutical production sites are divided into three categories:

- global sites, which serve all markets: located mainly in Europe, these facilities are dedicated to the manufacture of our active ingredients, injectable drug products, and a number of our main solid-form drug products;

- regional sites, which serve markets at regional level, in Europe and particularly the BRIC-M countries (Brazil, Russia, India, China and Mexico), giving us a strong industrial presence in emerging markets; and

local sites, which serve their domestic market only.

Sanofi Pasteur produces vaccines at sites located in the United States, Canada, France, Mexico, China, Thailand, Argentina and India. The pharmaceutical site at Le Trait (France) also contributes to Sanofi Pasteur s industrial operations by making available its aseptic filling facilities.

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

Our principal sites are approved by the FDA:

- the Biologics facilities in the United States (Allston, Framingham and Northborough), France (Lyon Gerland) and Belgium (Geel);
- the Injectables facilities in France (Le Trait, Maisons-Alfort), Italy (Anagni), Ireland (Waterford), Germany (Frankfurt) and the United States (Ridgefield);
- the Pharmaceuticals facilities in France (Ambarès and Tours), the United Kingdom (Haverhill and Holmes Chapel), and the United States (Saint Louis);
- the Consumer Healthcare facilities in France (Compiègne), and the United States (Chattanooga); and
- the Vaccines facilities in France (Marcy l Étoile and Le Trait which handle filling and packaging of Fluzone® ID for the US market), the United States (Swiftwater), and Canada (Toronto).

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

In May 2010, Genzyme s Allston facility in the United States entered into a consent decree with the FDA following FDA inspections at the facility that resulted in observations and a warning letter raising Current Good Manufacturing Practices (CGMP) deficiencies. A consent decree is a court order entered into by agreement between a company and the government (in this case the FDA) that requires the company to take certain actions as set out in the decree. Under the terms of the consent decree, the Sanofi Genzyme facility at Allston was permitted to continue manufacturing during the remediation process subject to compliance with the terms of the consent decree.

The consent decree required Sanofi Genzyme to implement a plan to bring operations at the Allston facility into compliance with applicable laws and regulations. The plan had to address all deficiencies reported to Genzyme or identified as part of an inspection completed by a third-party expert in February 2011. This workplan was submitted to the FDA in April 2011 and accepted by the FDA in January 2012. Modifications to the remediation workplan were accepted by the FDA in March 2012 and April 2015.

The workplan was completed on March 31, 2016. The next step was a third-party certification process, which was finalized on June 30, 2017. In August 2017, the FDA conducted an inspection of the facility and delivered a favorable conclusion, following which certification was received on October 4, 2017.

The Allston facility is required to engage a third-party expert to audit its manufacturing operations for an additional period of at least five years.

More details about our manufacturing sites are given below at section D. Property, Plant and Equipment .

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B.9. Insurance and Risk Coverage

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

These four key programs cover Property & Business Interruption, General & Product Liability, Stock and Transit, and Directors & Officers Liability.

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

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

Our Property & Business Interruption program covers all our entities worldwide, wherever it is possible to use a centralized program operated by our captive insurance company. This approach shares risk between our entities, enabling us to set deductibles and guarantees that are appropriate to the needs of local entities. It also incorporates a prevention program, including a comprehensive site visit program covering our production, storage, research and distribution facilities and standardized repair and maintenance procedures across all sites. Specialist site visits are conducted every year to address specific needs, such as testing of sprinkler systems or emergency plans to deal with flooding risks.

The Stock and Transit program protects all goods owned by Sanofi while they are in transit nationally or internationally whatever the means of transport, and all our inventories wherever they are located. Sharing risk between our entities means that we can set deductibles at appropriate levels, for instance differentiating between goods that require temperature controlled distribution and those that do not. We have developed a prevention program with assistance from experts, implementing best practices in this area at our distribution sites. This program, which is led by our captive insurance company, has substantial capacity, largely to deal with the growth in sea freight which can lead to a concentration of value in a single ship.

Our General & Product Liability program was renewed in 2017 for all our subsidiaries worldwide wherever it was possible to do so, despite the increasing reluctance in the insurance and reinsurance market to cover product liability risks for large pharmaceutical groups. For several years, insurers have been reducing product liability cover because of the difficulty of insuring some products that have been subject to numerous claims. These products are excluded from the cover provided by insurers, and hence from the cover obtained by us on the insurance market. This applies to a

few of our products, principally those described in Note D.22.a) to our consolidated financial statements included at Item 18 in this annual report. Because of these market conditions we have increased, year by year, the extent to which we self-insure.

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

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

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

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

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

All our insurance programs are backed by best in class insurers and reinsurers and are designed in such a way that we can integrate most newly acquired businesses on a continuous basis. Our cover has been designed to reflect our risk profile and the capacity available in the insurance market. By centralizing our major programs, we are able to provide world-class protection while reducing costs.

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ITEM 4. INFORMATION ON THE COMPANY

B.10. Health, Safety and Environment

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

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

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

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

Potential environmental contingencies arising from certain business divestitures are described in Note D.22.d to the consolidated financial statements. In 2017, Sanofi spent 67 million on rehabilitating sites previously contaminated by soil or groundwater pollution.

Due to changes in environmental regulations governing site remediation, our provisions for remediation obligations may not be

adequate due to the multiple factors involved, such as the complexity of operational or previously operational sites, the nature of claims received, the rehabilitation techniques involved, the planned timetable for rehabilitation, and the outcome of discussions with national regulatory authorities or other potentially responsible parties, as in the case of multiparty sites. Given the long industrial history of some of our sites and the legacy obligations arising from the past involvement of Aventis in the chemical and agrochemical industries, it is impossible to quantify the future impact of these laws and regulations with precision. See Item 3.D. Risk Factors Environmental Risks of Our Industrial Activities .

We have established, in accordance with our current knowledge and projections, provisions for cases already identified and to cover contractual guarantees for environmental liabilities relating to sites that have been divested. In accordance with Sanofi standards, a comprehensive review is carried out once a year on the legacy of environmental pollution. In light of data collected during this review, we adjusted our provisions to approximately 685 million as of December 31, 2017 versus 732 million as of December 31, 2016. The terms of certain business divestitures, and the environmental obligations and retained environmental liabilities relating thereto are described in Note D.22. to our consolidated financial statements.

To our knowledge, Sanofi did not incur any liability in 2017 for non-compliance with current HSE laws and regulations that could be expected to significantly jeopardize its activities, financial situation or operating income. We also believe that we are in substantial compliance with current HSE laws and regulations and that all the environmental permits required to operate our facilities have been obtained.

Regular HSE audits are carried out by Sanofi in order to assess compliance with standards (which implies compliance with regulations) and to initiate corrective measures (47 internal audits performed by 85 auditors in 2017). Moreover, around 200 specific visits were performed jointly with experts representing our insurers.

Sanofi has implemented a worldwide master policy on health, safety and environment to promote the health and well-being of the employees and contractors working on its sites and respect for the environment. We consider this master policy to be an integral part of our commitment to social responsibility. In order to implement this master policy, Sanofi key requirements have been drawn up in the key fields of HSE management, HSE leadership, safety in the workplace, process safety, occupational hygiene, health in the workplace and protection of the environment.

Health

From the development of compounds to the commercial launch of new drugs, Sanofi research scientists continuously assess the effect of products on human health. This expertise is made available to employees through two committees responsible for chemical and biological risk assessment. Sanofi s COVALIS Committee is responsible for the hazard determination and

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classification of all active pharmaceutical ingredients and synthesis intermediates handled at Sanofi facilities. This covers all active ingredients handled in production at company sites or in processes sub-contracted for manufacture. Any important issues involving raw materials or other substances that lack established occupational exposure limits may also be reviewed. The COVALIS Committee determines the occupational exposure limits required within Sanofi. Our TRIBIO Committee is responsible for classifying all biological agents according to their degree of pathogenicity, and applies rules for their containment and the preventive measures to be respected throughout Sanofi. See Item 3. Key Information D. Risk Factors Environmental Risks of Our Industrial Activities Risks from the handling of hazardous materials could adversely affect our results of operations .

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

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

Safety

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

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

heightened security inspections due to the toxic or flammable materials stored on the sites and used in the operating processes.

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

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

We believe that the safety management systems implemented at each site, the hazard studies carried out and the risk management methods implemented, as well as our third-party property insurance policies covering any third-party physical damage, are consistent with legal requirements and the best practices in the industry.

Environment

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

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

Compared with 2015 figures, we are undertaking to halve our carbon emissions by the end of 2025 and reach carbon-neutral status by 2050 on our scope 1 & 2 (industrial, R&D and tertiary sites, including the medical rep fleet). We have also set ourselves the target of achieving sustainable water resource management, especially at sites which are under hydric stress. On this new scope, by the end of 2017, we had reduced CO_2 emissions by 7% and water consumption by 6%.

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Overall waste recycling at sites is already above 72% and is expected to be more than 90% by the end of 2025. The discharge rate had dropped to 8% at the end of 2017 and we have committed to move towards a maximum of 1% by 2025. Biodiversity management at sites is also a priority, with the aim of making all employees aware of this challenge and implementing risk assessment and management plans at priority sites.

Finally, we are pursuing the policy we began in 2010 of managing pharmaceutical products in the environment throughout their life cycles. At the end of 2017, all priority chemical sites had been evaluated and were shown to present no risk to the environment. The assessment program was extended to other sites, starting with the pharmaceutical production sites. In 2017, eight sites implemented the program.

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

C/ Organizational Structure

C.1. Significant Subsidiaries

Sanofi is the holding company of a consolidated group consisting of over 300 companies. The table below sets forth our significant subsidiaries as of December 31, 2017. For a fuller list of the principal companies in our consolidated group, see Note F. to our consolidated financial statements, included in this annual report at Item 18.

Significant Subsidiary	Date of Incorporation	Country of Incorporation	Principal Activity	Financial and Voting

				Interest
Aventis Inc.	07/01/1968	United States	Pharmaceuticals	100%
Aventis Pharma SA	09/24/1974	France	Pharmaceuticals	100%
Genzyme Corporation	11/21/1991	United States	Pharmaceuticals	100%
Hoechst GmbH	07/08/1974	Germany	Pharmaceuticals	100%
Sanofi-Aventis Amérique du Nord	09/20/1985	France	Pharmaceuticals	100%
Sanofi-Aventis Deutschland GmbH	06/30/1997	Germany	Pharmaceuticals	100%
Sanofi-Aventis Europe	07/15/1996	France	Pharmaceuticals	100%
Sanofi-Aventis US LLC	06/28/2000	United States	Pharmaceuticals	100%
Sanofi-Aventis Participations SAS	02/25/2002	France	Pharmaceuticals	100%
Sanofi Pasteur SA	02/08/1989	France	Vaccines	100%
Sanofi Pasteur Inc.	01/18/1977	United States	Vaccines	100%
Sanofi Winthrop Industrie	12/11/1972	France	Pharmaceuticals	100%
Chattem, Inc.	11/11/1909	United States	Pharmaceuticals	100%

Since 2009, we have transformed Sanofi through numerous acquisitions (see A. History and Development of the Company above), in particular those of Genzyme in April 2011 and Merial in September 2009. The financial effects of the Genzyme acquisition are presented in Note D.1.3. to our consolidated financial statements for the year ended December 31, 2013, included in our annual report on Form 20-F for that year. The financial effects of the Merial acquisition are presented in Note D.1.3. to our consolidated financial statements for the year ended December 31, 2010, included in our annual report on Form 20-F for that year. On

January 1, 2017, Sanofi and Boehringer Ingelheim (BI) finalized the strategic transaction agreed in June 2016, involving the exchange of Sanofi s Animal Health business (Merial) for BI s Consumer Healthcare business. The financial effects of this transaction are presented in Note D.1. to our consolidated financial statements, included at Item 18 of this annual report on Form 20 F. At the end of December 2016, Sanofi Pasteur and MSD (known as Merck in the United States and Canada) ended their Sanofi Pasteur MSD joint venture. The financial effects of the resulting divestment/acquisition are presented in Note D.1.2. to our consolidated

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financial statements for the year ended December 31, 2016, included in our annual report on Form 20-F for that year.

In certain countries, we carry on some of our business operations through joint ventures with local partners. In addition, we have entered into worldwide collaboration agreements (i) with Regeneron, relating to Zaltrap®, human therapeutic antibodies such as Praluent® and antibodies in immunology such as Dupixent® and Kevzara®; and (ii) with BMS, relating to Plavix®. For further information, refer to Note C. to our consolidated financial statements, Principal Alliances .

C.2. Internal Organization of Activities

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

During 2017, Sanofi gradually integrated the Consumer Healthcare operations of Boehringer Ingelheim (BI), acquired on January 1, 2017. Following the completion of the integration process and effective December 31, 2017, Consumer Healthcare business forms a distinct operating segment.

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

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

Pharmaceuticals: Sanofi, Aventis Pharma SA, Sanofi Biotechnology SAS (France), Sanofi-Aventis Deutschland GmbH (Germany) and Genzyme Corporation (US);

Vaccines: Sanofi Pasteur (France) and Sanofi Pasteur, Inc. (US).

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

in France: Sanofi Pasteur SA, Sanofi Chimie, Sanofi Winthrop Industrie, Sanofi, and Sanofi-Aventis Recherche & Développement;

in the United States: Sanofi Pasteur, Inc., Genzyme Corporation, and Genzyme Therapeutics Products LP;

in Canada: Sanofi Pasteur Limited;
in Germany: Sanofi-Aventis Deutschland GmbH;

in Belgium: Genzyme Flanders BVBA Holding Co; and

in Ireland: Genzyme Ireland Limited.

C.3. Financing and Financial Relationships between Group Companies

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

Consequently, at December 31, 2017, the Sanofi parent company held 94% of our external financing and 89% of our surplus cash.

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

D/ Property, Plant and Equipment

D.1. Overview

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

We operate our business through office premises and research, production and logistics facilities in approximately 100 countries around the world. Our office premises house all of our support functions, plus operational representatives from our subsidiaries and the Company.

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

Breakdown of sites by use

Industrial	*60%*
Research	*12%*
Offices	*16%*
Logistics	*9%*
Other	*4%*

Breakdown of sites by ownership status

Leasehold	*25%*
Owned	*75%*

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

D.2. Description of Our Sites

Sanofi industrial sites

As part of the process of transforming Sanofi and creating Global Business Units, we are continuing to adapt the organization of the Industrial Affairs department in support of our new business model. Since June 2013, the Industrial Affairs department has been responsible for all production and quality operations within Sanofi. The department focuses on customer needs and service quality, the sharing of Sanofi Manufacturing System manufacturing practices, the development of a common culture committed to quality and the pooling of expertise within technology platforms, particularly in biological, injectable and pharmaceutical products. Since January 2016, the Industrial Affairs department has also been responsible for Sanofi Global HSE and Global Supply Chain.

At the end of 2017, we were carrying out industrial production at 79 sites in 36 countries:

- 8 sites for our Biologics operations;
- 9 sites for our Injectables operations;
- 37 sites for our Pharmaceuticals operations;
- 14 sites for our Consumer Healthcare operations;
- 11 sites for the industrial operations of Sanofi Pasteur in vaccines.

In 2017, we produced the following quantities:

Pharmaceuticals: 4,738 million units, comprising:

units manufactured and packaged: 3,072 million;

units packaged only: 320 million;

bulk products in unit equivalents: 379 million;

outsourced units: 976 million; and

Vaccines: 470 million containers (syringes and ampoules) filled, including outsourced production.

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

Production of biological, chemical and pharmaceutical products is the responsibility of our Industrial Affairs department, which is also in charge of most of our logistics facilities (distribution and storage centers).

Major drugs, active ingredients, specialties and medical devices are manufactured at the following sites:

Production Sites: Biologics

Belgium: Geel;

France: Lyon Gerland and Vitry-sur-Seine;

Germany: Frankfurt Insulin Biotech; and

United States: Allston, Framingham Biologics, Framingham Biosurgery and Northborough.

Production Sites: Injectables

China: Beijing;

France: Le Trait and Maisons-Alfort;

Germany: Frankfurt;

Hungary: Csanyikvölgy;

Ireland: Waterford;

Italy: Anagni;

Russia: Orel; and

United States: Ridgefield.

Production Sites: Pharmaceuticals

Algeria: Ain Benian and Oued Smar;

Bangladesh: Tongi;

Brazil: Campinas;

China: Hangzhou;

Colombia: Cali and Villa Rica;

Czech Republic: Prague;

United Arab Emirates: Dubai;

Egypt: Cairo;

France: Ambarès, Amilly, Aramon, Mourenx, Ploermel, Saint-Aubin-les-Elbeuf, Sisteron, Tours and Vertolaye;

Germany: Frankfurt Pharma & Chemistry

Hungary: Ujpest;

India: Goa, Ankleshwar Pharma & Chemistry;

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Indonesia: Jakarta;

Italy: Scoppito and Brindisi;

Japan: Kawagoe;

Pakistan: Karachi;

Romania: Bucharest;

Saudi Arabia: KAEC;

Singapore: Jurong;

South Africa: Waltloo;

Spain: Riells;