Sanofi
Form 20-F
March 04, 2016
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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

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

For the fiscal year ended December 31, 2015

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, 2015 was:

Ordinary shares: 1,305,696,759

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES x 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 x.

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 x 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 inRule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer x Accelerated filer ¨ Non-accelerated filer ¨

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

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

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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, 2015.

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

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

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

- trademarks used or that may be or have been used under license by Sanofi and/or its affiliates, such as Actonel® a trademark of Actavis; 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 trademark of the Group); Fludara® and Leukine® trademarks of Alcafleu; Flutiform® a trademark of Jagotec AG; Gardasil® and Zostavax® trademarks of Merck & Co.; Hexyon® and Repevax® trademarks of Sanofi Pasteur MSD; RetinoStat® and UshStat®, trademarks of Oxford Biomedica; Spedra and Stendra® trademarks of Vivus Inc.; Squarekids® a trademark of Kitasato Daiichi Sankyo Vaccine Co., Ltd.; 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® trademark of Actavis in the United States; DDAVP® a trademark of Ferring (except in the United States where it is a trademark of the Group); Enbrel® a trademark of Immunex in the United-States and of Wyeth on other geographical areas; GLAAS a trademark of Immune Design; Humalog®, Humulin , Mirioped, 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; Unisom® a trademark of Johnson & Johnson on certain geographical areas (except in the United States and Israël where it is a trademark of the Group 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 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 on sales data from IMS Health MIDAS (IMS), retail and hospital, in Moving Annual Total September 2015, in constant euros (unless otherwise indicated).

While we believe that the IMS sales data we present below are generally useful comparative indicators for our industry, they may not precisely match the sales figures published by the companies that sell the products (including our company and other pharmaceutical companies). In particular, the rules used by IMS to attribute the sales of a product covered by an alliance or license agreement do not always exactly match the rules of the agreement.

In order to allow a reconciliation with our basis of consolidation as defined in Item 5. Operating and Financial Review and Prospects Presentation of Net Sales, IMS data shown in the present document have been adjusted and include:

(i) sales as published by IMS excluding Sanofi sales generated by the vaccines business, equating to the scope of our pharmaceutical operations;

(ii) IMS sales of products sold under alliance or license agreements which we recognize in our consolidated net sales but which are not attributed to us in the reports published by IMS; and

(iii) adjustments related to the exclusion of IMS sales for products which we do not recognize in our consolidated net sales but which are attributed to us by IMS.

Data relative to market shares and ranking information presented herein for our Consumer Health Care products, are based on sales data from Nicholas Hall.

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

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Data relative to market shares and ranking information presented herein for our animal health business are based on sales data from Vetnosis 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 the Company as at the date of this annual report and undue reliance should not be placed on such statements.

Words such as believe, anticipate, plan, expect, intend, target, estimate, project, predict, forecast, guideline, should and 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 the 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

Abbreviations used in the Form 20-F

ADR/ADS	American Depositary Receipt/American Depositary Share
AFEP	*Association francaise des entreprises privees* (French association of large companies)
AMF	*Autorité des marches financiers* (the French market regulator)
ANDA	Abbreviated New Drug Application
ECB	European Central Bank
BLA	Biologic License Application
BMS	Bristol-Myers Squibb
CGU	Cash generating unit
CHC	Consumer Health Care
CHMP	Committee for Medicinal Products for Human Use
CNS	Central Nervous System
COSO	Committee of Sponsoring Organizations of the Treadway Commission
COVALIS	Health risk prevention committee
CSR	Corporate Social Responsibility
CVMP	Committee for Medicinal Products for Veterinary Use
CVR	Contingent Value Right
ECHA	European Chemicals Agency
ECOVAL	Internal committee for assessing the environmental risks of our pharmaceutical products
EMA	European Medicines Agency
EMTN	Euro Medium Term Note
EPA	U.S. Environmental Protection Agency
EPS	Earnings per share
EU	European Union
FCPA	U.S. Foreign Corrupt Practices Act
FCPE	*Fonds commun de placement d entreprise* (Corporate investment funds)
FDA	U.S. Food and Drug Administration
GAVI	Global Alliance for Vaccines and Immunisation
GLP-1	Glucagon-like peptide-1
GMP	Good Manufacturing Practice
GRI	Global Reporting Initiative
HSE	Health, Safety and Environment
IASB	International Accounting Standards Board
IFRS	International Financial Reporting Standards
ILO	International Labor Organisation
LEED	Leadership in Energy and Environmental Design
LSD	Lysosomal storage disorder
MEDEF	*Mouvement des entreprises de France* (French business confederation)
NASDAQ	National Association of Securities Dealers Automated Quotations
NDA	New Drug Application
OECD	Organisation for Economic Co-operation and Development
OTC	Over The Counter
PaHO	Pan American Health Organisation
PRAC	Pharmacovigilance Risk Assessment Committee
R&D	Research & Development
REACH	Registration, Evaluation, Authorization and restriction of Chemicals
ROA	Return on assets
SEC	U.S. Securities and Exchange Commission
TRIBIO	Internal biological risk committee
TSR	Total Shareholder Return
TSU	Therapeutic Strategic Unit
UNICEF	United Nations Children s Fund
USDA	United States Department of Agriculture
WHO	World Health Organization

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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, 2015, 2014 and 2013 are included in Item 18 of this annual report.

The consolidated financial statements of Sanofi for the years ended December 31, 2015, 2014 and 2013 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, 2015. 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, 2015.

Sanofi reports its financial results in euros.

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Item 2. Offer Statistics and Expected Timetable

SELECTED CONDENSED FINANCIAL INFORMATION

(million, except per share data)	As of and for the year ended December 31, 2015	2014	2013	2012	2011
IFRS Income statement data[a]					
Net sales	34,542	31,694	30,966	34,947[a]	33,389[a]
Gross profit	23,942	21,769	20,989	24,859[a]	24,193[a]
Operating income	5,624	6,064	4,982	6,430[a]	5,861[a]
Net income excluding the held-for-exchange Animal Health business	4,512	4,392	3,797	-[a]	-[a]
Net income attributable to equity holders of Sanofi	4,287	4,390	3,716	4,888	5,646
Basic earnings per share ( ):					
Net income excluding the held-for-exchange Animal Health business	3.38	3.25	2.75	-[a]	-[a]
Net income attributable to equity holders of Sanofi	3.28	3.34	2.81	3.70	4.27
Diluted earnings per share ( ):					
Net income attributable to equity holders of Sanofi	3.25	3.30	2.77	3.68	4.26
IFRS Balance sheet data					
Goodwill and other intangible assets	51,583[d]	53,740	52,529	58,265	62,221
Total assets	102,321	97,392	96,055	100,399	100,672
Outstanding share capital	2,603	2,620	2,641	2,646	2,647
Equity attributable to equity holders of Sanofi	58,049	56,120	56,904	57,352	56,193
Long term debt	13,118[d]	13,276	10,414	10,719	12,499
Cash dividend paid per share ( )	2.93[f]	2.85	2.80	2.77	2.65
Cash dividend paid per share ($)[e]/[g]	3.19[f]	3.46	3.86	3.65	3.43

(a) Including the Animal Health business, the net income/loss of which is presented in a separate line item, ***Net income/(loss) of the held-for-exchange Animal Health business****, in the consolidated income statements for 2015, 2014 and 2013 (see Notes D.2.1. and D.36. to our consolidated financial statements included at Item 18 of this annual report). For 2012 and 2011, it is not practicable to provide information excluding the Animal Health business without unreasonable effort or expense.*

(b) Based on the weighted average number of shares outstanding in each period used to compute basic earnings per share, equal to 1,306.2 million shares in 2015, 1,315.8 million shares in 2014, 1,323.1 million shares in 2013, 1,319.5 million shares in 2012 and 1,321.7 million shares in 2011.

(c) 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., 1,320.8 million shares in 2015, 1,331.1 million shares in 2014, 1,339.1 million shares in 2013, 1,329.6 million shares in 2012 and 1,326.7 million shares in 2011.

(d) Excluding the Animal Health business which is presented in separate line items, ***Assets held for sale or exchange*** *and* ***Liabilities related to assets held for sale or exchange.***

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

(f) Dividends for 2015 will be proposed for approval at the annual general meeting scheduled for May 4, 2016.

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

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SELECTED EXCHANGE RATE INFORMATION

The following table sets forth, for the periods and dates indicated, certain information concerning the exchange rates for the euro from 2011 through March 2016 expressed in U.S. dollars per euro. The information concerning the U.S. 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 U.S. 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[1]**	**High**	**Low**
2011	1.30	1.40	1.49	1.29
2012	1.32	1.29	1.35	1.21
2013	1.38	1.33	1.38	1.28
2014	1.21	1.32	1.39	1.21
2015	1.09	1.10	1.20	1.05
Last 6 months				
2015				
September	1.12	1.12	1.14	1.11
October	1.10	1.12	1.14	1.10
November	1.06	1.07	1.10	1.06
December	1.09	1.09	1.10	1.06
2016				
January	1.08	1.09	1.10	1.07
February	1.09	1.11	1.14	1.09
March[2]	1.09	1.09	1.09	1.09

(1) *The average of the Noon Buying Rates on the last business day of each month during the relevant period for the full year average, and on each business day of the month for the monthly average. The latest available Noon Buying Rate being February 26, 2016, we have used European Central Bank Rates for the period from February 29, 2016 through March 3, 2016.*

(2) *In each case, measured through March 3, 2016.*

On March 3, 2016 the European Central Bank Rate was 1.0901 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 or circumvented, our financial results could be materially and adversely affected.

Through patent and other proprietary rights such as data exclusivity or supplementary protection certificates in Europe, we hold exclusivity rights for a number of our research-based products. However, the protection that we are able to obtain varies in its duration and scope from product to product and country to country. This protection may not be sufficient to maintain effective product exclusivity because of local differences in the patents, in national laws or applicable legal systems, or developments in law or jurisprudence, which may give rise to inconsistent judgments when we assert or defend our patents.

Moreover, patent and other proprietary rights do not always provide effective protection for our products. Manufacturers of generic products or biosimilars are increasingly seeking to challenge patent validity or coverage before the patent 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 consider that our patent or other proprietary rights are valid, enforceable or infringed. Our competitors may also successfully avoid patents, for example, through design innovation, and we may not hold sufficient evidence of infringement to bring suit.

In certain cases, to terminate or avoid patent litigation, we or our partners may be required to obtain licenses from the holders of third-party intellectual property rights that cover aspects of our existing and future products in order to manufacture, use and/or sell them. Any payments under these licenses may reduce our profits from such products and we may not be able to obtain these licenses on favorable terms or at all. Third parties may also request a preliminary 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 the country. If they obtain a

preliminary or permanent injunction from a court of law or if we fail to obtain a required license for a country where the valid third-party intellectual property right as confirmed by a court of law, exists or 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 protection granted to such products.

We are involved in litigation worldwide to enforce certain of our patent rights against generics, proposed generics and biosimilars of our small molecule and biological pharmaceutical products (see Item 8. Financial Information A. Consolidated Financial Statements and Other Financial Information Information on Legal or Arbitration Proceedings for additional information). Even in cases where we ultimately prevail in an infringement claim, legal remedies available for harm caused to us by infringing products may be inadequate to make us whole. A competitor may launch a generic or a biosimilar product at risk before the initiation or completion of the court proceedings, and the court may decline to grant us a preliminary injunction to halt further at risk sales and remove the infringing product from the market. Additionally, while we would be entitled to obtain damages in such a case, the amount that we may ultimately be awarded and able to collect may be insufficient to compensate all harm caused to us. A successful result against a competing product for a given patent or in a specific country is not necessarily predictive of our future success against another competing product or in another country because of local variations in the patents and patent laws.

We have increased the proportion of biological therapeutics in our pipeline relative to traditional small molecule pharmaceutical products. We expect to face increasing competition from biosimilars in the future. With the accelerated regulatory pathways provided in the U.S. 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 hereinabove. 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 the Group s business, results of operations and financial condition). If a biosimilar version of one of our products were approved, it could reduce our sales of that product.

However, with our presence as a manufacturer of generics and anticipated entry into biosimilars, we will utilize patent

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challenge strategies against other innovators patents, similar to those of long-established generic companies, but there is no assurance that these strategies will be successful.

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

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

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

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

Often, the side effect profile of pharmaceutical drugs cannot be fully established based on preapproval clinical studies involving only 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, including restrictions of therapeutic indications, new contraindications, warnings or precautions, and occasionally even the suspension or withdrawal of a product marketing authorization. Following a recall or a withdrawal, pharmaceutical companies can face significant product liability claims.

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

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

Due to insurance conditions, even when the Group has insurance coverage, recoveries from insurers may not be totally successful. Moreover, insolvency of an insurer could affect our ability to recover claims on policies for which we have already paid a premium.

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

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

Obtaining marketing authorization is a long and highly regulated process requiring us to present extensive documentation and data to the regulatory authorities. Regulatory processes differ from one authority to another. Either at the time of the filing of the application for a marketing authorization or later during its review, each regulatory authority may impose its own requirements which can evolve over time, including requiring local clinical studies, and 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 pharmaceuticals 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 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 considerable time. This system may result in additional market authorization suspensions or withdrawals. All of these requirements have increased the costs associated with maintaining regulatory approvals and achieving reimbursement for our products. Post-regulatory approval

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Item 3. Key Information

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 scope of a drug s indication, impose marketing restrictions, or suspend or withdraw the product can result in a reduction in sales volume, as well as an increased risk of litigation.

Moreover, to monitor our compliance with applicable regulations, the FDA, the EMA and comparable agencies in other jurisdictions routinely conduct inspections of our facilities and may identify potential deficiencies. We have received FDA Warning Letters in the past following the inspection of some of our facilities and may receive such letters in the future. If we fail to adequately respond to warning letters identifying a deficiency following an inspection, or fail to comply with applicable regulatory requirements at all or within the targeted timeline, we could be subject to enforcement, remedial and/or punitive actions by the FDA, the EMA or other regulatory authorities. In addition, in order to comply with our duty to report adverse safety signals to regulatory authorities, we must regularly train our employees and third parties (such as external sales forces and distributor employees) on regulatory matters. If we fail to train these people, or fail to train them appropriately, we may be exposed to the risk that safety events are not reported or not reported in a timely manner in breach of our reporting obligations.

To the extent that new regulations raise the costs of obtaining and maintaining product authorizations, or limit the economic value of a new product to its originator, the growth prospects of our industry and of the Group would be diminished. Approximately 65% of our current development portfolio consists of biological products that may in the future bring new therapeutic responses to current unmet medical needs, but that may also lead to more regulatory and technical constraints and/or costly investments from an industrial standpoint as biological products are complex to produce. These constraints and costs could adversely affect our business, results of operations and financial condition.

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

The marketing of our products is heavily regulated. The Group s business covers an extremely wide range of activities worldwide and involves numerous partners. We have adopted a Code of Ethics that calls for employees to comply with applicable legislation and regulations, as well as with the specific values and rules of conduct set forth in that Code. We also have policies and procedures designed to help ensure that we, our employees, officers, agents, intermediaries and other third parties comply with applicable laws and regulations (including the U.S. Foreign Corrupt Practices Act (FCPA), the

UK Bribery Act, the OECD Anti-Bribery Convention and other anti-bribery laws and regulations).

Notwithstanding these efforts, deviations may occur and there can be no assurance that we, our officers and/or our directors will not face liability under laws and regulations for actions taken with respect to our business.

Any failure to comply directly or indirectly (including as a result of a business partner s breach) with the laws and regulations applicable to us could lead to substantial liabilities and harm the Group s reputation. Governments and regulatory authorities around the world have been strengthening enforcement activities in recent years. Sanofi and certain of its subsidiaries are under investigation or could become the subject of additional investigations by various government entities and are defending a number of lawsuits relating to antitrust and/or pricing and marketing practices (including, for example, in the United States, class action lawsuits and whistleblower litigation). The Group also faces significant litigation and government investigations or audits, including allegations of securities law violations, 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), punitive damages, penalties and injunctive or administrative remedies, potentially leading to the imposition of additional regulatory controls or

exclusion from government reimbursement programs or markets, and could have a material adverse effect on our business, results of operations or financial conditions.

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

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

All aspects of our business, including research and development, manufacturing, marketing, pricing or sales are

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subject to extensive legislation and 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 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 potential regulatory changes may further limit the exclusivity enjoyed by innovative products on the market and directly impact pricing 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, changes in the various tax laws of the jurisdictions where affiliates of the Group operate, or changes in their application, with respect to matters such as tax rates, transfer pricing, dividends, controlled companies or a restriction in certain forms of tax relief, could affect our effective tax rate and our future results. For example, both the OECD s initiative on Base Erosion and Profits Shifting (BEPS) and the European Union s initiative on the Code of Conduct for Business Taxation could lead to significant changes to tax laws and regulations in the future. Additionally, due to the complexity of the fiscal environment, the ultimate resolution of any tax matters may result in payments greater or lesser than amounts accrued.

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

Risks Relating to Our Business

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

Discovering and developing a new product is a costly, lengthy and uncertain process. To be successful in the highly competitive pharmaceutical industry, we must commit substantial resources each year to research and development in order to develop new products to compensate for the decreasing sales of our products facing expiry of patents and regulatory data exclusivity or

competition from new products of competitors that are perceived as being superior. In 2015, we spent 5,259 million on research and development, amounting to 14.2% of our aggregate 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 not invest in the right technology platforms, therapeutic areas, and product classes to build a robust pipeline and fulfill unmet medical needs. Fields of discovery, in particular 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 may become less attractive if a competitor addressing the same unmet need reaches the market earlier.

The research and development process can take up to 15 years from discovery to commercial product launch. This process is conducted in various stages in order to test, along with other features, the 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 and human resources, even

in late stage development (Phase III). 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.

We have up to 18 new medicines and vaccines on track to arrive on the market between 2014-2020, including six key launches (Toujeo®, Praluent®, Dengvaxia®, sarilumab, LixiLan and dupilumab). However, there can be no assurance that all of these products will be approved, or with the targeted indications, and/or within the expected timeline, or that, if approved, they will achieve commercial success.

Following each product marketing approval, the medical need served by the product and the corresponding reimbursement are evaluated by governmental agencies and/or third party payers, requiring in some cases additional

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studies, including comparative studies, which may both effectively delay marketing of the new product and add to its development costs.

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

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

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

- price controls imposed by governments in many countries;
- removal of a number of drugs from government reimbursement schemes (for example products determined to be less cost-effective than alternatives);
- increased difficulty in obtaining and maintaining satisfactory drug reimbursement rates;
- increase in cost containment policies related to health expenses in a context of economic slowdown;
- 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 the price of drugs based on international comparisons; and
- aggressive pricing strategies by some of our competitors.

In addition to the pricing pressures they exert, governmental and private third-party payers and purchasers of pharmaceutical products may reduce volumes of sales by restricting access to formularies (including exclusive formulary) or otherwise discouraging physicians from prescribing our products. In the United States, price is increasingly important to managed care organizations (MCOs) and as the MCOs grow in size following market consolidation, competition among pharmaceutical companies to have their product included in the formulary is aggressive. For example, for Lantus®, since 2014, we have increased the level of rebates granted in order to maintain

favorable formulary positions with key payers in the U.S. Exclusion of one of our drugs from a formulary can significantly reduce sales in the MCO patient population.

Also in the United States, the federal health care reform law is increasing 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 cost containment measures and rebates and fees on pharmaceutical companies and current federal budget proposals would impose further restrictions on pricing and reimbursement. In addition, some U.S. states are considering legislation that would influence the marketing and prices of, and access to, drugs. U.S. federal and state officials will likely continue to focus on healthcare reform implementation in the future.

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, 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 the unfavorable financial environment could have negative consequences for our business .

In addition, if we lose patent protection in patent litigation, we face the risk that government and private third-party payers and purchasers of pharmaceutical products may claim damages alleging they have over-reimbursed a drug. For example, in Australia, our patent on clopidogrel was ultimately held invalid. Following this decision, the Australian Government is seeking damages for its alleged over-reimbursement of clopidogrel drugs due to the preliminary injunction we had obtained against the sale of generic clopidogrel during the course of the litigation.

As a consequence of the growing number of mergers of retail chains and distributors and resulting consolidation of the distribution channel, distributors have increased their capacity to negotiate price and other terms. Due to these cost containment policies and pressure on our prices, our revenues and margins are, and could continue to be, negatively affected.

We are also unable to predict the availability or amount of reimbursement for our product candidates. Price negotiations in a country may be incompatible with the global positioning of our products, which may lead us not to launch the product in that country, 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.

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We may lose market share to competing remedies, 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 healthcare providers and provide them with innovative data about the product and its uses. If these education efforts are not effective, we may not be able to increase the sales of our new 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. Substitution is often permitted for generic products that are considered to be interchangeable or clinically identical. With respect to biosimilars, in the United States only biosimilars that refer to an innovator drug that was approved under a Biologics License Application may be designated as interchangeable with the original biologic and only in circumstances where specific criteria are met. In many European countries, automatic substitution of biologics is officially prohibited or not recommended. Nevertheless competition even from non-substitutable biosimilars would likely result in a decrease in prices, additional rebates, promotion effort 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 and France. Therefore, the market for our products could also be affected if a competitor s innovative drug in the same market were to become available as a generic because a certain number of patients can be expected to switch to a lower-cost alternative therapy. We expect this generic competition to continue and to affect more of our products, including those with relatively modest sales.

A substantial share of the revenue and income of the Group 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, 2015 compared with year ended December 31, 2014 Net Sales by Product Pharmaceuticals segment). Lantus® is particularly important; it was the Group s leading product with revenues of 6,390 million in 2015, representing 17.2% of the Group s aggregate net sales for the year. Lantus® is a flagship product of the Diabetes business. Accounting for recent market trends, we announced in October 2015 that we project global diabetes sales over the period from 2015 to 2018 to decline at an average annualized rate of between 4% and 8% at constant exchange rate (CER). Nevertheless our actual sales may differ from these expectations given the numerous underlying assumptions (for example the outlook for insulin glargine sales, and expectations for Lyxumia® and BGM (Blood Glucose Monitoring)). Furthermore, the launch of new medicines and vaccines in other therapeutic areas and the performance of our other businesses may not be sufficient to reduce the relative contribution of Lantus® to our overall performance.

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

biosimilar or generic products.)

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

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

Many of our products are manufactured using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. Third

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parties supply us with a substantial portion of our raw materials, active ingredients and medical devices, which exposes us to the risk of a supply shortage or interruption in the event that these suppliers are unable to manufacture our products to Group quality standards or experience financial difficulties. Further, some raw materials essential to the manufacture of our products are not widely available from sources we consider reliable; for example, we have approved only a limited number of suppliers of heparins for use in the manufacture of Lovenox®. Any of these factors could adversely affect our business, operating results or financial condition. See Item 4. Information on the Company B. Business Overview B.8. Production and Raw Materials for a description of these outsourcing arrangements.

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

We must also be able to produce sufficient quantities of our products to satisfy demand. We may have difficulties transforming and adapting our existing plants to manufacture new products, including biologics, and scaling up production of our products currently under development once they are approved. Our biological products in particular, are subject to the risk of manufacturing stoppages or the risk of loss of inventory because of the difficulties inherent in the processing of biological materials and the potential difficulties in accessing adequate amounts of raw materials meeting required standards. Effective insurance coverage for biologics products in the event of contaminated batches may also be difficult to obtain as the cause of the contamination can be difficult to ascertain (for the impact on our financial statements see Impairment charges or write downs in our books and changes in accounting standards could have a significant adverse effect on the Group s results of operations and financial results.)

For example, in the U.S we encountered production issues which caused delays in the supply of Pentacel® vaccine starting from 2012. While these problems have either been remedied or are in the process of being remedied, we continue to face strong demand for our vaccines that requires us in certain cases to manage the supply allocation. We are working to increase our capacities but cannot reasonably estimate how long it will take to address these constraints. There can be no guarantee that we will not face similar issues in the future or that we will successfully manage such issues when they arise.

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

The complexity of these processes, as well as strict internal and health authority standards for the manufacture of our products, subject us to risks because the investigation and remediation of any identified or suspected problems can cause production delays, substantial expense, product recalls, or lost sales and inventories and delay the launch of new products, which could adversely affect our operating results and financial condition, and cause reputational damage and the risk of product liability (see Product liability claims could adversely affect our business, results of operations and financial condition).

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

Supply shortages generate even greater negative reactions when they occur with respect to life saving medicines with limited or no viable therapeutic alternatives. Shortages of products lead to lower product revenues but also can have a negative impact on the confidence of patients, customers and professional healthcare providers and the image of the Group. Government authorities and regulators in the United States and in the European Union are also considering measures to reduce these risks. It cannot be ruled out that these ongoing initiatives may generate

additional costs for the Group if they result in a requirement to establish back up supply channels or to increase inventory levels to avoid shortages.

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

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

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

We conduct a number of significant research and development programs and market some of our products in collaboration with other biotechnology and pharmaceutical companies. For example, we currently have a global strategic collaboration with Regeneron for the discovery, development, commercialization and manufacturing of therapies based on monoclonal antibodies. With Alnylam we have an agreement to develop and commercialize treatments for rare genetic diseases. We also have collaborative arrangements with Merck & Co., Inc. for the distribution of vaccines in Europe (See Item 4. Information on the Company B. Business Overview B.2. Main pharmaceutical products and Item 4. Information on the Company B. Business Overview B.3. Vaccine Products for information on our alliances). 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 partner 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 .

When we research and market our products through collaboration arrangements, the performance of certain key tasks or functions are the responsibility of our collaboration partners and, therefore we are subject to the risk that they do not perform effectively. We are also subject to the risk that decisions may be under the control of or subject to the approval of our collaboration partners, and we may have differing views. Failures in the development or differing priorities may adversely affect the activities conducted through the collaboration arrangements. Any conflicts that we may have with our partners during the course of these agreements or at the time of their renewal or renegotiation may affect the marketing of certain of our products and may

cause a decline in our revenues and negatively affect our results of operations.

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

We run the risk of delayed payments or even non-payment by our customers, which consist principally of wholesalers, distributors, pharmacies, hospitals, clinics and government agencies. This risk is accentuated by recent concentrations among distributors, as well as by current global credit and economic conditions, including the worldwide economic slowdown, in particular in the emerging markets. The United States poses particular customer credit risk issues, because of the concentrated distribution system in which more than half of our consolidated U.S. pharmaceutical sales are accounted for by three wholesalers. We are also exposed to large wholesalers in other markets, particularly in Europe. Worldwide, the Group s three main customers represent 24.7% of our gross total revenues. An inability of one or more of these wholesalers to honor their debts to us would adversely affect our financial condition (see Note D.34. to our consolidated financial statements included at Item 18 of this annual report).

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

Global economic conditions and the 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.

[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, and is covered by our independent registered public accounting firms report on the consolidated financial statements.*

[2] *Information in this section is in addition 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, and is covered by our independent registered public accounting firms report on the consolidated financial statements.*

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Further, our net sales may be negatively impacted by the continuing challenging global economic environment, as high unemployment, increases in co-pays, and lack of developed third party payer systems in certain regions may lead some patients to switch to generic products, delay treatments, skip doses or use less effective treatments to reduce their costs. In the United States there has been an increase in the number of patients in the Medicaid program, under which sales of pharmaceuticals are subject to substantial rebates and, in many U.S. 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.

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

Our Consumer Health Care (CHC) and Animal Health businesses could also be adversely impacted as difficult economic conditions may limit the financial resources of people and livestock producers.

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 Group, 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 .

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

Counterfeit versions of our products harm our business.

Counterfeiting activities and the presence of counterfeit products in a number of markets and over the Internet continue to be a challenge for maintaining a safe drug supply. Counterfeit products are frequently unsafe or ineffective, and can be life-threatening. To distributors and users, counterfeit products may be visually indistinguishable from the authentic version. Reports of adverse reactions to counterfeit drugs along with increased levels of counterfeiting could be mistakenly attributed to the authentic product, affect patient confidence in the authentic product and harm the business of companies such as Sanofi. If one

of our products were to be the subject of counterfeits, we could incur substantial reputational and financial harm. See Item 4. Information on the Company B. Business Overview B.6. Markets B.6.2. Competition.

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

Our business depends heavily on the use of information technologies. Certain key areas such as research and development, production and sales are to a large extent dependent on our information systems, including cloud-based computing, or those of third party providers, including for the storage and transfer of critical, confidential or sensitive information. We commercialize a number of devices using new technologies which if they malfunction could lead to a risk of harm to patients (see Product liability claims could adversely affect our business, results of operations and financial condition) including the unavailability of our products.

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

which could result in financial, legal, business or reputational harm.

The expansion of social media platforms and mobile 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 issues 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 the Group 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. Negative or inaccurate posts or comments about Sanofi, our business, directors or officers on any social networking website could seriously damage our reputation. In addition, our employees and partners may use social media and mobile technologies inappropriately, which may give rise to liability for the Group, or which could lead to

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breaches of data security, loss of trade secrets or other intellectual property or public disclosure of sensitive information, including information about our employees, clinical trials or customers. Such uses of social media and mobile technologies could have a material adverse effect on our reputation, business, financial condition and results of operations.

Impairment charges or write downs in our books and changes in accounting standards could have a significant adverse effect on the Group 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 impaired upon indications of impairment (primarily relating to pharmacovigilance, discontinued research and development projects, patent litigation and the launch of competing products), with adverse effects on our financial condition and the value of our assets.

If any of our strategic equity investments decline in value and remain below cost for an extended period, we may be required to write down our investment. We own a significant stake in Regeneron Pharmaceuticals Inc. (22.1% of share capital as of December 31, 2015), which is listed on the NASDAQ and has been accounted for using the equity method since 2014. Any material deterioration in Regeneron s share price or financial performance would be an indicator that the value of our investment might have become impaired. This would require us to perform an impairment test, which could have a negative impact on our financial statements.

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

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

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 the Group 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 the Group Structure and Strategy

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

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

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

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

The successful launch of a new pharmaceutical product involves substantial investment in sales and marketing activities. We have up to 18 new medicines and vaccines on track to arrive on the market between 2014-2020; including six key launches (Toujeo®, Praluent®, Dengvaxia®, sarilumab, LixiLan and dupilumab). However there can be no assurance that all of these products will be approved, or with the targeted indications, and/or within the expected timeline or that, if approved, they will achieve commercial success. The launch strategy we develop (in terms of timing, pricing, market access, marketing efforts and dedicated sales forces)

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may not deliver the benefits that we expect. The competitive environment for a given product may also have changed by at 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 (see also Our research and development efforts may not succeed in adequately renewing our product portfolio above).

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 (pending relevant mandatory labor group consultations) of five global business units (GBU) to meet significant growth objectives requires substantial attention from our management. There is no guarantee that we will be able to fully implement this new organization within the targeted timeline, that it will enable the Group 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 will deliver the expected benefits.

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

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

We pursue a strategy of selective acquisitions, in-licensing and collaborations in order to reinforce our pipeline and portfolio. The implementation of this objective depends on our ability to identify business development opportunities and execute them at reasonable cost and on acceptable financing terms. Moreover, entering into in-licensing or collaboration agreements generally requires the payment of significant milestones well before the relevant products reach the market, without any assurance that such investments will ultimately become profitable in the long term (see Note D.21.1. to the consolidated financial statements included at Item 18 of this annual report and also We rely on third parties for the discovery, manufacture and marketing of some of our products).

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.

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

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

In December 2015, we announced our intention to acquire Boehringer Ingelheim s consumer healthcare (CHC) business with an enterprise value of 6.7 billion in exchange for our animal health business (Merial). The transaction would also include a gross cash payment from Boehringer Ingelheim to Sanofi of 4.7 billion. The transaction would allow Sanofi to become a global leader in CHC but there is no certainty that the transaction will be ultimately completed as contemplated, within the expected time frame or at all. We cannot guarantee that Boehringer Ingelheim s CHC business will be successfully integrated with ours and that we will be able to retain key personnel. The expected benefits of the transaction may never be fully realized or may take longer to realize than expected.

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 the unfavorable financial environment could have negative consequences for our business).

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

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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)), 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). 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 the generics and consumer healthcare sectors, whose business models and trade channels are different from our traditional pharmaceutical business, in particular regarding promotional efforts and trade terms.

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

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

Environmental Risks of Our Industrial Activities

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

Manufacturing activities, such as the chemical manufacturing of the active ingredients in our products and the related storage and transportation of raw materials, products and wastes, expose us to various risks, including:

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

These operating risks can cause personal injury, property damage and environmental contamination, and may result in the shutdown of affected facilities and/or the imposition of civil, administrative, criminal penalties and/or civil damages.

The occurrence of any of these events may significantly reduce the productivity and profitability of a particular manufacturing facility and adversely affect our operating results and reputation.

Although we maintain property, business interruption and casualty insurance that we believe is in accordance with customary industry practices, this insurance may not be adequate to fully cover all potential hazards incidental to our business.

Environmental liabilities and costs related to compliance with applicable regulations may have a significant adverse effect on our results of operations.

The environmental laws of various jurisdictions impose actual and potential obligations on our Group 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 U.S. 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,

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or of subsidiaries that we demerged, divested or may divest. We have disputes outstanding regarding certain sites no longer owned by the Group. An adverse outcome in such disputes might have a significant adverse effect on our operating results. See Note D.22.e) to the consolidated financial statements included at Item 18 of this annual report and Item 8. Financial Information A. Consolidated Financial Statements and Other Financial Information Information on Legal or Arbitration Proceedings .

Environmental regulations are evolving (*i.e.*, in Europe, REACH, CLP/GHS, SEVESO, IPPC/IED, the Waste Framework Directive, the Emission Trading Scheme Directive, the Water Framework Directive and 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 Group and could subject our handling, manufacture, use, reuse or disposal of substances or pollutants, site restoration and compliance to more rigorous scrutiny than is currently the case. Consequently, compliance with these laws could result in significant capital expenditures as well as other costs and liabilities, thereby adversely affecting our business, results of operations or financial condition. For more detailed information on environmental issues, see Item 4. Information on the Company B. Business Overview B.10. Health, Safety and Environment (HSE).

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

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

Risks Related to Financial Markets[3]

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

Because we sell our products in numerous countries, our results of operations and financial condition could be adversely affected by fluctuations in currency exchange rates. We are particularly sensitive to movements in exchange rates between the euro and the U.S. dollar, the Japanese yen, and to currencies in Emerging Markets. In 2015, 36% of our aggregate net sales were realized in the

United States, 32% in Emerging Markets (including countries that are, or may in future become, subject to exchange controls), and 6% 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 U.S. dollar value of our ADSs and dividends (if any).

Holders of ADSs face exchange rate risk. Our ADSs trade in U.S. 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 U.S. dollar will affect the U.S. dollar amounts received by owners of ADSs upon conversion by the depositary of cash dividends, if any. Moreover, these fluctuations may affect the U.S. dollar price of the ADSs on the New York Stock Exchange (NYSE), whether or not we pay dividends in addition to the amounts, if any, 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 U.S. dollars.

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

Holders of ADSs may have more difficulty exercising their rights as a shareholder than if they directly held shares. For example, if we issue new shares and existing shareholders have the right to subscribe for a portion of them, the depositary is allowed, at its own discretion, to sell for their benefit that right to subscribe for new shares instead of making it available to them. 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.

[3] *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, and is covered by our independent registered public accounting firms report on the consolidated financial statements.*

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

As of December 31, 2015, L Oréal held approximately 9.05% of our issued share capital, accounting for approximately 16.36% 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 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 U.S. 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. The two first milestones were not met. On October 29, 2015, Sanofi disclosed that, based upon actual sales trends to date, it does not expect that product sales milestone #1 will be met. There can be no assurance that the other product sales milestones will be achieved. Failure to achieve the sales milestones would have an adverse effect on the value, if any, of the CVRs.

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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 2015, our net sales were 34,542 million. This figure excludes net sales of our Animal Health activity. Our aggregate net sales (including Animal Health, see definition at Item 5 Results of Operations Year Ended December 31, 2015 Compared with Year Ended December 31, 2014 below) were 37,057 million. We are the fifth largest pharmaceutical group in the world and the third largest in Europe in terms of sales (IMS data 2015 Moving Annual Total September 2015).

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 name used in France, except for Allegra® (sold in France as Telfast®), Tritace® (sold in France as Triatec®), Amaryl® (sold in France as Amarel®) and Ambien® CR (an extended-release formulation of zolpidem tartrate, not sold in France);

- For the Pharmaceuticals activity, unless otherwise stated, all market share percentages and rankings are calculated based on net sales figures expressed as the Moving Annual Total (MAT) in September 2015 from IMS Health MIDAS (retail and hospital), except Nicholas Hall for Consumer Health Care;

- For the Human Vaccines (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 competitors;

- For the Animal Health activity, the market share percentages and rankings are calculated based on sales data from Vetnosis.

The Group is organized around three principal activities: pharmaceuticals, vaccines via Sanofi Pasteur, and animal health via Merial[(1)]. 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 invest in the following activities (see B. Business Overview B.1. Strategy below): Diabetes, Cardiovascular, Rare Diseases and Multiple Sclerosis (MS), Consumer Health Care, Oncology, Generics, Established Prescription Products[(2)], Vaccines, and Animal Health. Unlike the Vaccines and Animal Health activities, which are also operating segments within the meaning of IFRS 8, the Diabetes, Cardiovascular, Rare Diseases and Multiple Sclerosis (MS), Consumer Health Care, Oncology, Generics, and Established Prescription Products activities are units whose performance is monitored primarily on the basis of net sales, and the products each unit sells are included in our Pharmaceuticals operating segment. We are also active in Emerging Markets[(3)], selling products from all three of our principal activities (pharmaceuticals, vaccines and animal health). The performance of Emerging Markets is monitored primarily on the basis of net sales.

Net sales of our activities for the year 2015 are presented in Item 5 Results of Operations Year Ended December 31, 2015 Compared with Year Ended December 31, 2014 .

Within our pharmaceuticals activity, which generated net sales of 29,799 million in 2015, we specialize in the following therapeutic areas:

- Diabetes: with Lantus®, a long-acting human insulin analog which is the world-leading brand in the insulin market; Toujeo®, a new formulation of insulin glargine; Amaryl®, an oral once-daily sulfonylurea; Apidra®, a rapid-acting human insulin analog; Insuman®, a range of rapid-acting or intermediate-acting human insulins; Lyxumia®, a once-daily GLP-1 receptor agonist administered once daily before breakfast; and a range of integrated care solutions;

- Cardiovascular: with Praluent® a cholesterol-lowering drug that inhibits PCSK9, for patients with heterozygous familial hypercholesterolemia or with clinical atherosclerotic cardiovascular disease, and Multaq®(4), an anti-arrhythmic drug in atrial fibrillation (AF);

(1) On December 15, 2015, Sanofi and Boehringer Ingelheim signed an exclusivity agreement to exchange Sanofi s Animal Health business for Boehringer Ingelheim s Consumer Health Care business. The transaction would also involve a gross cash payment from Boehringer Ingelheim to Sanofi. The two parties aim to close the transaction, which is subject to execution of definitive agreements and thereafter to regulatory clearances in the fourth quarter of 2016 (see B.1. Strategy below and Note D.2.1. to our consolidated financial statements included in Item 18 of this annual report).

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

(3) All markets excluding the U.S., Canada, Western Europe (France, Germany, U.K., Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Sweden, Portugal, the Netherlands, Austria, Switzerland, Ireland, Finland, Norway, Iceland and Denmark), Japan, South Korea, Australia, and New Zealand.

(4) Consolidated in established prescription products until December 31, 2015, see the Net Sales table below.

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- Rare Diseases: with a portfolio of enzyme replacement therapies including Cerezyme® and Cerdelga® for Gaucher disease, Myozyme®/Lumizyme® for Pompe disease, Fabrazyme® for Fabry disease, and Aldurazyme® for mucopolysaccharidosis Type 1 (MPS I);

- Multiple sclerosis (MS): with Aubagio® a once-daily oral immunomodulator, and Lemtrada® (alemtuzumab), a monoclonal antibody. Both products have been developed to treat patients with relapsing forms of MS;

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

- Established Prescription Products: our main thrombosis medicines include Plavix®, an anti-platelet agent indicated for a number of atherothrombotic conditions and Lovenox®, a low molecular weight heparin indicated for prevention and treatment of deep vein thrombosis and for unstable angina and myocardial infarction. Our Established Prescription Products also include two hypertension treatments: Aprovel® and CoAprovel®. In nephrology, our two main products are Renagel® and Renvela®, oral phosphate binders for the treatment of high phosphorous levels for use in patients undergoing dialysis for chronic kidney disease. In biosurgery, our two main products are medical devices, Synvisc® and Synvisc-One®, viscosupplements used to reduce pain in patients suffering from osteoarthritis of certain joints. Other products include Stilnox®, indicated in 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.

Our pharmaceutical portfolio also includes a wide range of other products: Consumer Health Care products, a category in which we are the fifth largest global player and a wide range of Generics products.

Our Vaccines activity is operated through Sanofi Pasteur. Net sales from vaccines amounted to 4,743 million in 2015, with leading vaccines in five areas: pediatric vaccines, influenza vaccines, adult and adolescent booster vaccines, meningitis vaccines, and travel and endemic vaccines.

Our Animal Health activity is carried out through Merial, one of the world leaders in this market. Merial is dedicated to the research, development, manufacture and marketing of innovative pharmaceutical products and vaccines used by

veterinarians, farmers and pet owners. It achieved net sales of 2,515 million in 2015 with a wide range of products to improve the health, well-being and performance of a large variety of animals (both livestock and pets).

We obtained regulatory approval for three new products in 2015: Toujeo® in the U.S., the E.U. and Japan; Praluent® in the U.S. and the E.U.; and Dengvaxia® in Brazil, Mexico and the Philippines.

Partnerships are essential to our business and a certain number of our products, either 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 U.S. subsidiary s

office is located at 55 Corporate Drive, Bridgewater, NJ 08807; telephone: +1 (908) 981 5000.

Main changes since 2011

In 2011, Merial became our dedicated Animal Health division. Merial was founded in 1997 and was a joint venture between Merck and Co. Inc. and Sanofi until September 17, 2009, when Sanofi acquired the share held by Merck in Merial.

On April 4, 2011, following a tender offer, we acquired control of Genzyme, a biotechnology group headquartered in Cambridge, Massachusetts (U.S.).

In December, 2015, we announced we had opened exclusive negotiations with Boehringer Ingelheim with a view to an asset swap. The proposed transaction would consist of an exchange of the Sanofi Animal Health business (Merial) with an enterprise value of 11.4 billion and the Boehringer Ingelheim Consumer Healthcare business with an enterprise value of 6.7 billion. The Boehringer Ingelheim Consumer Health Care business in China would be excluded from the transaction. The transaction would also include a gross cash payment from Boehringer Ingelheim to Sanofi of 4.7 billion. Until final completion of the transaction, which is subject to execution of definitive agreements and thereafter to regulatory clearances, expected in the fourth quarter of 2016, we will continue to monitor the performance of the Animal health business (which remains an operating segment) and to report the performance of that business at Group level.

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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, with once again over 30 annual New Molecular Entities (NME)/ Biologic License Application (BLA) approvals by the U.S. Food and Drug Administration (FDA). Patients around the world, and a rising middle class in emerging markets, are demanding better care, empowered by access to new information and digital technology. It is a particularly exciting time scientifically, with the promise of genomics being realized and immuno-oncology transforming cancer treatments.

At the same time, the industry faces challenges. Economic growth in emerging markets has slowed. Affordability is a key concern globally, with pricing and reimbursement pressure from payers in developed markets, particularly Europe and the U.S.. Biosimilars have entered the U.S. market for the first time. More focused competitors are building leadership positions in their priority therapy areas.

In this dynamic market, we have leading positions in four of our main businesses (see below). We have a number of strong products to be launched across multiple therapeutic areas and a track record in building major brands and franchises that have transformed patient care. We have been successful in sourcing external innovation from key partners including Regeneron and Alnylam. We have strong skills for managing mature businesses. We are also clear about the challenges we face, namely a portfolio with a broad set of businesses, a competitive environment and loss of exclusivity for certain products, pressure on margins as we fund product launches and pipeline expansion, and a complex organization.

New strategic roadmap

To build on these strengths and meet these challenges, Sanofi has developed a new strategic roadmap, announced on November 6, 2015. The Group will continue to be a global healthcare company focused on disease prevention and treatment. The strategic roadmap has four pillars, namely reshape the portfolio, deliver outstanding launches, sustain innovation in R&D, and simplify the organization.

Reshape the portfolio

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

Below is a brief overview of our strategy in each business.

Sustain leadership

- **Diabetes and Cardiovascular.** Sanofi remains committed, for the long term, to fighting the global epidemic of diabetes and to treating cardiovascular disease, the leading cause of death globally. Our three priorities to return the diabetes business to growth beginning in 2019 are to develop the insulin franchise, with Lantus®, Toujeo®, and of lixisenatide/insulin glargine association project; strengthen our pipeline; and lead the market shift to managing diabetes outcomes, in part through the new collaboration with our world-class partner Verily (formerly Google Life Sciences). We have taken concrete steps to strengthen our pipeline already through licensing agreements with Lexicon for sotagliflozin, a SGLT-1/2 inhibitor, and with Hanmi for a weekly GLP-1, a long-acting insulin, and a weekly insulin-GLP-1 combination. In

cardiovascular, we have the opportunity to transform the management of hypercholesterolemia through Praluent®, developed jointly with Regeneron.

- **Vaccines.** Over the next five years, we expect to outgrow the market in vaccines. Our growth will be driven by Dengvaxia®, and our leading products in flu, pediatric combinations, and boosters. Vaccination rates for these products remain below public health targets. 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. To secure growth for the longer term, we are working on novel vaccines such as Clostridium difficile.

- **Rare Diseases.** We intend to sustain our market share through the patient-centered approach unique to Sanofi Genzyme, product differentiation, and market access. Our objective is to grow the market through screening and manufacturing expansion. We also expect to advance our strong pipeline where four of our assets have received breakthrough or fast-track designation from the FDA.

- **Emerging Markets.** Sanofi is the leader in emerging markets and is a major multinational player in the BRIC-M countries (Brazil, Russia, India, China and Mexico). We intend to sustain leadership through greater focus on key countries, prioritizing resource allocation, adapting the industrial footprint, and developing market-specific innovations.

Build competitive positions

- **Multiple Sclerosis.** Sanofi already has a competitive position in multiple sclerosis. In the coming years, we

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intend to complete the global launches of Aubagio® and Lemtrada® and then maximize our support through product life-cycle management. We will also strengthen our portfolio, in high efficacy and in neuroprotection.

- **Oncology.** Sanofi is rebuilding its oncology portfolio. We intend to maximize our clinical assets, particularly isatuximab, an anti-CD38 monoclonal antibody for multiple myeloma, and to build a transformative pipeline in immuno-oncology and cancer-cell dependencies.

- **Immunology.** With sarilumab in rheumatoid arthritis and dupilumab in atopic dermatitis and asthma as the lead indications, developed in collaboration with Regeneron, we have the cornerstones of an important new franchise in immunology.

- **Consumer Health Care.** Our aim is to achieve leadership and we intend to do so by maximizing the value of existing brands, shaping new categories, and building scale through bolt-on acquisitions such as our proposed business swap with Boehringer Ingelheim (see next section).

Explore strategic options

- **Animal Health.** The Animal Health business has made a strong return to growth. We are the world leader in medical products for pets and the fourth player overall. On December 15, 2015, we announced exclusive negotiations with Boehringer Ingelheim to swap businesses. The proposed transaction would consist of an exchange of the Sanofi Animal Health business with an enterprise value of 11.4 billion and the Boehringer Ingelheim Consumer Healthcare business with an enterprise value of 6.7 billion. The Boehringer Ingelheim Consumer Health Care business in China would be excluded from the transaction. The transaction would also include a gross cash payment from Boehringer Ingelheim to Sanofi of 4.7 billion. The transaction would allow Sanofi to become the number one ranked player in the Over-the-Counter (OTC) drug market.

- **Generics in Europe.** Our European Generics business has approximately 1 billion in sales, including both Western and Eastern Europe. We rank fifth in a consolidating market and have achieved above-average profitability. We are exploring which strategic option will best position the European Generics business for continued success.

Deliver outstanding launches

Our second strategic priority is to deliver outstanding launches of new medicines and vaccines. We are on track to deliver up to 18 new products to the market by 2020. We have focused the organization on six major product launches among the 18, namely Toujeo®, Praluent®, Dengvaxia®, sarilumab, lixisenatide/insulin glargine, and dupilumab.

These products are described in greater detail in B. Business Overview B.2. Main Pharmaceutical Products, and B.3. Vaccines .

Sustain innovation in R&D

Our strategy depends on continued innovation in R&D. Sanofi will continue to strengthen its R&D pipeline, increasing the number of high-quality projects in the early-stage pipeline and replenishing the late-development pipeline as products launch. We will align the R&D organization with the new Global Business Unit structure (see below). Sanofi has a number of anchor collaborations in R&D, most notably with Regeneron for monoclonal antibodies, increasingly focused on immuno-oncology, and with Alnylam for RNAi therapeutics in rare genetic diseases. Fostering these collaborations is an important part of our R&D strategy.

Our R&D investments will follow our business priorities, focusing on those businesses where we aim to sustain leadership and build competitive positions. We expect to increase our R&D investments up to 6 billion annually by 2020.

Simplify the organization

Our final strategic priority is to drive focus and simplification within our organization. As we launch new products, it is important that Sanofi works together in an integrated way. That is why, as of January 1, 2016, Sanofi created:

- Five Global Business Units (GBUs):
  - the General Medicines & Emerging Markets GBU consists of Sanofi s Established Prescription Products, Generics, Consumer Healthcare, and all pharmaceutical businesses in Emerging Markets;
  - the Specialty Care GBU, to be called Sanofi Genzyme consists of Sanofi s medicines in Rare Diseases, Multiple Sclerosis, Oncology and Immunology;
  - the Diabetes & Cardiovascular GBU consists of Sanofi s Diabetes Care medicines as well as Cardiovascular medicines;
  - Sanofi Pasteur and Merial are both GBUs and continue to manage their current portfolios of vaccines and animal health products.
- Centralized global functions, aligned with the GBUs;
- The aligned R&D organization referred to above.

Our new structure will allow us to be more aligned in our strategy and more effective in our execution across R&D and commercial, and from global to country level. Full implementation of the new organizational structure remains subject to ongoing negotiations with labor unions/employee representatives.

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Reshaping the plant network is a second element in our program of simplification. We will continue to reshape the network to better match our evolving business by implementing a more focused approach in Emerging Markets, improving competitiveness and simplifying product lines. At the same time, we will continue to invest in biologics capacity to support our product launches and growth.

One of the outcomes of simplification will be a reduction in costs. To balance the need for increased resources and to partly offset lower diabetes sales expectations, we expect to generate 1.5 billion in cost savings by 2018. The savings will largely be reinvested in the business. Two-thirds of the cost savings are expected to come from simplification of the organization worldwide and from a more focused portfolio. Of those two-thirds, half is expected to come from improvements in gross margins. The other half is expected to come from Selling, General and Administrative expenses (SG&A). The remaining third of the cost savings is expected to come from investment prioritization.

The third element of the simplification program is to unite the different parts of the Group behind a single vision, a common set of values, and a shared culture.

B.2. Main Pharmaceutical Products

Within the pharmaceuticals business, our most important marketed products can be grouped into the key fields of diabetes, cardiovascular disease, rare diseases, multiple sclerosis and oncology. We have also developed a significant presence in consumer health care and generics.

The sections below provide additional information on the indications and market position of our 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.

The table below shows the net sales of the main pharmaceutical products for the year ended December 31, 2015.

Therapeutic Area / Product Name	2015 Net Sales (million)	Drug Category / Main Areas of Use
Diabetes Solutions		
Lantus® (insulin glargine)	6,390	Long-acting analog of human insulin
Amaryl® (glimepiride)	393	· Type 1 and 2 diabetes Sulfonylurea
Apidra® (insulin glulisine)	376	· Type 2 diabetes Rapid-acting analog of human insulin
Toujeo® (Glargine U300)	164	· Type 1 and 2 diabetes Long-acting analog of human insulin
		· Type 1 and 2 diabetes

Insuman® (insulin)	141	Human insulin (rapid and intermediate acting) · Type 1 and 2 diabetes
Lyxumia® (lixisenatide)	38	GLP-1 receptor agonist · Type 2 diabetes
Rare Diseases		
Cerezyme® (imiglucerase for injection)	757	Enzyme replacement therapy · Gaucher disease
Myozyme®/Lumizyme® (alglucosidase alpha)	650	Enzyme replacement therapy · Pompe disease
Fabrazyme® (agalsidase beta)	592	Enzyme replacement therapy · Fabry disease
Aldurazyme® (laronidase)	195	Enzyme replacement therapy · Mucopolysaccharidosis Type 1
Cerdelga® (eliglustat)	66	Enzyme replacement therapy · Gaucher disease Type 1

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Therapeutic Area / Product Name	2015 Net Sales (million)	Drug Category / Main Areas of Use
Multiple Sclerosis		
Aubagio® (teriflunomide)	871	Immunomodulating agent
		· Multiple Sclerosis (MS)
Lemtrada® (alemtuzumab)	243	Humanized monoclonal antibody
		· Multiple Sclerosis (MS)
Oncology		
Jevtana® (cabazitaxel)	321	Cytotoxic agent
		· Prostate cancer
Thymoglobulin® (anti-thymocyte globulin)	256	Polyclonal anti-human thymocyte antibody preparation
		· Acute rejection in organ transplantation
		· Aplastic anemia
		· Graft-versus-Host Disease
Eloxatin® (oxaliplatin)	227	Cytotoxic agent
		· Colorectal cancer
Taxotere® (docetaxel)	222	Cytotoxic agent
		· Breast cancer
		· Non small cell lung cancer
		· Prostate cancer
		· Gastric cancer
		· Head and neck cancer
Mozobil® (plerixafor)	143	Hematopoietic stem cell mobilizer
		· Hematologic maligancies
Zaltrap® (aflibercept)	77	Recombinant fusion protein
		· Oxaliplatin resistant metastatic colorectal cancer
Established Prescription Products		
Plavix® (clopidogrel bisulfate)	1,929	Platelet adenosine disphosphate receptor antagonist
		· Atherothrombosis

Lovenox® (enoxaparin sodium)	1,719	· Acute coronary syndrome with and without ST segment elevation Low molecular weight heparin · Treatment and prevention of deep vein thrombosis
Renagel® (sevelamer hydrochloride) / Renvela® (sevelamer carbonate)	935	· Treatment of acute coronary syndromes Oral phosphate binders · High phosphorus levels in patients with chronic kidney disease (CKD) on dialysis
Aprovel® (irbesartan) / CoAprovel® (irbesartan & hydrochlorothiazide)	762	Angiotensin II receptor antagonist · Hypertension
Synvisc® / Synvisc-One® (hylan G-F 20)	413	Viscosupplements · Pain associated with osteoarthritis of the knee
Multaq® (dronedarone)	341	Anti-arrhythmic drug · Atrial Fibrillation (AF)
Stilnox® / Ambien® / Myslee® (zolpidem tartrate)	306	Hypnotic · Sleep disorders
Allegra® (fexofenadine hydrochloride)	194[(1)]	Anti-histamine · Allergic rhinitis · Urticaria

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Therapeutic Area / Product Name	2015 Net Sales (million)	Drug Category / Main Areas of Use
Praluent® (alirocumab)	9	Cholesterol-lowering drug that inhibits PCSK9 · Heterozygous familial hypercholesterolemia · Clinical atherosclerotic cardiovascular disease
Consumer Health Care		
Total	3,492	
Generics		
Total	1,917	

(1) Excluding Allegra® OTC sales.

a) Diabetes Solutions

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 principal diabetes products are Lantus®, and Toujeo®, long acting analogs of human insulin; Amaryl®, a sulfonylurea; Apidra®, a rapid acting analog of human insulin; Insuman®, a human insulin; and Lyxumia® (lixisenatide), a once-daily prandial GLP-1 receptor agonist.

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 E.U. in 2012) aged two years with type 1 diabetes.

Lantus® is the most-studied basal insulin with over ten 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;
- AllSTAR , the first state of the art 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® remains the world s no. 1 selling insulin brand in terms of both sales and units and is available in over 120 countries worldwide. The leading countries for sales of Lantus® in 2015 were the U.S., China, France and Germany.

2015 sales of Lantus® were 6,390 million, down 10.8% (constant exchange rate). In the U.S., sales of Lantus® decreased 20.5% to 4,023 million, mainly reflecting higher discounts as compared to last year, a slowdown of basal insulin market growth and an unfavorable mix effect towards highly-discounted government channels such as Medicaid (which also included Medicaid delayed bills from multiple States). A biosimilar of Lantus® from Eli Lilly and Company (Lilly) was launched in several European markets in the third quarter (including Germany, the U.K., Spain and eight other countries) and in Japan. In Emerging Markets, 2015 sales of Lantus® were up 17.3% to 1,137 million, driven by China.

In the U.S., Sanofi s pediatric regulatory exclusivity for the Lantus compound expired in February 2015. The Lantus® compound patent expired in August 2014 in the U.S., and in November 2009 in Europe and Japan. A Patent Term Extension in Japan expired in November 2014. The Supplementary Protection Certificate for Lantus® including pediatric extension expired in major European countries in May 2015. Sanofi also has patents protecting the Lantus® formulation and devices which deliver Lantus®.

On September 28, 2015, Sanofi and Lilly announced that they had agreed to dismiss the patent infringement lawsuit in the U.S. and to discontinue similar disputes worldwide. For more information refer to Item 8 Consolidated Financial Statements and Other Financial Information Information on Legal or Abitration Proceedings Lantus® and Lantus SoloSTAR® Patent Litigation (United States, France and Japan).

On December 16, 2015, the FDA granted approval in the U.S. to Lilly and Boehringer Ingelheim for their insulin glargine product for use with KwikPen®, a pre-filled dosing device, under the trade name Basaglar® (NDA 205-692). It is a long-acting human insulin analog to improve glycemic control in adult and pediatric patients with type 1 diabetes and in adults with type 2 diabetes.

Following this settlement in the U.S. Lilly will not sell its insulin glargine product before December 15, 2016.

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Toujeo®

Sanofi s next generation basal insulin Toujeo (insulin glargine 300 units/mL) has been granted marketing authorization by three major regulatory authorities: the FDA (February 25, 2015), the European Commission (April 28, 2015) and the Japanese Ministry of Health, Labor and Welfare (J-MHLW) where its approved brand name is Lantus® XR (June 30, 2015).

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

Toujeo® has now been launched in 20 countries, including the U.S., Germany, the U.K. and Japan. Toujeo® is currently pending marketing authorization with other health authorities around the world and it is expected that an additional 24 countries including France, Italy and Spain will launch Toujeo® in 2016 making this next-generation basal insulin treatment for type 1 and type 2 diabetes widely available.

Apidra®

Apidra® (insulin glulisine) is a rapid-acting analog of human insulin. Apidra® is 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.

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 (OptiSet® and 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 Germany and in Emerging Markets. At the end of 2015, limited manufacturing capacity at a Sanofi manufacturing site in Frankfurt, Germany, for

Insuman pre-filled pens and cartridges caused supply difficulties for some Insuman suspension products. A shortage is therefore expected for the first half of 2016 with some limited, and temporary supply disruptions of some products in the E.U.

Lyxumia®

Lyxumia® (lixisenatide) is a once-daily 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 E.U. countries. Applications for regulatory approval have also been submitted in several other countries around the world and are being reviewed. Lyxumia® has been approved in over 60 countries and

launched in over 35 countries around the world. The countries with the largest sales are Japan, Spain, the U.K. and Belgium. Recent launches include Russia and Korea. Lyxumia® has been withdrawn from the market in Germany.

Lixisenatide was submitted to the FDA on July 27, 2015 after the results of ELIXA demonstrated cardiovascular safety in type 2 diabetes patients with high cardiovascular risk. A launch is anticipated in the third quarter of 2016. Other major launches expected in 2016 include France in the fourth quarter.

Additional Phase IIIb studies are ongoing including research into the safety and efficacy of Lyxumia® in the pediatric setting.

Afrezza®

Afrezza® is a rapid-acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes. The product was launched in the U.S. at the beginning of February 2015. In January 2016, Sanofi exercised its option to terminate the license and collaboration agreement with MannKind Corporation, the developer of Afrezza, and will transfer the rights for Afrezza back to MannKind on April 4, 2016.

Integrated Care Solutions

Sanofi is committed to developing integrated care solutions to improve diabetes health outcomes for people with diabetes. This approach integrates technology, therapeutic innovations, personalized services and support solutions.

Sanofi and Verily (formerly Google Life Sciences) entered into a collaboration to improve diabetes health outcomes.

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We will work together on new digital technology and tools for diabetes. The aim is to use data and miniaturized technology to provide patients with more tools to self-manage their disease, and healthcare professionals with the ability to better support and treat patients. Together they will strive to shift from episodic, event-driven diabetes care to continuous, value-based care.

In the framework of their partnership, Sanofi and AgaMatrix have co-developed MyStar Dose Coach®, a dose helper for Insulin Glargine with an integrated blood glucose meter, which has obtained the CE mark. Sanofi and AgaMatrix have already co-developed intelligent solutions in diabetes care such as blood glucose monitoring solutions BGStar®, iBGStar® and MyStar Extra® which are easy to use, accurate, reliable and fit the lifestyle of people with diabetes today.

b) Cardiovascular
Praluent®

Praluent® is a human monoclonal antibody (mAb) that blocks the interaction of PSCK9 with LDL receptors, increasing the recycling of LDL receptors and reducing LDL-C 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 efficacy and safety of Praluent® across various high cardiovascular risk patients (due to but not limited to diabetes, family hypercholesterolemia or previous 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 effective dose of statins.

The effect of Praluent® on cardiovascular morbidity and mortality within post ACS patient population is being investigated in the ongoing ODYSSEY OUTCOMES trial. In parallel, the ability of Praluent® to reduce major cardiovascular events is being investigated and results are anticipated in 2017.

Praluent® has been approved by both the FDA in the U.S. and the European Commission. As of March 2016, Praluent® has been launched in the U.S., Germany, the U.K., Austria and Nordic countries.

On August 5, 2015, an application for Praluent® was submitted in Japan and submission in the rest of the world is progressing according to plans.

The main countries contributing to Praluent® sales in 2015 were the U.S. and Germany.

Multaq®

Multaq® (dronedarone) is among the most extensively studied anti-arrhythmic drugs in atrial fibrillation (AF) and has 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.

Multaq® is a multichannel blocker with anti-arrhythmic (prevention of AF recurrences) properties and is the first and only anti-arrhythmic drug to have shown a significant reduction in cardiovascular hospitalization and death in patients with paroxysmal and persistent AF.

The main countries contributing to Multaq® sales in 2015 were the U.S., Germany and Italy.

c) Rare Diseases

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

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 20-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 U.S., Europe and Latin America.

Cerdelga®

Cerdelga® (eliglustat) is the 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 naïve Gaucher disease patients and in patients who switch from enzyme replacement therapy (ERT). The Cerdelga® development program is the largest ever in Gaucher disease, with almost 400 patients treated in 29 countries.

The principal market for Cerdelga® currently is the U.S. It received European Medicines Agency (EMA) approval in January 2015 and was approved in Japan in March 2015.

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Myozyme® / Lumizyme®

Myozyme® / 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 U.S. and the E.U. and is approved in 76 countries. Outside the U.S., Myozyme® is marketed for patients with both infantile- and late-onset disease. Lumizyme® has been marketed since June 2010 in the U.S.. 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. Both products are recombinant forms of the same human enzyme.

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 E.U. since 2001 and in the U.S. since 2003. Fabrazyme® is approved in 75 countries.

Fabrazyme® is administered by intravenous infusion.

Aldurazyme®

Aldurazyme® (laronidase) is an enzyme replacement therapy used to treat Mucopolysaccharidosis Type 1 (MPS I). MPS I occurs in approximately one in 85,000 newborns worldwide, but the incidence and patient severity vary among regions.

The principal markets for Aldurazyme® are the U.S., Europe and Latin America.

d) Multiple Sclerosis (MS)

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 two million people suffer from MS worldwide.

Genzyme is focused on the development and commercialization of therapies to treat MS. Genzyme s 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. In addition to its marketed therapies Lemtrada® and Aubagio®, Genzyme has an MS R&D pipeline focused on

investigational treatments to address unmet needs for relapsing and progressive forms of MS. Genzyme s R&D programs are pursuing research in selective immunomodulation, neuroprotection and remyelination.

Aubagio®

Aubagio® (teriflunomide) is a small molecule immunomodulatory agent with anti-inflammatory properties, reversibly inhibits dihydroorotate dehydrogenase, a mitochondrial enzyme involved in de novo pyrimidine synthesis. 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 CNS. 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 MRI. Aubagio® is the first and only oral MS therapy to significantly slow the progression of disability in two Phase III trials (TEMSO and TOWER) and 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), global post-marketing registries for pregnancy, and a post-approval study that will evaluate long-term safety in the marketed population using data from selected national health registries in Europe.

Aubagio® was approved in the U.S. in August 2013 and is now approved in more than 60 countries around the world, including the E.U. and Brazil, with additional marketing applications under review by regulatory authorities globally. To date, more than 48,000 people have been treated with Aubagio® worldwide.

Lemtrada®

Lemtrada® (alemtuzumab) is a humanized monoclonal antibody targeting the CD52 antigen. Alemtuzumab was developed to treat patients with relapsing forms of MS.

In September 2013, Lemtrada® was granted marketing authorization in the E.U. for treatment of adult patients with relapsing forms of MS with active disease defined by clinical or imaging features. Since then, Lemtrada® has been approved by regulatory authorities in several countries in the world including Brazil. In November 2014, the U.S. 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

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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 U.S. through a restricted program called the LEMTRADA Risk Evaluation and Mitigation Strategy (REMS) Program. Lemtrada® is currently approved in more than 45 countries. Additional marketing applications for Lemtrada® are under review by regulatory agencies around the world.

e) Oncology

We have a portfolio of 10 marketed products in Oncology, and diversified our presence beyond chemotherapy (Taxotere®, Jevtana®, Eloxatin®) with Thymoglobulin® and Mozobil® and with an angiogenesis inhibitor, Zaltrap®, launched in 2012 in the United States and in 2013 in the E.U..

Jevtana®

Jevtana® (cabazitaxel), a cytotoxic agent, is a semisynthetic 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 the result of a 14-year research and development program to address the significant unmet medical need after taxane-based treatment progression.

Jevtana® was launched in the U.S. in 2010 and this therapy is now covered by Centers for Medicare and Medicaid Services (CMS), and by most of the private insurance companies that pay for oncology care.

In 2011, Jevtana® received marketing authorization from the European Commission. In July 2014, the Japanese Health Authority (Pharmaceuticals and Medical Devices Agency, or PMDA) granted marketing authorization for Jevtana®, which is now approved in over 80 countries.

Sanofi has initiated a broad development program with Jevtana®. Two post-marketing requirement Phase III studies are ongoing in first- and second-line chemotherapy treatment of metastatic castration resistant prostate cancer patients. The clinical program is also evaluating Jevtana® in pediatric patients with brain cancer (phase I/II ongoing).

The main countries contributing to sales of Jevtana® in 2015 were the U.S., France, Germany, Japan, Italy, Spain and the U.K.

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 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).

The top four countries contributing to sales of Taxotere® in 2015 were Japan, China, Taiwan and South Korea. Generics of docetaxel were launched in Europe, in the U.S., and in Japan (see B.7. Patents, Intellectual Property and Other Rights below).

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.

Following the end of Eloxatin® European regulatory data exclusivity in April 2006, a number of oxaliplatin generics have been launched throughout Europe. Market exclusivity in the U.S. was lost in 2012. In the second quarter of 2013, Eloxatin® received regulatory approval for advanced Hepatocellular Carcinoma (HCC) in China. Several generics of oxaliplatin are available globally, including Canada where Eloxatin® lost exclusivity in December 2015.

The main three countries contributing to sales of Eloxatin® in 2015 were Canada, China and South Korea.

Thymoglobulin®

Thymoglobulin® (Anti-thymocyte Globulin) is a polyclonal anti-human thymocyte antibody preparation that acts as a broad immuno-suppressive and immuno-modulating agent. The product s primary mechanism of action is T-cell depletion, which is complemented by a host of other immuno-modulating 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/or 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 2015 were the U.S., China, France, Japan and South Korea.

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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 main countries contributing to Mozobil® sales in 2015 were the U.S., the U.K.,Germany and France.

Zaltrap®

Zaltrap® (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.

In the U.S., Zaltrap® is approved under the U.S. proper name ziv-aflibercept for use in combination with FOLFIRI, in patients with metastatic colorectal cancer (mCRC) that is resistant to or has progressed following an oxaliplatin-containing regimen. Zaltrap® has been marketed in the U.S. since August 2012.

In the E.U., Zaltrap® was approved in February 2013 by the European Commission to treat mCRC that is resistant to or has progressed after an oxaliplatin-containing regimen.

Zaltrap® was approved in a further 18 countries in 2014, and is now approved in over 50 countries worldwide. Marketing authorization applications are under review in several other countries.

The main countries contributing to sales of Zaltrap® in 2015 were the U.S., Germany, France, Spain, Italy and the U.K..

For additional information on the commercialization of this product, see Item 5 Financial Presentation of Alliances Alliance Arrangements with Regeneron .

f) Established Prescription Products and Other Products
Plavix® / Iscover®

Plavix® (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, recent ischemic stroke or established peripheral arterial disease.

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 (MI), including 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, 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;

- 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.

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 U.S. and other markets.

Generics were launched in Japan starting in June 2015 (for stroke indication), October 2015 (for MI) and are expected to be launched in the fourth quarter of 2016 for the PAD indication.

Plavix® is the leading anti-platelet in the Chinese market.

The main countries contributing to sales of Plavix® / Iscover® in 2015 were Japan and China.

Lovenox® / Clexane®

Lovenox® (enoxaparin sodium) has been used to treat almost 500 million patients in more than 100 countries since its launch and 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 the area of prophylaxis of deep vein thrombosis (DVT) in patients hospitalized for an acute medical condition.

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In the U.S., three enoxaparin generics have been approved as well as Sanofi s own Lovenox® generic. No biosimilar of Lovenox® has been authorized in the E.U. yet.

In 2015, Lovenox® was the leading injectable anti-thrombotic in all European countries.

Aprovel® / Avapro® / Karvea®

Aprovel® (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. These products achieve control of blood pressure in over 80% of patients, with a good safety profile.

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 in 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 markets.

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

The main countries contributing to sales of Aprovel® / Avapro® / Karvea® in 2015 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 U.S., 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 E.U. and 65,000 in Brazil. In the E.U., 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.

As of January 31, 2016, there have been no approvals of generics in the U.S.. However, Sanofi expects potential generics approvals in the U.S. in 2016. Generics of the product are currently marketed in some European countries.

In Europe, the product lost its exclusivity in January 2015 and generics are currently marketed in some countries. Sanofi has launched an authorized generic in some markets.

The main countries contributing to sales of Renagel® and Renvela® in 2015 were the U.S., France, Germany, Italy, Brazil and the U.K..

Allegra® / Telfast®

Allegra® (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 U.S., the Allegra® family moved to over-the-counter (OTC) use in adults and children two years of age and older in 2011. Allegra® was also launched on the OTC market in Japan in November 2012, though it also remains available on prescription (see g) Consumer Health Care 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 (for more information see Item 8 Financial Information A. Consolidated Financial Statements and Other Financial Information Information on Legal or Arbitration Proceedings).

Stilnox® / Ambien® / Myslee®

Stilnox® (zolpidem tartrate) is indicated in 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

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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 U.S. 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 U.S. and Europe. In Japan, generics of Myslee® entered the market in 2012.

In 2015, the main countries contributing to Stilnox® / Ambien® / Myslee® sales were Japan and the U.S.

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 (OA) of the knee, hip, ankle, and shoulder joint in countries that have adopted CE marking, and for pain due to knee osteoarthritis in the U.S. Synvisc-One® is approved for use in patients with OA of the knee in U.S. 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. The Phase III trial evaluating Synvisc-One® in hip osteoarthritis did not reach its primary endpoint in 2015.

In 2015, the main countries contributing to Synvisc® and Synvisc-One® sales were the U.S., Mexico, France, Canada, Germany and Brazil.

Auvi-Q® / Allerject ®

On October 30, 2015, Sanofi announced a voluntary recall for Auvi-Q® and Allerject® in the U.S. and Canada.

Sanofi has ultimately decided to return all U.S. and Canadian rights to Auvi-Q® to the developer of Auvi-Q®.

g) Consumer Health Care (CHC)

Consumer Health Care is one of the key platforms in Sanofi s global growth strategy. In 2015, Consumer Health Care sales reached 3,492 million, an increase of 4.6% (or 2.8 % at constant exchange rates). Nearly 48% of these sales were generated in Emerging Markets, 19.1% in Western Europe and 25.8% in the U.S..

Consumer Health Care activities were consolidated within the Global Consumer Health Care Division at the end of 2013. During 2014, this new division became operational and its development continued in 2015, focusing on meeting consumer needs in terms of health and well-being, and

developing the capacity of our Group to meet those needs by mobilizing:

- Our medical and scientific resources, working in close collaboration with healthcare professionals, physicians and pharmacists;

Our regulatory, medical and commercial know-how, in order to launch self-care versions of products previously available only on prescription; and

- Our international dedicated sites integrated in the industrial network, manufacturing products to the highest pharmaceutical quality standards.

Sanofi is the fifth largest player in the global consumer healthcare market and one of the fastest growing companies in this sector.

The sustained growth of our Consumer Health Care business is based on three complementary development priorities:

- **Maximizing the existing brand portfolio** by accelerating our innovation processes and giving priority to the six major global categories (Allergies, Cough & Cold, Digestive Health, Feminine Hygiene, Analgesics, Vitamins, Minerals and Supplements) forming our core business;

- **Enhancing the strategy of launching self-care versions of products** previously available only by prescription. In 2015, Sanofi prepared for the marketing of Cialis® OTC, on the basis of a license agreement signed in 2014 with Lilly granting Sanofi exclusive rights to apply for approval of Cialis® as an OTC product in the U.S., Europe, Canada and Australia, and to market it on the same markets following receipt of all necessary regulatory approvals and once certain patents protecting the product have expired;

- **Pursuing the external growth strategy** via the targeted acquisition of products or companies enabling us to strengthen our consumer offering. On December 15, 2015, we announced exclusive negotiations with Boehringer Ingelheim to enter into a proposed transaction that would consist of an exchange of the Sanofi Animal Health business with an enterprise value of 11.4 billion and the Boehringer Ingelheim Consumer Healthcare business with an enterprise value of 6.7 billion. The Boehringer Ingelheim Consumer Health Care business in China would be excluded from the transaction. The transaction would also include a gross cash payment from Boehringer Ingelheim to Sanofi of 4.7 billion. The transaction would allow Sanofi to become the leader in the OTC drug market.

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Highlights of our numerous product launches throughout the world in 2015 include extensions of the brands listed below.

- In the U.S.:

  Allegra® gelcaps, designed to ease the ingestion of the product. This version of the product is the first extension of the brand since its transition to OTC status in 2011;

  The pediatric version of Nasacort® Allergy 24HR, marketed one year after the transition of the brand to OTC status in 2014;

  IcyHot SmartRelief® for shoulders and knees, a new version of the innovative drug-free pain-relief device, based on Transcutaneous Electrical Nerve Stimulation (TENS) technology, blocking pain signals and stimulating the production of endorphins, the body s naturally produced pain relievers. The IcyHot SmartRelief® brand has been available throughout the U.S. since the fall of 2014;

  Aspercreme®, a lidocain-based cream providing a new, odorless and non-irritant solution for consumers suffering from pain and constantly looking for new means to attenuate it.

- In France, the launch of a wide range of OTC pain-relief products, including DolipraneOrodoz 500 mg, an oro-dispersible tablet that may be taken with or without water; DolipraneTabs, a coated tablet masking the relatively bitter taste of paracetamol (500 mg and 1000 mg formulations); DolipraneCaps, an easy-to-swallow capsule containing 1000 mg of paracetamol; DolipraneLiquiz, an oral suspension in liquid, single-dose stick-packs for children. These new products fill out the pain-relief offering of Sanofi, in which Doliprane® plays a central role and covers the needs of patients of all ages, mainly on the French market and in various African countries.

Growth in 2015 was also supported by a range of Consumer Health Care products listed below that enable Sanofi to play a major role in the field of digestive health:

- No Spa® (drotaverine hydrochloride) is an abdominal anti-spasmodic, indicated for intestinal spasms, menstrual pain and bladder spasm. No Spa® is sold mainly in Russia and Eastern Europe where sales volumes have grown steadily;

- Enterogermina® is a probiotic in the form of a drinkable suspension in 5 ml bottles or capsules containing two billion Bacillus clausii spores. Enterogermina® is indicated for the maintenance and restoration of intestinal flora in the treatment of acute or chronic intestinal disorders (in babies and adults). Enterogermina® is sold primarily in Europe with strong growth in Latin America, India, Ukraine and Belarus;

- Essentiale® is a plant-based product for the treatment of liver problems. 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 to alleviate symptoms such as loss of appetite, pressure in the right epigastrium, food-related liver lesions and hepatitis. Essentiale® is sold mainly in Russia (no. 1 CHC product in the market), Eastern Europe, various countries in Southeast Asia and China;

- Maalox® is a well-established brand that contains two antacids, aluminum hydroxide and magnesium hydroxide. It is available in various forms, namely tablets, oral suspension and sachets, thus offering consumers a range of suitable solutions. Maalox® is available in 55 countries in Europe, Latin America and Asia;

- Magne B6® is a food supplement containing magnesium and vitamin B6. It has a wide range of therapeutic indications, including irritability, anxiety, sleep disorders and women s health issues (premenstrual syndrome and menopausal problems). Magne B6® is available primarily in Europe and Russia;

- The Lactacyd® range covers a number of intimate feminine-hygiene products. Lactacyd® is sold mainly in Brazil and in Asia where the range, enhanced with several new products, has continued to show strong growth in sales. In the fall of 2015, it was launched in Japan with the objective of developing the market for intimate feminine-hygiene products;

The above, long-standing products are supplemented by Chattem products in the U.S.. In addition to Allegra® OTC and Nasacort® Allergy 24H, the main products are ACT®, Aspercreme®, Gold Bond®, Icy Hot®, Cortizone-10®, Selsun Blue® and Unisom®;

Sanofi is also actively growing in the Vitamins, Minerals and Supplements (VMS) market with the Omnivit® range in various emerging-market countries and with the Cenovis® and Nature s Own® brands on the Australian market.

h) Generics

The Generics business recorded 2015 net sales of 1,917 million, up 7.6% at constant exchange rates (CER).

In Emerging Markets, the Generics business generated net sales of 1,094 million, an increase of 5.2% CER, driven by Eurasia/Middle East and Venezuela. Net sales in Western Europe increased by 4.1% CER to 569 million, boosted by a good performance in Germany. In the U.S., net sales advanced by 15.4% CER to 171 million, mainly due to increased sales of the authorized generic of Lovenox®. In the Rest of the World region, net sales rose by 90.7% CER to 83 million, due mainly to the performance in Japan of the authorized generic of Allegra® and of the authorized generic of Plavix® launched by Sanofi and our partner Nichi-Iko Pharmaceuticals at the end of the second quarter of 2015.

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Sales in the U.S. grew by 15.4% at constant exchange rates, driven by authorized generics of Lovenox® and Arava®.

B.3. Vaccine Products

Sanofi Pasteur, the vaccines division of Sanofi, offers a broad range of vaccines. In 2015, Sanofi Pasteur provided more than one billion doses of vaccines, making it possible to immunize more than 500 million people across the globe against 20 serious diseases, and generated net sales of 4,743 million. Sales were favorably impacted by record sales of influenza vaccines and a strong performance of the pediatric combinations, boosters and meninge franchises.

Sanofi Pasteur is a world leader in the vaccine industry in terms of sales. In the U.S., Sanofi Pasteur is the leading producer of influenza and meningitis vaccines.

In Europe, Sanofi Pasteur s vaccine products are developed and marketed by Sanofi Pasteur MSD, a joint venture that serves 19 countries. Created in 1994 and held equally by Sanofi Pasteur and Merck & Co., Inc., Sanofi Pasteur MSD also distributes Merck vaccines, such as Gardasil® and Zostavax®. In 2015, Sanofi Pasteur MSD net sales amounted to 824 million.

Sanofi Pasteur continued to expand in Asia, Latin America, Africa, the Middle East and Eastern Europe. In addition, 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).

See B.5.3 Vaccines Research and Development below for a presentation of the Sanofi Pasteur R&D portfolio.

The table below lists net vaccine sales by product range.

(million)	2015 Net Sales
Polio/Pertussis/Hib Vaccines	1,348
Influenza Vaccines	1,322
Meningitis/Pneumonia Vaccines	614
Adult Booster Vaccines	496
Travel and Other Endemic Vaccines	375
Vaxserve	481
Other Vaccines	107
Total Vaccines	**4,743**

a) Pediatric, Combination and Poliomyelitis (Polio) Vaccines

Sanofi Pasteur is one of the key players in pediatric vaccines in both mature 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, more than 230 million doses of Pentaxim® have been distributed in over 100 countries, and the vaccine has been

included in the national immunization programs of more than 25 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 E.U., where it is sold under the brand name Hexyon® in Western Europe by Sanofi Pasteur MSD and under the brand name Hexacima® in Eastern Europe by Sanofi Pasteur. The roll-out of this new hexavalent vaccine began in July 2013 in Germany and has ramped up significantly with 27 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.

Pentacel®, a pediatric combination vaccine protecting against five diseases (diphtheria, tetanus, pertussis, polio and Hib), was launched in the U.S. in 2008. There has been a tight supply of Pentacel® since 2013, which has improved over the past two years, yet requires careful supply management to meet strong market demand. Supply constraints are expected to continue throughout the first half of 2016.

Pediacel® is a fully liquid pentavalent vaccine protecting against diphtheria, tetanus, pertussis, polio and Hib.

Act-HIB®, for the prevention of Hib, is also an important growth driver within the pediatric product line.

Quadracel® 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. Quadracel® was already licensed in Canada (1997) and Australia (2002) and was licensed in the U.S. in April 2015. The U.S. commercial launch of Quadracel® is planned for 2016.

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 in May 2014 and was launched on the Indian market in the last quarter of 2014. Over 22 million doses were delivered to UNICEF in 2015.

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In Japan, a key milestone was achieved in July 2014 with the licensure of Squarekids®, a quadrivalent pediatric combination vaccine offering protection against diphtheria, tetanus, pertussis and polio. Squarekids® was co-developed with our partner Kitasato Daiichi Sankyo Vaccine. The commercial launch took place in December 2015.

Sanofi Pasteur is the world s leading developer and manufacturer of polio vaccines, with both Oral Polio Vaccines (OPV) and Injectable 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. In November 2013, GAVI announced its support for the introduction of IPV in the national immunization programs of the world s 73 poorest countries. The combined use of OPV and IPV is expected to improve the level of protection in countries threatened by the possible resurgence of polio. GAVI support has paved the way for the implementation of the recommendation made by the WHO expert group on immunization that all countries introduce at least one dose of IPV in their routine immunization schedule by the first half of 2016. The end of February 2014 marked an important milestone in the global fight against polio with the UNICEF decision to award Sanofi Pasteur unprecedented quantities of IPV for use in GAVI countries. IPV routine immunization in GAVI countries began in September 2014 in Nepal. Beyond GAVI countries, the expanded use of Sanofi Pasteur s Imovax® Polio vaccine began with IPV introduction in the Philippines in October 2014. In 2015 and early 2016 there has been significant progress in the global fight against polio, with to date 120 countries using IPV and more than 70 countries expected to introduce IPV by the first half of 2016, including two countries where polio remains endemic: Afghanistan and Pakistan. In 2015, Sanofi Pasteur delivered 27 million doses of IPV standalone to UNICEF for GAVI countries. In India, ShanIPV manufactured by Shantha, and reserved for the Indian market, received marketing authorization in 2015 and was launched in December 2015.

b) Influenza Vaccines

Sanofi Pasteur is a world leader in the production and marketing of influenza vaccines with over 220 million doses delivered in 2015. In recent years, influenza vaccine demand has experienced strong growth in many countries, particularly in the U.S., 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. Sanofi Pasteur remains focused on meeting the increasing demand for seasonal influenza vaccines through the launch of innovative vaccines. The differentiated product strategy is

strengthening the leadership of Sanofi Pasteur in the influenza market with the following products:

- Fluzone® High-Dose vaccine, launched in the U.S. 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 vaccine to document the superior clinical benefit for Fluzone® High-Dose vaccine, compared to the standard dose of Fluzone® vaccine (Fluzone® High-Dose vaccine was 24% more effective than Fluzone vaccine in a large-scale efficacy study). In 2015, Fluzone® High-Dose continued to generate strong sales growth;

- Fluzone® Quadrivalent vaccine 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. In June 2013, Sanofi Pasteur obtained FDA authorization for Fluzone® Quadrivalent to be commercialized in the U.S. for children over six months, adolescents and adults. Since 2014, Fluzone® Quadrivalent/ FluQuadri® vaccine has launched in over 20 other countries, including Mexico and Canada;

- Intradermal (ID) trivalent influenza vaccines (Intanza®/IDflu® launched in 2010 in Australia, Canada, the E.U. and several other countries and Fluzone® ID launched in the U.S. in 2011) also contribute to Sanofi Pasteur s flu differentiation strategy. The innovative ID vaccines represent new and innovative offer efficiency and provide simplicity of administration. In 2015, Fluzone® ID Quadrivalent was launched in the U.S.;

- Vaxigrip vaccine is a trivalent vaccine that is licensed in over 150 countries globally for people at least six months old. Sanofi Pasteur is planning to launch a quadrivalent formulation of Vaxigrip in the coming years. The E.U. license for Vaxigrip quadrivalent influenza vaccine (QIV) + 3 years is expected in the second half of 2016 with a launch starting in 2017. With regards to Vaxigrip QIV 6-35 months, a license application in the E.U. is expected to be submitted in the course of 2018.

c) Adult and Adolescent Boosters

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.

Adacel®, the first trivalent adolescent and adult booster offering protection against diphtheria, tetanus and pertussis, was licensed and launched in the U.S. in 2005. Since its launch in the U.S. and expansion to over 60 countries, more

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than 140 million doses of Adacel® have been sold. This vaccine plays an important role in efforts to better control pertussis, by preventing the disease in adolescents and adults and reducing exposure to infants who are not immunized or only partially immunized.

Repevax® (also marketed under the trademark Adacel-Polio®) is a combination vaccine that provides the same benefits as Adacel®, but also offers protection against polio. Repevax® is useful in markets that recommend adolescent and/or adult immunizations to protect against both pertussis and polio. This vaccine is licensed in more than 30 countries worldwide.

d) Meningitis and Pneumonia Vaccines

Sanofi Pasteur is at the forefront of the development of vaccines to prevent bacterial meningitis. In 2014, Sanofi Pasteur celebrated 40 years of providing vaccines protecting against meningitis. In 2005, Sanofi Pasteur introduced Menactra®, the first quadrivalent conjugate vaccine against meningococcal meningitis, which is considered the deadliest form of meningitis in the world. In 2011, the FDA granted Sanofi Pasteur a license to expand the indication of Menactra® to children as young as nine months of age. Menactra® is now indicated for people aged nine months through 55 years in the U.S., Canada, several Middle Eastern countries such as Saudi Arabia and numerous other countries in all regions of the world. The most recent launches include Russia, South Korea and Japan in 2015.

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. Sanofi Pasteur is the leader in most of the world s travel and endemic vaccine markets and benefits from long-term expertise in this domain.

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.

IMOJEV®, a Japanese encephalitis vaccine, is the most recent addition to our travel and endemic vaccines portfolio and was successfully launched in Australia and Thailand in 2012. In 2014, IMOJEV® obtained an extension of indication for use in children starting from nine months of age and obtained WHO prequalification, which provides access to the products in low-income countries. IMOJEV® is being progressively rolled out in endemic countries throughout Asia.

f) Dengue

Dengue fever constitutes a major public-health and economic burden in the endemic areas of Asia-Pacific 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 is 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. 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.

In 2014, the results of two large-scale Phase III efficacy studies conducted in 10 countries in Asia and Latin America were published in *The Lancet* and *The New England Journal of Medicine,* respectively. These studies involved 31,000 participants aged two to 16 years living in highly endemic countries. The results showed an overall efficacy against symptomatic dengue of 56.5% in Asia and 60.8% in Latin America, with a favorable safety profile during the 25-month active surveillance period. Overall, the results of these studies combined showed efficacy against

all four dengue serotypes. Importantly, these studies consistently showed highly significant reductions in severe dengue and hospitalization due to dengue during the 25-month active surveillance periods (80% reduction in severe disease and 67.2% reduction in hospital cases in Asia and 95% protection against severe dengue and 80.3% reduction in risk of hospitalization in Latin America).

The established safety and efficacy profile of this dengue vaccine candidate after 25 months in these two large-scale Phase III studies points to the significant public health impact that this vaccine candidate could have in countries where dengue is endemic.

In January 2015, the rolling submission for Dengue vaccine was initiated in several endemic countries in Asia and Latin America, the first licenses for the Dengue vaccine were granted in December 2015 in Mexico, the Philippines and Brazil. The first shipment of doses occurred in the Philippines in February 2016.

g) Other Products

Growth in other products is mainly driven by VaxServe, a leading specialty distributor and solutions provider in the U.S. market (sales of 481 million in 2015). VaxServe, a Sanofi Pasteur company, offers a broad portfolio of products from Sanofi Pasteur and other manufacturers and is a strategic asset that enables us to position ourselves closer to our customers and better serve their needs.

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B.4 Animal Health: Merial

Our Animal Health activity is carried out through Merial, one of the world leaders in this market. Merial is dedicated to the research, development, manufacture and marketing of innovative pharmaceutical products and vaccines used by veterinarians, farmers and pet owners. The company offers a complete range of products to improve the health, well-being and performance of a large variety of animals (both livestock and pets).

The range of veterinary products covers four main segments, namely parasiticides, anti-infectious drugs, other pharmaceuticals (such as anti-inflammatory agents, anti-ulcer agents, etc.) and vaccines. Merial s top-selling products are Frontline®, a topical flea and tick anti-parasitic intended for dogs and cats, the highest selling veterinary product in the world; Heartgard®, a parasiticide for control of heartworm in pets; Nexgard®, an oral anti-parasitic for the treatment and prevention of fleas and ticks in dogs; LongRange® and Ivomec®, two parasiticides for the control of internal and external parasites in livestock; Vaxxitek®, a high-technology vector vaccine, protecting chickens against infectious bursal disease (IBD) and Marek s disease; Previcox®, a highly selective anti-inflammatory/COX 2 inhibitor for relief of pain and control of inflammation in dogs; Eprinex®, a parasiticide for use in livestock and Circovac®, a porcine circovirus type 2 (PCV2) vaccine. Merial plays an important role in veterinary public-health activities of governments around the world. The company is the world leader in vaccines for foot-and-mouth disease, rabies and catarrhal fever.

Merial s net sales amounted to 2,515 million in 2015. The performance in 2015 was boosted by the strong sales of Nexgard® which, in the second year following its launch, became one of the ten top-selling animal-health products in the world.

In the Livestock segment, growth at Merial is in line with that of the market as a whole. The Avian sector grew strongly in 2015, particularly in the emerging countries. The Ruminant sector also experienced solid growth, due in large part to the success of LongRange® (eprinomectin, an injectable anti-parasitic against internal and external parasites in cattle) in the U.S.

The Merial range of anti-parasitic products for pets was recently filled out with:

- The approval in December 2013 in Europe by EMA of Broadline®, a broad-spectrum internal and external anti-parasitic for treatment and prevention in cats, valid throughout the E.U. Broadline® is a combination of four active ingredients and protects cats for one month. The product was launched in Europe in March 2014;

- The positive opinion of the 27 E.U. Member States in May 2014, followed by the approval of marketing authorizations starting in June 2014 for Frontline Tri Act®/
  Frontect® for the treatment and prevention of flea and tick infestations when repellent activity is necessary against sand flies, biting flies and/or mosquitoes;

- The approval by the European Commission of NexGard Spectra , (afoxolaner and milbemycin oxime) on 19 January 2015. This new chewable tablet, building on the success of NexGard® against fleas and ticks, offers additional protection against heartworm and treats infections caused by intestinal worms in dogs.

Targeted acquisitions have also been made. In the Pet segment, Merial secured the supply of Heartgard® by acquiring the Barceloneta site in Puerto Rico from Merck & Co. Inc. and has since March 2015 made use of the site s expertise in chewables manufacturing technology. In the Livestock segment, Merial acquired Bayer s equine portfolio, consisting of Legend®/Hyonate® (hyaluronate sodium) and Marquis® (ponazuril). Legend®/Hyonate® is an injectable solution that treats non-infectious joint dysfunction in horses and Marquis Antiprotozoal Oral Paste is the first FDA-approved treatment for equine protozoal myeloencephalitis (EPM), a disease that affects the central nervous system in horses.

The principal markets for Merial are the U.S., France, Italy, Brazil, China, the U.K., Germany, Australia, Korea and Japan. Mature markets represent 74% of total net sales and the rate of growth exceeds 10% in 2015.

In December 2015, we announced we had opened exclusive negotiations with Boehringer Ingelheim with a view to an asset swap. The proposed transaction would consist of an exchange of the Sanofi Animal Health business (Merial) with an enterprise value of 11.4 billion and the Boehringer Ingelheim Consumer Healthcare business with an enterprise value of 6.7 billion. The Boehringer Ingelheim Consumer Health Care business in China would be excluded from the transaction. The transaction would also include a gross cash payment from Boehringer Ingelheim to Sanofi of 4.7 billion. Until final completion of the transaction, which is subject to execution of definitive agreements and thereafter to regulatory clearances, expected in the fourth quarter of 2016, we will continue to monitor the performance of the Animal health business (which remains an operating segment) and to report the performance of that business at Group level.

B.5. Global Research & Development

The mission of Sanofi s Global 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.

To meet these challenges, R&D has evolved towards a global organization integrating all R&D activities across three

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major segments: Pharmaceuticals, Vaccines, and Animal Health. Our therapeutic areas encompass a wide range of diseases that represent a large and growing burden on populations and healthcare systems, in line with global trends and the most pressing health needs, including diabetes, cardiovascular diseases and oncology, as well as immune-mediated, degenerative, infectious, and rare diseases.

To carry out our mission, meet these challenges and maximize our 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 innovation.

Medical value, scientific quality and operational effectiveness are the three drivers that underpin our strategy. We focus 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, we can translate basic research findings into medical practice more quickly and efficiently and improve the scientific quality of our projects.

B.5.1. Research & Development Organization

Over recent years, we have moved from a pure pharmaceutical R&D organization to a global and integrated R&D organization where forces are combined to meet a diversity of health needs. Our R&D activities are organized into three major segments:

- Sanofi Pharma R&D, which is dedicated to the discovery and development of human medicines. This is a project-driven organization, which in 2015 included several units covering different therapeutic areas such as diabetes, cardiovascular, oncology, immune-mediated diseases, rare diseases, multiple sclerosis, neurodegenerative diseases, infectious diseases and ophthalmology. These project-focused units are supported by Scientific Platforms and Enabling Functions, responsible for the operational aspects of R&D, such as Chemistry, Manufacturing and Controls (CMC), toxicology, clinical operations, medical and regulatory affairs, and external innovation;

- Sanofi Pasteur R&D, which is responsible for all new approaches and technological discoveries in vaccines against infectious diseases. Its research priorities include new vaccines, the improvement of existing vaccines, combination vaccines, administration systems and innovative technologies; and

- Merial R&D, which aims to deliver and support effective, innovative, safe and cost-effective animal health products.
  Although the specifics of animal health are different from human health, some synergies are achieved via support from Scientific Platforms and Enabling Functions.

Our R&D operations are concentrated in four major hubs: North America, Germany, France and Asia. Within these hubs, a regional leadership ensures local resource optimization and effective engagement within the ecosystems.

B.5.2. Pharmaceuticals

Our pharmaceuticals research and development projects are respectively managed by a Research Working Group (RWG) and a Development Working Group (DWG). These working groups are responsible for the oversight of all major aspects of the research and development portfolios respectively. They drive project prioritization and approval of major stage-gate transitions as well as project terminations. The RWG is temporarily chaired by a Research transition group and the DWG is chaired by the Development Deputy. Both groups include senior members of Sanofi Global R&D as well as experts from a variety of fields necessary for informed decision making.

In addition for all major late stage projects, integrated oversight is provided by an Integrated Development Council (IDC) chaired by the CEO. The IDC includes senior representatives from R&D, Global Business Units and Industrial Affairs, and is responsible for reviewing and approving project strategies, major phase transitions (Phase III, filing, major label modifications), and assessing the launch readiness (pricing, reimbursement, marketing, medical plans). The IDC also reviews major deviations from approved strategies and plans, including registration issues and project discontinuation. The Executive Committee endorses decisions made by IDC.

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 Our research and

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development efforts may not succeed in adequately renewing our 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.

The clinical portfolio for new products can be summarized as follows as of February 9, 2016.

	Phase I	Phase II	Phase III /registration
Diabetes solutions	SAR425899	efpeglenatide (SAR439977)	Lyxumia® (lixisenatide)
	SAR438335		lixisenatide / insulin glargine
	SAR438544		SAR342434 (insulin lispro)
	SAR440067 (LAPS ins.)		sotagliflozin (SAR439954)
Oncology	SAR408701	isatuximab (SAR650984)	
	SAR428926		
	SAR439684		
	SAR566658		
Cardiovascular diseases	SAR407899		
	SAR439152		
Immune mediated diseases	SAR113244	SAR156597	sarilumab (SAR153191)
			dupilumab (SAR231893)
Multiple Sclerosis	GZ402668		
Neurodegenerative diseases	SAR228810		
Infectious diseases		ferroquine (combo OZ439) (SSR97193)	
Ophthalmology	SAR366234		
	UshStat® (SAR421869)		
	SAR422459		
Rare diseases	GZ402666	olipudase alfa (GZ402665)	patisiran (SAR438027)

SAR339375	GZ402671	revusiran (SAR438714)
fitusiran (SAR439774)	sarilumab (uveitis)	
GZ389988		

Phase I studies are the first studies performed in humans, who are mainly healthy volunteers. 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 Solutions

Main compounds currently in Phase III and in the registration Phase

- **Lyxumia® (Lixisenatide)** is already registered in the E.U. and many other countries outside the U.S. and is presented in the section B.2. Main Pharmaceutical Products above.

The New Drug Application (NDA) has been submitted in the U.S. in July 2015 and accepted for filing by the FDA.

- LixiLan: One-daily fixed-ratio combination of insulin glargine 100 Units/mL and lixisenatide. The two Phase III studies, LixiLan®-L and LixiLan®-O, which enrolled more than 1,900 patients worldwide to evaluate the safety and efficacy of the fixed-ratio combination when used in patient populations insufficiently controlled after oral antidiabetic agents and after basal insulin therapy, respectively met their primary endpoints.

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The dossier was submitted to the FDA in December 2015. Sanofi redeemed a priority review voucher (PRV) with the submission to designate the NDA for an expedited 6-month review. The FDA accepted the LixiLan New Drug Application on February 22, 2016. The FDA decision is expected in August 2016.

The LixiLan regulatory submission is planned in the E.U. in March 2016.

- **Insulin lispro biosimilar (SAR342434):** The program entered into Phase III in November 2014. The Phase III clinical program will compare SAR342434 to Humalog® (insulin lispro, Lilly) in addition to Lantus® treatment in patients with type 1 diabetes (SORELLA 1) and in patients with type 2 diabetes (SORELLA 2). The entry into Phase III follows the successful completion of the Phase I study, in which SAR342434 rapid-acting solution demonstrated similar activity and exposure compared to Humalog®.

- **Sotagliflozin (SAR439954):** investigational new oral dual inhibitor of SGLT1/2 which could be a potential treatment option for people with diabetes. The product was in-licensed from Lexicon in November 2015. The product is in Phase III in the treatment of type 1 diabetes and in Phase II in the treatment of type 2 diabetes.

Main products in early stage

- Sanofi and Hanmi signed a license agreement to develop a portfolio of long-acting diabetes treatments:

1. **Efpeglenatide (SAR439977)**, a long-acting GLP1 receptor agonist currently in Phase II;

2. a weekly insulin: **SAR440067 (LAPS insulin 115)** in Phase I; and

3. a fixed-dosed weekly GLP1-R agonist/insulin drug combination.

- Finally, the **dual GLP-1/glucagon receptor (SAR425899)** moved into a multiple ascending dose study, a **dual GLP-1/GIP receptor agonist (SAR438335)** entered Phase I in November 2015, both for the treatment of patients with type 2 diabetes.

SAR438544 (stable glucagon analog) entered in Phase I in December 2015 is intended for the treatment of diabetes patients with severe hypoglycemia.

Sanofi Diabetes maintains a significant network of R&D collaborations with world leading academic institutions and startup companies, including collaborations with Gentofte Hospital (Copenhagen), Gubra (a Danish biotech company specialized in gut hormone R&D), and Selecta. Sanofi and the Juvenile Diabetes Research Foundation (JDRF) continue to jointly fund selected innovation projects in the field of type 1 diabetes research.

Sanofi remains strongly committed to bringing integrated care to people with diabetes, and will continue to establish partnerships with a view to creating new solutions to improve patient outcomes.

Sanofi has entered in a strategic research collaboration with Evotec in 2015 in an effort to develop beta cell-modulating diabetes treatments, which may reduce or even eliminate the need for insulin injections and may be a step towards a cure for type 1 diabetes.

Sanofi and Verily (formerly Google Life Sciences) started a collaboration to improve care and outcomes for people with type 1 and type 2 diabetes. The collaboration will pair Sanofi s leadership in diabetes treatments and devices with Google s expertise in analytics, miniaturized electronics and low power chip design. This includes health indicators such as blood glucose and hemoglobin A1c levels, patient-reported information, medication regimens and sensor devices.

b) Oncology

Main products in Phase II

- **Isatuximab (SAR650984)** is a naked humanized immunoglobulin (IgG1) monoclonal antibody (mAb) that has been in licensed from Immunogen Inc. It selectively binds to CD38, a cell surface antigen widely expressed in multiple myeloma cancer cells, and other hematological malignancies. The program is in Phase II with five ongoing studies in multiple myeloma. One as a single agent, and the others are investigating Isatuximab in combinations with: (i) lenalidomide/dexamethasone, (ii) carfilzomib; (iii) pomalidomide, and (iv) cyclophosphamide/ bortezomib/dexamethasone.

Main products in early stage

- **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. The compound entered the Sanofi Phase I pipeline in 2014 with one ongoing study.

- **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 program is in Phase I with one ongoing study.

- **SAR428926** is Antibody Drug Conjugate (ADC) that binds to Lysosomal Associated Membrane Protein 1 (LAMP1), a protein localized in the lumen of the lysosomes in normal tissue and which is found aberrantly expressed at the cell surface in a number of tumor tissues. SAR428926 is expected to selectively deliver its cytotoxic to LAMP1-expressing tumor cells. The compound entered the Sanofi Phase I pipeline in 2015 with one ongoing study.

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- **SAR439684** is a PD-1 inhibitor derived from our alliance with Regeneron and is currently in Phase I.

Projects discontinued in 2015

- **Coltuximab ravtansine (SAR3419) i**s an Antibody Drug Conjugate (ADC) maytansin-loaded anti-CD19 mAb that has been in-licensed from Immunogen Inc and was being developed in Phase II in B-cell malignancies. This program has been discontinued in Phase II and the rights returned to Immunogen.

- **SAR405838** is a potent inhibitor of the HDM2/P53 interaction. The program in Phase I was discontinued in monotherapy as well as in combination with Merck KGaA s pimasertib.

- **SAR245409** (XL765) was in-licensed from Exelixis, Inc. and developed by Sanofi. This oral agent is dual inhibitor of both (i) phosphoinositide-3-kinase (PI3K), and (ii) the mammalian target of rapamycin (mTOR). The product in Phase II has been discontinued.

- **SAR245408** (XL147) was in-licensed from Exelixis, Inc. and developed by Sanofi. This oral phosphoinositide- 3-kinase (PI3K) inhibitor in a Phase I has been discontinued.

- **SAR125844** is a potent and selective MET tyrosine kinase inhibitor. The development of this product in Phase I has been discontinued and Sanofi decided to explore out-licensing opportunities.

c) Cardiovascular diseases

Main products in early stage

- **SAR439152 (MYK-461)** myosin inhibitor derived from our partnership with MyoKardia, entered in Phase I in Obstructive Hypertrophic Cardiomyopathy indication.

- **SAR407899** Rho-kinase inhibitor has been reactivated in Phase I in the Microvascular Angina (MVA) indication.

Projects discontinued in 2015

- **Fresolimumab (GZ402669)** is a TGF-ß antagonist for the treatment of Focal Segmental Glomerulosclerosis (FSGS). The Phase II clinical trial was terminated, with no further development planned.

d) Immune Mediated diseases

Main products in Phase III

- **Sarilumab (SAR153191)**, a monoclonal antibody against the Interleukin-6 Receptor derived from our alliance with Regeneron, is under development for moderate to severe rheumatoid arthritis (RA). The U.S. Biological License Application (BLA) was submitted on October 30, 2015 and accepted for review on January 8, 2016. The clinical program consists of seven trials of which four have been completed. Two pivotal trials in RA, SARIL-RA-MOBILITY in methotrexate inadequate responders assessing signs and symptoms and inhibition of structural damage, and SARIL-RA-TARGET in inadequate responders to anti-TNF treatment assessing signs and symptoms and effect on physical function, met all primary endpoints. One Phase III trial (SARIL-RA-MONARCH) which evaluates sarilumab versus adalimumab as monotherapy is ongoing with data expected in the second quarter to support the filing in Europe planned for the third quarter of 2016.

Additional studies are:

- The SARIL-RA-EXTEND study, an uncontrolled extension study which enrolled patients from MOBILITY and is enrolling participants by invitation from the TARGET and ASCERTAIN (to benchmark safety against tocilizumab) studies, aims to evaluate the long term safety and efficacy of Sarilumab in combination with disease-modifying anti-rheumatic drugs (DMARD) in patients with active RA;

- The SARIL-RA-EASY is a usability study comparing two devices: the auto-injector and the pre-filled syringe.

- **Dupilumab (SAR231893)** is a monoclonal antibody against the Interleukin-4 alpha Receptor derived from our alliance with Regeneron. Dupilumab modulates signaling of both the IL-4 and IL-13 pathways. It is currently being developed in several indications: atopic dermatitis in Phase III, asthma in Phase III, nasal polyposis with a Positive Phase IIA proof of concept study, and eosinophilic esophagitis in Phase II.

- **Atopic Dermatitis**, the Phase III program consists of:

  - Two identical 16-week monotherapy treatment trials (SOLO 1 & SOLO 2): Monotherapy Administered to Adult Patients with Moderate- to-Severe Atopic Dermatitis . These are randomized, double-blind, placebo-controlled, parallel group studies to confirm the efficacy and safety of dupilumab monotherapy in adults with moderate-to-severe atopic dermatitis (AD). Results are expected during the first quarter of 2016.

  - A long-term treatment trial in combination with topical corticosteroids: Study to Assess the Efficacy and Long-term Safety of dupilumab in Adult Patients With Moderate-to-Severe Atopic Dermatitis . This is a randomized, double-blind, placebo-controlled study to demonstrate the efficacy and long-term safety of dupilumab in adult patients with moderate-to-severe AD. Interim results are expected during the second quarter of 2016.

  - An open-label extension study of dupilumab in patients with AD. This is a multicenter study to assess the long-term safety and efficacy of repeat doses of

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dupilumab in adults with moderate-to-severe AD who have previously participated in controlled studies of dupilumab.
The BLA submission in AD for adult treatment is planned for the third quarter of 2016.

- **Asthma,** the Phase III program consists of:
  - A randomized, double-blind, placebo-controlled, dose-ranging study to evaluate dupilumab in patients with moderate to severe uncontrolled asthma completed in May 2015.
  - A 52-week randomized, double-blind, placebo-controlled, parallel group study to evaluate the efficacy and safety of dupilumab in patients with persistent asthma.
  - An open-label extension study of dupilumab in patients with asthma who have previously participated in dupilumab asthma clinical studies.
- **Nasal Polyposis:** an evaluation of dupilumab in patients with bilateral nasal polyposis and chronic symptoms of sinusitis. A randomized, double-blind, Phase II, placebo controlled, two-arm study has been completed and further activities are ongoing in preparation for the next stage of development.
- **Eosinophilic Esophagitis:** Phase II study of dupilumab in adult patients with active eosinophilic esophagitis (EoE). A randomized, double-blind, parallel, placebo-controlled study to assess the efficacy, safety and tolerability of dupilumab in this population, has been initiated.

Main products in Phase II

- **SAR156597** (humanized bi-specific monoclonal antibody targeting the cytokines IL-4 and IL-13) is currently in Phase IIA for the treatment of Idiopathic Pulmonary Fibrosis.

Main products in early stage

- **SAR113244** is an anti-CXCR5, a first-in-class humanized monoclonal antibody in Phase I for the treatment of Systemic Lupus Erythematosus (SLE). A Phase IB multiple ascending dose study in SLE patients is ongoing.

Projects discontinued in 2015

- **SAR391786** (REGN1033) Sanofi decided to opt out of the anti-GDF8 monoclonal antibody developed in collaboration with Regeneron and evaluated in Sarcopenia.

e) Multiple Sclerosis

- **GZ402668 (GLD52)**, an IgG1 monoclonal antibody binding to CD52 a cell surface antigen present at high level on T ab B lymphocytes, for the treatment of relapsing forms of Multiple Sclerosis (RMS) is in Phase I, the study end being expected for the first quarter of 2016.

Projects discontinued in 2015

- **Vatelizumab (SAR339658)**, a humanized monoclonal antibody directed at the VLA-2 (Very Late Antigen 2) integrin receptor, in-licensed from Glenmark Pharmaceuticals was developed in the treatment of relapsing-remitting multiple sclerosis (RRMS). A prospectively planned interim analysis (IA) completed in October 2015 did not meet the pre-defined primary efficacy endpoint and treatment has been discontinued. No safety concerns prompted this decision. The compound has been discontinued.

f) Age Related Degenerative Diseases

- **SAR228810,** an anti-protofibrillar Abeta mAb against Alzheimer s, completed Phase I in mild to moderate Alzheimer s patients. Phase I data support moving to next development step.

g) Infectious Diseases

- **Ferroquine** (OZ439) is a first in class combination for malaria (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 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 is expected to start in the second quarter of 2016 in Asia.

h) Rare Diseases (Genzyme)

Main products in Phase III

Alnylam collaboration: In October 2012, Genzyme entered into an exclusive license agreement with Alnylam, covering 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.

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- **patisiran (SAR438027)** (mRNA inhibition AlnylamALN-TTR02). The Phase III clinical trial is ongoing in the treatment of Familial Amyloid Polyneuropathy. The Japanese Phase I study has been completed and PMDA (Japanese Health Authority) has granted permission for Japan s inclusion in the APOLLO trial.

- **revusiran (SAR438714)** (mRNA inhibition AlnylamALN- TTRsc). Revusiran represents a second generation formulation for Alnylam s RNAi platform. Unlike the lipid nanoparticle formulation utilized by patisiran, the revusiran formulation utilizes a GalNAc (N-acetylgalactosamine) conjugation. This allows for the subcutaneous delivery of the product, as opposed to the intravenous administration of patisiran. Revusiran has shown equivalent knockdown of TTR in studies in both normal healthy volunteers as well as in patients. The Phase III program in the treatment of Familial Amyloidotic Cardiomyopathy is ongoing.

Main products in Phase II

- **GZ402665 (rhASM) olipudase alfa** is an enzyme replacement therapy targeting the treatment of non-neurological manifestations of acid sphingomyelinase deficiency (ASMD), Niemann-Pick B disease. A Phase I/II study in the pediatric population has dosed four patients to-date. These four patients complete the enrollment of the adolescent cohort (ages 12 years old to less than 18 years old). The child cohort (ages six years old to less than 12 years old) will begin enrollment in the second quarter of 2016. The Phase II/III adult trial started at the end of 2015.

- **GZ402671 (CGS inhibitor)** in Phase II for the treatment of Fabry disease. The Phase II trial in Gaucher disease type 3 is planned for the third quarter of 2016.

Main products in early stage

- **GZ402666 (Neo GAA)** is a second generation enzyme replacement therapy targeting the treatment of Pompe disease. The program is currently in Phase I with a start planned in the second quarter of 2016 for the pivotal trial in the Late Onset population.

- **SAR339375** is an anti-miR targeting microRNA-21 for the treatment of Alport syndrome, a life-threatening kidney disease with no approved therapy. The program is currently in Phase I. This program is partnered and led by Regulus Therapeutics.
- **GZ389988** (TrKA) is a small molecule which inhibits binding of nerve growth factor (NGF) to its primary TrkA receptor, and is being developed as a treatment for pain resulting from osteoarthritis. The molecule is currently in Phase I with enrollment completed in October 2015.

- **fitusiran (SAR439774** AlnylamALN-AT3), siRNA targeting anti-thrombin and derived from our license agreement with Alnylam is in Phase I in the treatment of hemophilia A/B. One pivotal study is expected to start in the third quarter of 2016.

i) Ophthalmology

Main products in Phase II

- A proof-of-concept study is being conducted for **SAR153191** **sarilumab** (Phase II) in an ophthalmology indication: this anti-IL-6-receptor monoclonal antibody could be a safe and efficient option for treating non-infectious uveitis affecting the posterior segment of the eye at risk of vision loss. Early analysis results are under assessment.

Main products in early stage

- **UshStat® (SAR421869)**: a gene therapy product which uses a lentivector gene delivery technology to introduce a functional MYO7A gene to 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 on-going.

- **SAR422459**: a gene therapy product which uses a lentivector gene delivery technology to introduce a functional ABCR gene to 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 I/IIA.

- **SAR366234** administered as eye drops, is via its active metabolite, an agonist of EP2 receptor of the prostaglandin E2 which activation induces an increase of the aqueous humor outflow and the reduction of intra ocular pressure (IOP). Elevated IOP is a well-established risk factor for glaucoma characterized by progressive optic nerve degeneration resulting in vision loss. The product is currently assessed in Phase I.

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B.5.3 Vaccines

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

Portfolio

The Sanofi Pasteur R&D portfolio includes 12 vaccines currently in advanced development as shown in the table below. The portfolio is well balanced, with five vaccine products for novel targets and seven vaccines which are enhancements of existing vaccine products.

Phase I	Phase II	Phase III	Submitted
Streptococcus pneumonia* Pneumonia and meningitis vaccine	**Men Quad TT** 2nd generation meningococcal ACYW conjugate vaccine	**C. difficile toxoid vaccine*** Toxoid vaccine against *clostridium difficile*	**Dengvaxia*** Mild-to-severe dengue fever vaccine
Herpes Simplex virus Type 2* HSV-2 vaccine	**Rabies VRVg** Purified vero rabies vaccine	**Vaxigrip® QIV IM** Quadrivalent inactivated influenza vaccine (6-35 months) (E.U.)	**PR5i,** DTP-HepB-Polio-Hib[(1)] Pediatric hexavalent vaccine (U.S.)
	Fluzone® QIV HD High-dose quadrivalent inactivated influenza vaccine	**Japan Penta** DTP- Polio-Hib	**Vaxigrip® QIV IM** Quadrivalent inactivated influenza vaccine (+3 years) (E.U.)
	Tuberculosis* Recombinant subunit vaccine	Pediatric pentavalent vaccine	

(1) *D=Diphtheria, T=Tetanus, P=Pertussis, Hib=Haemophilus influenzae b, HepB=Hepatitis B.*

* *New targets*

Project highlights

Influenza Vaccine

To sustain our global leadership in the development of influenza vaccines, our R&D efforts are focused on innovative approaches. Following up on the development of quadrivalent flu vaccines (see B.3. Vaccine Products), Sanofi Pasteur will continue to assess new formulations and alternative delivery systems, as well as universal vaccine approaches, in order to address specific patient needs and to continue to offer

innovative solutions in the future.

Meningitis Vaccine

Neisseria meningitidis bacteria are a leading cause of meningococcal disease in the U.S., Europe, the African meningitis belt and other endemic regions such as Brazil and Australia.

Sanofi Pasteur is developing a second-generation quadrivalent conjugated meningococcal vaccine. This vaccine uses an alternative conjugation technology. Phase II clinical trial results have demonstrated its safety and immunogenicity. Sanofi Pasteur is continuing the development of this vaccine to suit a wider range of age groups and a flexible range of vaccination schedules.

Rabies Vaccine

A new generation serum-free Vero cell human rabies vaccine (VerorabVax®) is under development to allow both of our currently available human rabies vaccines, Verorab and Imovax Ravies, to be replaced by a single vaccine. The results of a Phase II clinical trial, demonstrated the non-inferiority of VRVg versus Verorab® in pre-exposure prophylaxis. VRVg was approved in France as a line extension of Verorab® in 2011. More recent Phase II data, conducted to license VerorabVax® in countries where Verorab was not previously licensed, has provided data indicating a requirement to adjust the formulation.

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Pediatric Vaccine

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, acP (DTaP) from KDSV, and inactivated polio IPV & 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., a hexavalent combination vaccine (6-in-1 vaccine PR5i) designed to protect against diphtheria, tetanus, pertussis, polio, Hib and hepatitis B. An application for licensure of this vaccine was submitted to the European Medicines Agency in Europe by Sanofi Pasteur MSD in January 2015. On December 17, 2015 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending the marketing authorization for the product which will be commercialized as Vaxelis in the E.U.. On February 19, 2016, Sanofi Pasteur MSD was granted the marketing authorization for Vaxelis. Likewise, a Biologics License Application was submitted to the U.S. FDA in August 2014, and on November 2, 2015 the FDA issued a Complete Response Letter (CRL) for PR5I, which will be commercialized through a partnership of Merck & Co., Inc. and Sanofi Pasteur. Both Sanofi Pasteur and Merck & Co., Inc. are currently reviewing the CRL and plan to further communicate with the FDA. PR5I is expected to be the first hexavalent vaccine in the U.S. market.

New Vaccine Targets

C.diff Toxoid *Clostridium difficile* is a major public-health concern in North America and Europe. In hospitals, it is the leading cause of infectious diarrhea in adults, particularly the elderly. The epidemiology of *Clostridium difficile* associated disease has been increasing at a worrying rate since 2003, driven primarily by the emergence of a treatment-resistant, highly virulent strain: CD027. There is currently no vaccine available and our C.diff vaccine is the only candidate in Phase III. C.diff is a toxoid-based vaccine. Sanofi Pasteur received a positive response from the FDA Center for Biologics Evaluation & Research (CBER) on the Fast Track Development Program submission in 2010. A multinational, large scale, Phase III study, named Cdiffense , began in August 2013. This trial is focused on evaluating the vaccine s efficacy in preventing the first episode of *Clostridium difficile* infection in at-risk individuals, including adults with imminent hospitalization or current or impending residence in a long-term care or rehabilitation facility. Phase II results were communicated in May 2014 showing

the C.diff vaccine candidate to be generally well tolerated and immunogenic in the target population.

Tuberculosis Statens Serum Institute (SSI) of Denmark has granted Sanofi Pasteur a license to its technology with regard to 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 the 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 was initiated in July, 2013, in South Africa in infants. A Phase II proof-of-concept study was initiated in young adolescents in South Africa in March 2014.

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. The vaccine candidate is a live, attenuated virus and is being assessed as a therapeutic and, possibly, prophylactic vaccine to reduce recurrence and transmission. A NIH-sponsored Phase I trial was initiated in October 2013 to evaluate the vaccine. In October 2014, Sanofi Pasteur signed a contract with Immune Design Corp. to collaborate on the development of a Herpes simplex virus vaccine.

Pneumococcal Vaccine *Streptococcus pneumoniae* bacteria are the leading etiological agent causing severe infections (over three million deaths per year worldwide, including one million children). Diseases caused by Streptococcus pneumoniae (pneumococcus), such as pneumonia, meningitis and febrile bacteraemia, constitute a major, global public-health problem; additionally otitis media, sinusitis and bronchitis are more

common but less serious manifestations of infection. The WHO recommends the use of pneumococcal conjugate vaccines (PCV) in all countries. The anti-microbial resistance in *Streptococcus pneumoniae* has complicated the treatment of pneumococcal disease and further emphasized the need for vaccination to prevent large-scale morbidity and mortality.

Sanofi Pasteur has entered into a long-term strategic collaboration with SK Chemical Co. to co-develop an innovative PCV. The collaboration agreement includes research & development, production, and commercialization of a preventative pneumococcal disease vaccine.

Rotavirus The results of the Phase III evaluating the vaccine against rotavirus lead us not to consider submitting an application for license.

B.5.4. R&D expenditures for late stage development

Aggregate research and development expenditures (including Animal Health) amounted to 5,259 million in 2015, comprising 4,530 million in the Pharmaceuticals

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segment, 552 million in Human Vaccines and 177 million in Animal Health. Research and development expenditures were the equivalent of about 14.2% of net sales in 2015, compared to about 14.3% in 2014 and 14.5% in 2013. 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. Preclinical research in the pharmaceutical segment amounted to 1,072 million in 2015 compared to 986 million in 2014 and 951 million in 2013. Of the remaining 3,458 million relating to clinical development in the Pharmaceuticals segment (3,188 million in 2014 and 3,136 million in 2013), the largest portion was generated by Phase III or post-marketing studies, reflecting the cost of monitoring large scale clinical trials.

For each of our current late stage (Phase III in 2015) compounds in the Pharmaceuticals segment, we set out below the date at which this compound entered into Phase III development, information concerning any compound patent in the principal markets for innovative pharmaceutical products (the U.S., the E.U. and Japan) as well as comments regarding significant future milestones that are reasonably determinable at this date. Because the timing of such milestones typically depends on a number of factors outside of our control (such as the time to validate study protocols and recruit subjects, the speed with which endpoints are realized, as well as the substantial time taken by regulatory review) it is frequently not possible to provide such estimates, and any such estimates as are given should be understood to be indicative only. See also Item 3. Key Information D. Risk Factors Risks Relating to Our Business .

Phase III	Entry into Phase III[1]	Compound Patent Term[2]			Comments
	(month/year)	U.S.	E.U.	Japan	
Lyxumia®	May 2008[5]	2020	2020	2020	Dossier approved in Europe in February 2013; dossier submitted and withdrawn in the U.S. in December 2013. Re-submitted with complementary Phase III study in July 2015, and accepted for review in September 2015
(lixisenatide)[3][4]					
(AVE0010)					Expected approval in the third quarter of 2016.
LixiLan	January 2014	2020	2020	2020	Phase III program ongoing.
					Submission in Type 2 diabetes in U.S. done in December 2015, and accepted for review in February 2016
					Submission in Type 2 diabetes in E.U. expected in the first quarter of 2016.
SAR342434	November 2014	NA	NA	NA	Phase III program ongoing in Type 1 & 2 diabetes.
Insulin Lispro					Phase III results expected in the second quarter of 2016.
sotagliflozin	November 2015	2028	2027	2027	Phase III program ongoing in Type 1 diabetes.
(SAR439954)					
sarilumab	August 2011	2028	2027	2027	Phase III program in the treatment of Rheumatoid Arthritis ongoing.
(SAR153191)					Submitted in U.S. in October 2015, and accepted for review in January 2016
					Submission expected in the third quarter of 2016 for E.U.

dupilumab (SAR231893)	October 2014	2027	2029	2029	Phase III program in the treatment of Atopic Dermatitis & Asthma ongoing.
patisiran (SAR438027)	December 2013	2029	2029	2029	Submission in AD expected in the third quarter of 2016 for U.S. Phase III program ongoing in Familial Amyloid Polyneuropathy.
revusiran (SAR438714)	December 2014	2032	2032	2032	Phase III program ongoing in Familial Amyloid Cardiomyopathy.

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

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

(3) Application pending in some countries.

(4) See also table in section B.7. Patents, Intellectual Property and Other Rights for more information.

(5) Development of lixisenatide as stand alone entity. A program evaluating the benefit of a combination of lixisenatide / Lantus® is in development.

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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 U.S., the E.U., 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 in many cases 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 E.U. 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 2015, 2014 and 2013 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 is based on sales data from IMS Health MIDAS, retail and hospital at MAT September 2015, in constant euros (unless otherwise indicated). For more information on market shares and ranking, see Presentation of Financial and Other Information at the beginning of this document.

B.6.1. Marketing and Distribution

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

- Emerging Markets (see definition in Item 4. Information on the Company Introduction above) represent 32.4% of our 2015 aggregate net sales (including Animal Health). Sanofi is the leading healthcare company in emerging markets. In 2015, our sales in emerging markets grew by 7.8% at constant exchange rates. Latin America grew by 4% in 2015. Full-year aggregate net sales, as defined in Item 5, in China, Russia and Brazil were up 19.5%, down 2.8% and down 6.2% respectively. In Africa and the Middle East, aggregate net sales were up 6.8% million sustained by the performance in Middle East;

- The U.S. represents 36.2% of our aggregate net sales; we rank twelfth with a market share of 3.7% (3.5% in 2014). Sales in the U.S. were down 1% at constant exchange rates in 2015;

- Western Europe represents 21.7% of our aggregate net sales; we are the leading pharmaceutical company in France where our market share is 7.9% (8.3% in 2014), and we rank third in Germany with a 4.5% market share. In 2015, sales in Western Europe were up 0.9% at constant exchange rates;

- Other countries represent 9.7% of our aggregate net sales; our market share in Japan is 2.9% (3.2% in 2014). Full-year 2015 aggregate net sales in Japan were down 6.6% at constant exchange rates.

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, 2015 Compared with Year Ended December 31, 2014.

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. Established prescription products also 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.

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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. As of December 31, 2015, we had a global sales force of 34,172 people.

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, respectively.

Animal Health products are sold and/or distributed by various channels depending on national legislation applicable to veterinary products. Merial takes into account characteristics specific to each country and thus markets its products to veterinarians, pharmacies or wholesalers. In the event of an epidemic, Merial delivers directly to governments.

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.

Our prescription drugs compete in all major markets against patented drugs from major pharmaceutical companies such as: Novo Nordisk, Boehringer Ingelheim and Merck in diabetes; Lilly in diabetes and oncology; Bristol-Myers Squibb in oncology; Novartis in diabetes, multiple sclerosis, and oncology; Shire in rare diseases; Pfizer in rare diseases and oncology; Biogen Idec, Teva and Merck Serono in multiple sclerosis; Bayer in multiple sclerosis and oncology; Roche and Johnson & Johnson in oncology; AstraZeneca in cardiovascular disease and oncology; Amgen in cardiovascular disease.

Sanofi is the fifth-largest player in the global CHC market and competes with multinational corporations such as Bayer, GSK-Novartis, Johnson & Johnson, Pfizer, as well as local players, especially in emerging markets.

Our generics business is the eighth largest globally by sales and competes with multinational corporations such as Teva, Sandoz (a division of Novartis), Mylan and Actavis and local players, especially in emerging markets.

In our Human Vaccines business, Sanofi is one of the top four players, competing primarily with large multinational players, Merck (outside Europe), GlaxoSmithKline, and Pfizer.

In the Animal Health field in 2015, Sanofi is in competition mainly with major international groups such as Zoetis, Merck and Elanco, Boehringer Ingelheim and Bayer; and with Virbac, Ceva and Vetoquinol, French companies with a global presence.

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, these 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. Such launch may occur notwithstanding the fact that the owner of the original product may already have 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.

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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 E.U., 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 counterfeit drugs. The WHO estimates that counterfeit products account for 10% of the market worldwide, rising to 30% in some countries. However, in markets where powerful regulatory controls are in place, counterfeit 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.

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.

In 2015, the International Council for Harmonization (ICH), formerly the International Conference on Harmonization

(ICH), launched its reforms building on a 25-year track record of successful delivery of harmonized guidelines for the development and regulation of the pharmaceutical industry.

The aim is to reinforce the foundations of ICH, expand harmonization globally beyond the current ICH Members (the three founding members: E.U., Japan, U.S., plus Canada and Switzerland as observers) and will facilitate the involvement of additional regulators and industry associations around the world. Countries and regional harmonization initiatives can now automatically join ICH either as observers or via ICH s global cooperation group.

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 and regular interactions in the form of clusters (i.e. pediatrics, oncology, advanced therapy medicinal products, vaccines, pharmacogenomics, orphan drugs, biosimilars, and blood products) between the U.S. and the E.U.

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 Trans-Pacific Partnership, under discussion since 2008, was concluded on October 5, 2015. This free trade agreement, which was negotiated between Australia, New Zealand, the U.S., Peru, Chile, Mexico, Canada, Singapore, Brunei, Malaysia, Vietnam and Japan, affects 40% of the global economy. Provisions which affect the BioPharma industry include patent exclusivity term for biologics.

The Transatlantic Trade and Investment Partnership (TTIP) is still being negotiated. The proposed free trade agreement, between the E.U. and the U.S., aims to promote multilateral economic growth. Specifically with respect to the biopharma industry, the agreement aims to enable regulators to work together more closely to ensure medicines are safe and effective.

The requirement of many countries, including Japan and several Member States of the E.U., to negotiate selling prices or reimbursement rates for pharmaceutical products with government regulators significantly extends the time for market entry beyond the initial marketing approval. While marketing approvals for new pharmaceutical products in the E.U. have been largely centralized with the EMA, pricing and reimbursement remain a matter of national competence.

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In the E.U., there are three main procedures by which to apply 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 E.U. marketing authorization. Such a marketing authorization is valid throughout the E.U. and the drug may be marketed within all E.U. Member States.

- If a company is seeking a national marketing authorization in more than one Member State, the mutual recognition or decentralized procedure is available to facilitate the granting of harmonized national authorizations across Member States. Both the decentralized and the mutual recognition 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 E.U. 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 E.U. 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 E.U. 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.

Another relevant aspect in the E.U. regulatory framework is the sunset clause : a provision leading to the cessation of the validity of any marketing authorization if it is not followed by marketing within three years or, if marketing is interrupted for a period of three consecutive years.

In 2015, the EMA recommended 93 medicines for marketing authorization (versus 82 in 2014), including 39 new active substances.

Among the 93 medicines recommended, 18 (19.3%) had an orphan designation (versus 17 in 2014 and 11 in 2013), providing medicines for patients with rare diseases. Five medicines were evaluated under accelerated assessment in 2015 (versus 7 in 2014 and only one in 2013), this mechanism is reserved for medicines that have the potential to address unmet medical needs. Three medicines received a recommendation for a conditional marketing authorization, one of the EMA s early access routes to patients, intended for medicines that address an unmet medical need and that target seriously debilitating or life-threatening diseases, 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. The E.U. pharmaceutical legislation for medicinal products describes the respective obligations of the marketing authorization holder 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 E.U. Member States in which the marketing authorizations are held. In accordance with applicable legislation, each E.U. 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 marketing authorization holders (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.

In July 2012, pharmacovigilance legislation came into force, with significant impacts on the regulatory environment. Changes include the creation of a new scientific advisory committee, the Pharmacovigilance Risk Assessment Committee (PRAC) at EMA level, with a key role in the assessment of all aspects of the risk management of 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

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procedures. 120 Sanofi products underwent PRAC review through signal and referral procedures from July 2012 to December 2015, generating 73 labeling variations (17 new variations in 2015) 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 E.U. market.

The pharmacovigilance legislation was amended in 2012. The amendments aim to further strengthen the protection of patient health by promoting prompt and appropriate regulatory action on European medicines. In particular, the amendments include major changes to notification requirements: MAHs of human medicines have to notify E.U. regulators of any action to withdraw a product from the market, together with the reason for this action.

The 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 will be conditional on such studies being performed. Consequently, the pharmaceutical industry will have 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.

The pharmacovigilance legislation also introduced a periodic safety report to be prepared by pharmaceutical companies (Periodic Safety Update Report PSUR). This is not limited to safety data, but instead presents a critical analysis of the risk-benefit balance of the medicinal product, taking into account new or emerging information in the context of cumulative information on risks and benefits.

There is a legal requirement for an enhanced adverse reaction collection and management system (EudraVigilance) that delivers better health protection through simplified reporting, better quality data and better searching, analysis and tracking functionalities. It is associated with a legal requirement for MAHs to monitor the EudraVigilance data to the extent to which they have access. Following an EudraVigilance functionalities audit scheduled in 2016, the move to EMA centralized reporting is planned for mid 2017.

The database of medicinal products aims to deliver structured and quality assured information on medicinal products authorized in the E.U. that can support E.U. terminologies of products, substances, and organizations

used to power pharmacovigilance and regulatory systems. Since January 1, 2015, Marketing Authorization Holders (MAH) need to notify the EMA of any new marketing authorizations within 15 calendar days from the date of authorization and notify the EMA of any variation to the terms of the Marketing Authorization as soon as possible and no later than 30 calendar days from the date of which the changes have been 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 into EudraVigilance database.

There is a legal requirement for EMA to set up a repository for Periodic Safety Update Reports (PSURs) and their assessment reports, to allow centralized PSUR reporting and to enhance access to data and information, thereby supporting benefit risk assessments of medicines. In June 2015, the PSUR Repository has achieved its full functionality and its use in the E.U. will become mandatory on June 13, 2016.

In the U.S., 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 U.S. To commercialize a product in the U.S., an NDA under the Food, Drug and Cosmetic (FD&C) Act or Biological License Application (BLA) under the Public Health Service (PHS) Act is submitted to the FDA with data 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 the submission of a supplemental NDA (sNDA) for a drug or supplemental BLA (sBLA) for a biological product.

The FD&C Act provides another abbreviated option for NDA approved products, called the 505(b)(2) pathway. This pre-market application may rely on the FDA finding that the reference product has been found to be safe and effective by the FDA based upon the innovator s preclinical and clinical data.

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

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length of time and cost required for development of generics can be considerably less than for the originator s drug. The ANDA pathway in the U.S. can only be used for generics of drugs approved under the FD&C Act.

The FDA Center for Drug Evaluation and Research approved 45 novel drugs in 2015 (versus 41 in 2014, 27 in 2013 and 39 in 2012). A breakdown of designations and pathways to expedite drug development and review includes Fast Track (14=31%), Breakthrough Therapy (10=22%), Accelerated Approval (6=13%), and Priority Review (24=53%). Of the 2015 novel drugs, 27 (60%) were designated in one or more expedited categories.

CDER identified 16 of the 45 novel drugs approved in 2015 (36%) as First-in-Class, one indicator of the innovative nature of a drug. Approximately 47% of the novel drugs approved in 2015 (21 of 45) were approved to treat rare or orphan diseases that affect 200,000 or fewer Americans.

Congress encouraged development of new human drugs and biological products for prevention and treatment of certain tropical diseases (FDAAA 2007) and rare pediatric diseases (FDASIA 2012) by offering additional incentives for obtaining FDA approval of such products. To date three tropical disease priority review vouchers (PRVs) and six pediatric rare disease PRVs have been granted. Regeneron purchased in 2014 a pediatric rare disease PRV from BioMarin which was redeemed for the priority review of their PCSK9 product Praluent®, thus cutting short the review time by 4 months. Sanofi purchased a second pediatric rare disease PRV from Retrophin in the summer of 2015, which was redeemed in December 2015 for the priority review of their fixed combination product Lixisenatide/insulin glargine Lixilan. On December 18, 2015, Congress extended the rare pediatric disease priority review voucher program to September 30, 2016. The extension was granted as part of the Congressional budget deal. Bills in both the House and Senate have been introduced which could extend the program beyond the September 2016 date.

In Japan, 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 require data to determine the appropriateness of the dosages for Japanese patients. These additional procedures have created a significant delay in the registration of some innovative products in Japan compared to the E.U. and the U.S.. In order to solve this drug-lag problem, the Japanese Ministry of Health, Labor and Welfare (J-MHLW) introduced the new National Health Insurance (NHI) pricing system on a trial basis in April 2010. 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. The pharmaceutical companies concerned are required to file literature-based submission within six months or to submit a clinical trial notification for registration within one year after the official development request of unapproved drugs or the off label indications. 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 be paid back to the government.

In order to promote the development of innovative drugs in Japan for putting them into early practical use in Japan ahead of the world, SAKIGAKE (which is a Japanese term meaning forerunner) review designation program was implemented from April 2015 on a trial basis. 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 6 months.

Based on the reform of the NHI price system finalized in 2013, 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, namely (a) pediatric/orphan drugs, (b) drugs to treat diseases which cannot be adequately controlled with existing drugs. The Premium policy will continue its trial stage.

The PMDA plans to achieve its targets for a total review time of 12 months for products with standard review status and 9 months for products with priority review status for 80% (currently 50%) of all applications by the end of 2018.

The PMDA also plans to eliminate the review lag between the application filing and approval of drugs and medical devices compared 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

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Medicinal Products (ATMPs) in the E.U. This law enables 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 will begin implementing an RMP, similar to the E.U. Pharmacogivilance system.

For generic products, the data necessary for filing are similar to E.U. and U.S. requirements. Pharmaceutical companies only need to submit quality data, and data demonstrating bioequivalence to the originator product, unless the drug is administered intravenously.

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 (e.g., 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 and therefore 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 E.U., a 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 LMWH and of insulins. Starting in 2011 and continuing in 2015, the CHMP initiated a revision of the majority of the existing biosimilar guidelines (general overarching guidelines, quality, non-clinical and clinical product specific guidelines).

End of 2014, the CHMP published its revised overarching guideline on biosimilars. The main change introduced by this new guidance is the possibility for biosimilar developers to use a comparator authorized outside the EEA in certain clinical studies and in vivo non-clinical studies. This concept is expected to facilitate the global development of biosimilars and to avoid unnecessary repetition of clinical trials. This revised guideline came into force as of April 30, 2015.

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, the CHMP has expressed that in specific circumstances, a confirmatory clinical trial may not be necessary. This would require that 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 position is that it is at present unlikely that these products may be characterized at the molecular level, and that each vaccine product must be evaluated on a case-by-case basis.

In the U.S., the Patient Protection and Affordable Care Act, signed into law by President Obama on March 23, 2010, amends 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.

To date, the FDA has published for consultation seven draft guidance documents concerned with biosimilar development and approval. Four of those seven guidance documents have been finalized. Guidance on labeling and interchangeability has not yet been published.

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 and clinical 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 Generics

In the E.U. the number of positive opinions by centralized procedure for generics has increased from last year (16 in 2013, eight in 2014, 21 in 2015). Most of the generics applications for chemical entities use mutual recognition and decentralized procedures, with about 8% of the procedures relating to nonprescription products. Pricing systems for generics remain at national level in the E.U.

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In the U.S., to help the FDA ensure that participants in the U.S. generic drug system comply with U.S. 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. ANDA review performance goals for 2015 state that FDA will review and act on 60 percent of original ANDA submissions within 15 months from the date of submission.

In December 2013 the FDA and EMA announced the launch of a joint initiative to share information on inspections of bioequivalence studies submitted in support of generic drug approvals. This collaborative effort provides a mechanism to conduct joint facility inspections for generic drug applications submitted to both agencies. Taking part in this initiative are the EMA and the E.U. Member States France, Germany, Italy, the Netherlands and the U.K..

In Japan, the NHI price system was reformed in 2014, including a new special price reduction rule for long-listed drugs. The new rule will reduce 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%. The rule was introduced in April 2014.

Under the new price system, NHI prices of first generics (currently set at 70%) will be set at 60% of the price of the originator product. A 50% rule will be applied to oral first generics once more than ten products with the same ingredients have obtained listing.

In addition, a max 20% Sakigake premium will be 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.6.3.4 Medical Devices

In the E.U., there is no pre-market authorization by a regulatory authority. Instead there is a Conformity Assessment Procedure (for medium and high risk devices), involving an independent third party Notified Body (NB). Once certified, medical devices bear the CE-mark allowing them to circulate freely in the EU/EFTA (European Free Trade Association) countries and Turkey. Medical Devices are currently regulated by three core Directives.

In September, 2012 the European Commission adopted proposals to introduce two Regulations that will overhaul and tighten the current E.U. rules governing medical devices (EU Medical Device Directive 93/42/EC amended in 2007, 2007/47/EC).

The European Parliament endorsed in 2013 essential measures that will strengthen patient safety and which are supported by the industry, such as improving the competence and control of Notified Bodies, introducing unannounced site visits by Notified Bodies, increasing the transparency and traceability of medical devices, introducing a stricter post-market follow-up, and improved stakeholder engagement. A scrutiny procedure would be used at least for high-risk Class III devices (novel technologies or specific public health threats).

The revised framework also formally introduces the concept of companion diagnostic, which is expected to deliver a more accurate definition of the patient population that will benefit from a given product. Sanofi has several companion diagnostics in development.

The E.U. Trilogue Negotiations on Medical Device (MD) and In Vitro Diagnostic (IVD) Regulations started in 2015 but will not be fully in force until 2019.

In the U.S., the FDA Center for Devices and Radiological Health (CDRH) is responsible for regulating firms who manufacture, repackage, relabel and/or import medical devices sold in the U.S. In addition, CDRH 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. 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.

The basic regulatory requirements that manufacturers of medical devices distributed in the U.S. 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.6.3.5 OTC drugs

In the E.U., EllaOne, an emergency contraceptive, become the fourth European Centralized Rx-to-OTC switch in January, 2015. GlaxoSmithKline Consumer Healthcare s Alli (orlistat) weight-loss medicine was the first in January, 2009, followed by Nycomed s 20mg pantoprazole tablets in June, 2009, and AstraZeneca s Nexium Control (esomeprazole) in 2013.

In the U.S., FDA approved one prescription-to-OTC switch in 2015 for Rhinocort Allergy Spray (budesonide).

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In Japan, the J-MHLW drug safety committee decided 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 their three-year safety evaluation period (the safety evaluation period is currently four years). During the three-year evaluation period, drugs that moved from prescription to OTC are categorized as products that require pharmacist consultations when purchasing.

Under the new plan, the J-MHLW requires marketing authorization holders to submit interim reports upon the completion of their postmarketing surveillance (PMS). Based on these interim reports and other reports on adverse events, the J-MHLW will evaluate serious adverse events two years after the launch of OTC drugs or later.

In 2016, the J-MHLW will set up a new panel that would pick prescription products candidates that should be switched to nonprescription status, with its first meeting scheduled as early as this summer. Under its plan, the J-MHLW would constantly accept requests for prescription-to-OTC changes from medical societies and other organizations as well as consumers, and then these requests would be publicly reviewed by the new panel. Based on its deliberations, the panel would refer the shortlisted requests to the Pharmaceutical Affairs and Food Sanitation Council s (PAFSC) committee on nonprescription drugs, which effectively makes decisions on marketing approval for OTCs. The ministry is also planning to seek public comments.

B.6.3.6 Transparency and public access to documents

- **Transparency regarding clinical trials**

Over recent years the pharmaceutical industry has been subject to growing pressure for greater transparency about clinical trials (conduct and results). Regulatory authorities are also being pushed 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 and results of clinical studies performed 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.

E.U. 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 E.U. 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 extending 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 a E.U.-wide marketing authorization is complete.

At the start of October 2014, the EMA adopted the Policy 0070 for publication of clinical trials 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 and article 58 applications (medicines that are intended exclusively for markets outside the E.U.) submitted after that date.

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

There is a two-step approach for the implementation of the policy:

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

- In a 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 the EMA Policy 70, a Sanofi internal project has been launched to define, develop, implement and control a sustainable process, 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 the U.S., 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.

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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 were 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 U.S. federal regulations.

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 module 1&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 E.U., there is no harmonized approach regarding transparency for Health Care Professionals (HCP). There is no common harmonized approach. 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 (Pharma Code) in some countries (such as the U.K., Denmark, France, or Portugal).

The European Federation of Pharmaceutical Industries Association (EFPIA) released in mid-2013 a new Code on Disclosure of Transfers of Value from Pharmaceutical Companies to HCPs and Healthcare Organizations (HCOs), the EFPIA HCP/HCO Disclosure Code . EFPIA members were required to comply with this new code and transpose it into their national codes in full by December 13, 2013.

This new 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 U.S., the Physician Payments Sunshine Act, or Sunshine Act , was passed as part of the Patient Protection and Affordable Care Act in 2010. The law is designed to bring transparency to financial relationships between physicians, teaching hospitals, and the pharmaceutical industry. Manufacturers and group purchasing organizations must report all payments or transfers of value including payments for research, 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 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 to 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: 1) R&D, 2) academic research support, 3) manuscript/writing fees, 4) information provisioning, and 5) other expenses.

B.6.3.7 Other new legislation proposed or pending implementation

In the U.S., the 21st Century Cares Act (HR 6) Help and Hope for Patients through Biomedical Innovation passed the House by a vote of 344-77 on July 10, 2015. A companion Senate bill has not yet been introduced.

- **Clinical trials regulation in E.U.**

The new Clinical Trials Regulation ((EU) No 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 E.U. 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 will streamline the rules on clinical trials across Europe, facilitating cross-border cooperation to enable larger, more reliable trials, as well as trials on 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 trials regulation was the impact on the competitiveness of the European life sciences industry caused by changes to the conditions of the clinical trial approval process. The new legislation was drafted as a more stringent form of regulation instead of a directive in order to reach better harmonization between countries, without interfering with Member States competences in terms of ethical aspects.

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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.

- As regards transparency requirements for clinical trial data submitted through a single E.U. 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).

- Selection of reference Member State by the sponsor was maintained.

During the three-year transition period, both sets of rules will apply in parallel.

- **Adaptive pathways (AP) and Priority medicines (PRIME) scheme**

The adaptive pathways approach is part of the EMA efforts to improve timely access for patients to new medicines. Adaptive pathway is a scientific concept for medicine development and data generation which allows for early and progressive patient access to a medicine. The approach makes use of the existing E.U. regulatory framework for medicines.

EMA AP Pilot project is a new approach to licensing medicines in the form of a soft regulatory pathway. Starting in March 2014, this pilot project is to be tested over a limited period of time to collect objective elements for potential new legislation. It is a prospectively planned process, starting with earlier authorization of a medicine in a restricted, well characterized patient population, based on limited clinical development. This will be followed by iterative phases of evidence gathering and adaptations of the marketing authorization to expand access to the medicine to broader patient populations.

AP builds on existing legislative/regulatory tools (scientific advice (SA), parallel SA with HTA bodies, centralized compassionate use, conditional approval, patients registries and enhanced pharmacovigilance activities).

Another initiative launched in 2015 is a new scheme for PRIME, to optimize the development and facilitate the accelerated assessment of new priority medicines of major public health interest to benefit patients as early as possible. The scheme is based on enhanced interaction and early dialogue with medicine developers. EMA expects to launch PRIME in the first quarter of 2016.

PRIME will provide enhanced scientific and regulatory support to companies developing medicines that may offer new therapeutic options to patients who currently have no treatment options, or a major therapeutic advantage over existing treatments.

PRIME reinforces early dialogue and builds on regulatory processes already in place within the E.U. legal framework, including scientific advice to optimize the generation of robust data and the accelerated assessment procedure to improve timely access for patients to priority medicines.

- **Falsified medicines**

The E.U. has reformed the rules for importing active substances for medicinal products for human use into the E.U. 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 E.U. for active substances are those of the ICH Q7. 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 E.U.

Several implementing measures for the Falsified Medicines Directive were adopted: the establishment of a common E.U. logo for online pharmacies was adopted in June 2014, giving Member States until July 2015 to prepare for its application. The 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 (CEE) will have to be serialized for December 2018 or February 2019.

- **Nagoya Protocol**

The Nagoya Protocol to the Convention on Biological Diversity on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization was adopted in Nagoya at the tenth Conference of the Parties of the Convention on Biological Diversity (CBD) on October 29, 2010. The Nagoya Protocol has been ratified by 68 countries and the E.U.; the protocol applies in

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91 countries since the end of 2015. The Nagoya Protocol 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.

On April 16, 2014, the European Parliament and the Council adopted the new Regulation ((EU) No 511/2014) on compliance measures for users, based on the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (the EU Access and Benefit Sharing (ABS) Regulation). It came into force in October 2014.

In October 2015, the European Commission published the implementing Act (Regulation n°2015/1866).

The pharmaceutical industry is due to implement compliance procedures for non-human biological materials used in the discovery, development, manufacturing and packaging of medicinal products to be submitted in the E.U., starting after 2015. These will also include documentation from the originating country and acquisition date for materials that were acquired before the Regulation came into force. An internal project on implementation of the Nagoya protocol has been put in place.

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**

In the E.U., 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 will also be mandatory for all other E.U. marketing authorization procedures (i.e. MRP, DCP and national submissions).

In Japan, electronic submission of CDISC-based clinical data may be required for J-NDA from 1st October, 2016. However, a transition period (2016 October to 2020 March) is set. Accordingly, from April 1, 2020, the electronic submission will be mandatory a move that would allow the authority to efficiently store and analyze the data to improve its efficacy and safety predictions.

Under its plan, the PMDA launched a pilot program in 2014 which ran to the end of 2015, to verify its capabilities for storing, managing, and analyzing submitted electronic data with its current setup. Although the agency aims to require such electronic data filings from 2016, it will also consider transitional measures to smooth the way for the full changeover.

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.

B.6.4. Pricing & Reimbursement

Rising overall healthcare costs are leading to efforts to curb drug expenditures in most markets in which Sanofi operates. 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 utilization 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

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measures. 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 recent events and trends:

- In the U.S., mandatory health insurance began on January 1, 2014. To encourage enrollment, individual penalty fees for not enrolling were implemented in 2014 along with special enrollment periods and grace policies, and were further increased in 2015 and 2016. Enrollment in 2015 varied throughout the year but approximated a total of 9 million lives, up from about 6 million lives in 2014 (excluding Medicaid expansion). While individual penalty fees play a role in encouraging growth, they alone may not stimulate substantial future enrollment.

- In Europe, the financial crisis of recent years seems to have stabilized. However, the effects of the crisis on the pharmaceutical industry continue to be felt. The lower pricing introduced in many countries has led to governments having to block parallel trade in order to ensure patient supply. In Germany, the price freeze implemented with AMNOG and scheduled to finish at the end of 2013 has now been extended to the end of 2017. The advent of effective Hepatitis C cures has also brought about discussion of greater cooperation among Member States in procurement and price negotiation.

- The global theme of universal healthcare, with implementation underway in several regions, has led to many issues in funding. Price controls for all products and all sectors of the market have been at issue and are expected to be a subject for scrutiny in the future. Competition from national production, whether through preferential conditions for local industry, technology transfer agreements, or industrialization programs, is a prevalent theme in many emerging markets, notable examples being Russia and Brazil.

We believe that third-party payers will continue to act to curb the cost of pharmaceutical products. While the impact of these 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 on 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 these post-marketing results.

We are also actively looking at tiered pricing options where this is possible, allowing wider access to populations that would otherwise be denied this for new innovative therapies.

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 approval. 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 (a Supplementary Protection Certificate or SPC), the U.S. (a Patent Term Extension or PTE) and Japan (also a PTE).

Additionally, the product may benefit from the protection of patents obtained during development or after the product s initial marketing approval. The protection a patent provides 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 2015, an EPO patent

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application may cover the 38 European Patent Convention member states, including all 28 member states of the E.U.. 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 by country. 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, E.U. regulations were signed to create a European patent (Unitary Patent) and a Unified Patent Court. However, they 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, only nine countries including France have ratified the agreement.

The Unitary Patent will provide a unitary protection within the participating states of the E.U. (when ratified by the member states with the exception of Spain). The Unified Patent Court will be a specialized patent court with exclusive jurisdiction for litigation relating to European patents and Unitary patents. The Court will be composed of a central division (with seat in Paris and the pharmaceutical section in London) and by 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 infringement when such challenges would negatively impact our business objectives. See Item 8 A. Consolidated Financial Statements and Other Financial Information Information on Legal or Arbitration Proceedings Patents of this annual report.

The expiration or loss of a patent covering a new molecule, typically referred to as a compound patent, may result in significant competition from generic products and can result in a dramatic reduction in sales of the original branded product. See Item 3. Key Information D. Risk Factors We may lose market share to competing remedies, biosimilar or generic products . In some cases, it is possible to continue to obtain commercial benefits from product manufacturing trade secrets or from other types of patents, such as patents on processes, intermediates, structure, formulations, methods of treatment, indications or delivery systems. Certain categories of products, such as traditional vaccines and insulin, have been historically relatively less reliant on patent protection and may in many cases have no patent coverage, although it is increasingly frequent for novel vaccines and insulins to be patent protected. Patent protection is also an important factor in our animal health business, but is of comparatively lesser importance to our Consumer Health Care and generics businesses, which rely principally on trademark protection.

Regulatory Exclusivity

In some markets, including the E.U. and the U.S., 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 the 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 U.S., the FDA will not grant final marketing approval 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 U.S. regulatory and patent-related exclusivities by a pediatric extension. See Pediatric Extension , below.

Further, in the U.S., 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 much larger health care reform legislation known as the Patient Protection and Affordable Care Act (PPACA). 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.

In the E.U., 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

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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) has required developing countries to amend their intellectual property laws to provide patent protection for pharmaceutical products since January 1, 2005, although it provides a limited number of developing countries an extension to 2016. 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 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 the Group Structure and Strategy The globalization of our business exposes us to increased risks in specific areas .

Pediatric Extension

In the U.S. and the E.U., under certain conditions, it is possible to extend a product s regulatory exclusivities for an additional period of time by providing data regarding pediatric studies.

In the U.S., 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, for pediatric research there is no extension of patent protection (for patented medicinal products), however, it may result in an extension of regulatory exclusivity from eight to ten years.

Orphan Drug Exclusivity

Orphan drug exclusivity may be granted in the U.S. to drugs intended to treat rare diseases or conditions (affecting fewer than 200,000 patients in the U.S. 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. If the FDA approves the drug for the designated indication, the drug will receive orphan drug exclusivity.

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 E.U. and Japan.

Product Overview

We summarize below the intellectual property coverage in our major markets of the marketed products described above at B.2. Main Pharmaceutical Products . Concerning animal health products, Merial s intellectual property coverage is described above (see B.4. Animal Health: Merial). In the discussion of patents below, we focus on active ingredient patents (compound patents) and for the 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 on 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

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patent. Where patent terms have been extended to compensate for regulatory delay, the extended dates are presented below. U.S. patent expirations presented below reflect U.S. Patent and Trademark Office dates, and also reflect six month pediatric extensions as applicable. Where patent terms have expired we indicate such information and mention if 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

E.U.. Specific situations may vary by country, most notably with respect to older patents and to countries having only recently joined the E.U..

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

Aldurazyme® (laronidase)

U.S.
Compound: November 2019

Later filed patents: June 2020

Regulatory Exclusivity: expired

E.U.
Compound: November 2020 in some E.U. countries only

Japan
Compound: November 2020

Orphan Regulatory exclusivity: October 2016

Allegra® (fexofenadine hydrochloride)

U.S.
Compound: expired
Generics on the market
Converted to Over-the-Counter

E.U.
Compound: expired
Generics on the market

Japan
Compound: expired
Generics on the market
Converted to over-the counter

Amaryl® (glimepiride)

U.S.
Compound: expired

E.U.
Compound: expired

Japan
Compound: expired

Apidra® (insulin glulisine)

U.S.	E.U.	Japan
Compound: June 2018 Later filed patents: ranging through January 2023	Compound: September 2019 in most of the E.U. Later filed patent: March 2022 Regulatory exclusivity: expired	Compound: May 2022 Later filed patent: July 2022 Regulatory exclusivity: April 2017

Aprovel® (irbesartan)

U.S.	E.U.	Japan
Compound: expired Generics on the market	Compound: expired Generics on the market	Compound: March 2016 (with PTE) Regulatory exclusivity: April 2016

Aubagio® (teriflunomide)

U.S.	E.U.	Japan
Compound: expired Later filed patents: coverage ranging through September 2030 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

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Item 4. Information on the Company

Cerdelga® (eliglustat)

U.S. Compound: April 2022 (2026 with PTE when granted) Later filed patents: November 2030 Regulatory exclusivity: August 2019 Orphan Drug Exclusivity: August 2021	**E.U.** Compound: July 2022 (2027 with SPC) Later filed patents: November 2030 Regulatory/Orphan exclusivity: January 2025	**Japan** Compound: July 2022 (2025 with PTE) Later filed patents: November 2030 Regulatory exclusivity: March 2023

Cerezyme® (imiglucerase)

U.S. Compound: expired	**E.U.** Compound: N/A	**Japan** Compound: N/A

Depakine® (sodium valproate)

U.S. Compound: N/A[(1)]	**E.U.** Compound: N/A[(1)] Later filed patent: Depakine® Chronosphere formulation (October 2017)	**Japan** Compound: N/A[(1)] Later filed patent: Depakine® Chronosphere formulation (October 2017)

(1) No rights to compounds in the U.S., E.U. and Japan.

Fabrazyme® (agalsidase beta)

U.S. Compound: N/A Later filed patents: expired Biologics Regulatory Exclusivity: expired	**E.U.** Compound: N/A	**Japan** Compound: N/A Later filed patents: expired Orphan regulatory exclusivity: expired

Insuman® (human insulin)

U.S. Compound: N/A	**E.U.** Compound: N/A	**Japan** Compound: N/A

Jevtana® (cabazitaxel)

U.S.	E.U.	Japan
Compound: March 2021	Compound: March 2016	Compound: March 2016 (2021 with PTE when granted)
Later filed patents: coverage ranging through October 2030	Later filed patents: coverage ranging through March 2026 with SPC granted in some E.U. countries	Later filed patents: coverage ranging through October 2030
Regulatory exclusivity: expired	Regulatory exclusivity: March 2021	Regulatory exclusivity: July 2022

Lantus® (insulin glargine)

U.S.	E.U.	Japan
Compound: expired[(1)]	Compound: Expired	Compound: expired

(1) On September 28, 2015 Sanofi and Lilly announced that they had agreed to dismiss the patent infringement lawsuit in the U.S. and to discontinue similar disputes worldwide. For more information refer to Item 8 Consolidated Financial Statements and Other Financial Information Information on Legal or Arbitration Proceedings Lantus® and Lantus SoloSTAR® Patent Litigation (United States, France and Japan) .

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Lemtrada® (alemtuzumab)

U.S.	E.U.	Japan
Compound: expired Later filed patent: September 2027 (pending)	Compound: expired Later filed patent: September 2027	Compound: expired Later filed patent: September 2027 (pending)

Lovenox® (enoxaparin sodium)

U.S.	E.U.	Japan
Compound: N/A Generics on the market	Compound: expired	Compound: expired Regulatory exclusivity: expired

Lumizyme® / Myozyme® (alglucosidase alpha)

U.S.	E.U.	Japan
Compound: N/A Later filed patents: coverage ranging through February 2023[(1)] Orphan Drug Exclusivity: expired Biologics Regulatory Exclusivity: April 2018	Compound: N/A Later filed patents: July 2021 Orphan Regulatory Exclusivity: March 2016 Biologics Regulatory Exclusivity: March 2016	Compound: N/A Later filed patents: July 2021 Orphan Regulatory Exclusivity: April 2017

(1) Genzyme filed a notice of appeal to the Federal Circuit to challenge successful inter partes review (IPR). For more information refer to Item 8 Consolidated Financial Statements and other Financial Information Information on Legal and Arbitration Proceedings Genzyme Myozyme® Lumizyme Patent Litigation (United States)

Lyxumia® (lixisenatide)

U.S.	E.U.	Japan
Compound: July 2020[(1)] Patent term extension to be determined once product is approved in the U.S.	Compound: July 2020[(1)] (2025 with SPC in most countries of E.U.) Regulatory Exclusivity: February 2023	Compound: July 2020[(1)] PTE coverage to July 2024 Regulatory Exclusivity: June 2021
Later filed improvement patents: coverage ranging through November 2030 (pending)	Later filed improvement patents: coverage ranging through November 2030 (pending)	Later filed improvement patents: coverage ranging through November 2030 (pending)

(1) Lixisenatide compound patent licensed exclusively from Zealand Pharma

Mozobil® (plerixafor)

U.S.	**E.U.**	**Japan**
Compound: N/A	Compound: N/A	Compound: N/A
Later filed patents: coverage ranging through July 2023	Later filed patents: July 2022 (2024 with SPC in some E.U. countries)	Later filed patents: July 2022
Orphan Drug Exclusivity: expired	Orphan Drug Exclusivity: August 2019	

Multaq® (dronedarone hydrochloride)

U.S.	**E.U.**	**Japan**
Compound: July 2016 with PTE	Compound: expired	Compound: expired
Later filed patents: coverage ranging through December 2031	Later filed patent: formulation June 2018 (2023 with SPC in most E.U. countries)	Later filed patent: formulation June 2018
Regulatory exclusivity: expired	Regulatory exclusivity: November 2019	

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Plavix® (clopidogrel bisulfate)

U.S.	E.U.	Japan
Compound: expired Generics on the market	Compound: expired Generics on the market	Compound: expired Regulatory exclusivity: expired

Praluent® (alirocumab)

U.S.	E.U.	Japan
Compound: December 2029 Later filed patents: coverage ranging through July 2032 (pending) Biologics Regulatory Exclusivity: July 2027	Compound: December 2029 (pending) Later filed patents: coverage ranging through July 2032 (pending) Regulatory exclusivity: December 2025	Compound: December 2029 Later filed patents: coverage ranging through July 2032 (pending)

Renagel® (sevelamer hydrochloride)

U.S.	E.U.	Japan
Compound: N/A Later filed patent formulation: October 2020	Compound: N/A Later filed patent formulation: October 2020	Compound: N/A Later filed patent formulation: October 2020

Renvela® (sevelamer carbonate)

U.S.	E.U.	Japan
Compound: N/A Later filed patents formulation: October 2025 (tablet) and December 2030 (sachet)	Compound: N/A Later filed patent formulation: September 2026 (sachet) Generics on the market	Compound: N/A Later filed patents formulation: November 2025 (tablet) and September 2026 (sachet)

Stilnox® (zolpidem tartrate)

U.S.	E.U.	Japan
Compound patent: expired Generics on the market	Compound patent: expired Generics on the market	Compound patent: expired Regulatory exclusivity: expired Later filed patent: Ambien® CR formulation (December 2019) not commercialized

Synvisc® (hyaline G-F 20)

U.S. Compound: expired	**E.U.** Compound: N/A	**Japan** Compound: expired

Synvisc-One® (hyaline G-F 20)

U.S. Compound: expired	**E.U.** Compound: N/A	**Japan** Compound: expired

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Toujeo® (insulin glargine)

U.S.	E.U.	Japan
Compound: expired Later filed patents: coverage ranging through April 2034 (applications pending) Regulatory exclusivity: February 2018	Compound: expired Later filed patents: coverage ranging through April 2034 (applications pending)	Compound: expired Later filed patents: coverage ranging through April 2034 (applications pending) Regulatory exclusivity: July 2019

Zaltrap® (aflibercept)

U.S.	E.U.	Japan
Compound: May 2020 (July 2022 if PTE is granted)* Later filed patents: coverage ranging through April 2032 (applications pending) Biologics Regulatory Exclusivity: November 2023	Compound: May 2020 (May 2025 with SPCs)* Later filed patents: coverage ranging through April 2032 (applications pending) Regulatory Exclusivity: February 2023	Compound: May 2020* (PTE to be determined once product is approved) Later filed patents: coverage ranging through April 2032 (applications pending)

* *patents under license of REGENERON PHARMACEUTICALS, INC.*

Patents held or licensed by the Group 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 U.S. (prior to the product being switched to over-the-counter status) and Plavix® in the E.U..

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 the Group 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 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 U.S., 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. Regulatory Framework 6.3.2. Biosimilars below. 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 following the initial U.S. marketing authorization of the original product. 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.

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The accelerated ANDA-type procedures are potentially applicable to many, but not all, of the products we manufacture. See B.6. Regulatory Framework 6.3.2. Biosimilars and Regulation below. We seek to defend our patent rights vigorously in these cases. Success or failure in the assertion of a given patent against a competing product is not necessarily predictive of the future success or failure in the assertion of the same patent or *a fortiori* the corresponding foreign patent against another competing product due to factors such as possible differences in the formulations of the competing products, intervening developments in law or jurisprudence, local variations in the patents and differences in national patent law and legal systems. See Item 3. Key Information D. Risk Factors Risks Relating to Legal and Regulatory Matters We rely on our patents and 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 U.S.

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 FDA s prior findings of safety and effectiveness of a drug that has obtained FDA approval. 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 FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (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 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 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 E.U., 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 approval 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 our divisions including CHC, generics and retail animal health business.

It is our policy to protect and register our trademarks with a strategy adapted to each product or service depending on their countries of commercialization: i.e., 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

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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.

B.8. Production and Raw Materials

For many years, we have chosen to keep the manufacture of our products in-house in order to have better control over quality and distribution. Our production process consists of three principal stages: the manufacture of pharmaceutical active ingredients, the transformation of those ingredients into products, and packaging.

Our general policy is to produce our main active ingredients and principal products at our own plants in order to reduce our dependence on external manufacturers and to maintain strict and precise control over the entire production cycle. In some cases, however, we rely on third parties for the manufacture and supply of certain active ingredients 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 internal directives. We have outsourced some of our production under supply contracts associated with acquisitions of products or businesses or plant divestitures, or to establish a local presence to capitalize on growth in emerging markets. In particular, we outsource part of the production of the active ingredients used in Stilnox® and Xatral®, and certain pharmaceutical product formulations. Our main pharmaceutical subcontractors are Famar, MSD, Unither, Delpharm, and Saneca. Those subcontractors follow our general quality and logistics policies, as well as meeting other criteria. See Item 3. Key Information D. Risk Factors Risks Relating to Our Business .

We also obtain active ingredients from third parties under partnership 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. Situated principally in Europe, these facilities are dedicated to the manufacture of our active ingredients, injectables, and a number of our principal products in solid form;
- regional sites, which serve markets at continental level, in Europe and particularly the BRIC-M countries (Brazil, Russia, India, China and Mexico), giving us a strong industrial presence in emerging markets;
- 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 sites at Le Trait (France) and Anagni (Italy) also contribute to Sanofi Pasteur s industrial operations by making available their aseptic filling and freeze-drying facilities.

In 2011, we diversified our industrial operations into rare diseases (with the acquisition of Genzyme) and via the integration of Merial, our Animal Health division.

Merial markets the pharmaceutical products Frontline®, Heartgard®, NexGard® and Previcox® (companion animals); LongRange®, Ivomec®, Eprinex® (ruminants) and Gastrogard® (equine). It also markets a broad range of vaccines: Vaxxitek® (avian), FMD vaccine (ruminants), Circovac® (swine) and Purevax® (companion animals). Some pharmaceutical products are outsourced (Eprinex®), but almost all veterinary vaccines are manufactured in house. Merial s dedicated Animal Health industrial operations cover all activities, from the purchase of raw materials through to delivery of the finished product, meeting customer needs through a reliable and flexible offering that meets quality expectations. There are 16 production sites spread across nine countries.

All of our production facilities Pharmaceuticals, Genzyme and Vaccines are good manufacturing practice (GMP) compliant, in line with international guidelines.

Our principal sites are approved by the U.S. Food and Drug Administration (FDA):

- our Pharmaceuticals facilities in France (Ambarès, Tours, Le Trait, Maisons Alfort, Compiègne and Lyon), the United Kingdom (Haverhill and Holmes Chapel), Ireland (Waterford), Germany (Frankfurt), Italy (Anagni), and the U.S. (Saint Louis, Kansas City and Chattanooga);

- the Genzyme facilities in the U.S. (Allston, Framingham, Ridgefield, Northpointe-Lynnwood, Woburn and Northborough) and in Belgium (Geel); and

- our Vaccines sites in France (Marcy l Étoile, and Le Trait which handles filling and packaging of Fluzone® ID for the U.S. market; the U.S. (Swiftwater, Canton and Rockville); and Canada (Toronto).

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Our Animal Health facilities in Athens, Worthington, Gainesville and Raleigh (U.S.) and Barceloneta (Puerto Rico, acquired in December 2014) are managed by the U.S. Department of Agriculture (USDA), while the sites at Paulinia (Brazil) and Toulouse (France) have FDA approval for some of their operations.

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 entered into a consent decree with the FDA relating to the facility at Allston in the United States, 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 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, Genzyme is permitted to continue manufacturing at the site during the remediation process, subject to compliance with the terms of the consent decree.

The consent decree requires Genzyme to implement a plan to bring the Allston facility operations into compliance with applicable laws and regulations. The plan must 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 includes a timetable of specified milestones. If the milestones are not met in accordance with the timetable, the FDA could require us to pay $15,000 per day, per affected drug, until these compliance milestones are met. During 2013, Genzyme was late in completing one of the actions specified in the remediation workplan. This was notified to the FDA, which could impose liquidated damages for the late completion. At filing date of this report, the FDA has not yet disclosed whether it intends to do so.

Genzyme recently proposed a third modification to the workplan associated with plans to modernize plant and equipment. The FDA is reviewing this proposed modification. Genzyme has informed the FDA that the remaining actions specified in the workplan are progressing in line with the proposed modification. If the FDA rejects Genzyme s proposal, Genzyme could be subject to liquidated damages of U.S.$15,000 per day in the event that actions in the version of the workplan accepted by the FDA are judged to be incomplete as of March 31, 2016.

Once all the compliance requirements of the consent decree are satisfied, Genzyme will be required to retain an auditor to monitor and oversee ongoing compliance at the Allston facility for an additional period of at least five years.

In April 2014, the FDA withdrew the warning letter relating to the Sanofi Pasteur sites at Toronto (Canada) and Marcy l Étoile (France). Sanofi Pasteur is implementing an ongoing program to improve compliance at those sites by applying a Global Quality Plan. This has already resulted in further improvements, as acknowledged in the most recent CGMP inspection conducted by the FDA at the Marcy l Étoile site in September 2015.

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

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.

Our captive insurance company, Carraig, participates in our coverage for various lines of insurance mainly 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 Group 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 Group entities worldwide, wherever it is possible to use a centralized program operated by our captive insurance company. This approach shares risk between Group 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 goods of all kinds owned by the Group that are in transit nationally or internationally, whatever the means of transport, and all our inventories wherever they are located. Sharing risk between Group 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

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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 has been renewed 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 the Group including 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, including generics coverage in the U.S. 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 the company 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 the legal entities under our control, and their directors and officers. Our captive insurance company is not involved in this program.

The Group also operates other insurance programs, but these are of much lesser importance than those described above.

All the 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, not only do we reduce costs, but we also provide world-class coverage for the entire Group.

B.10. Health, Safety and Environment (HSE)

The manufacturing and research operations of Sanofi 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 Sanofi to eliminate or reduce the effects of chemical substance discharge at our various sites. The sites in question may belong to the Group, be currently operational, or they 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 Group 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 audits conducted over the last few years, detailed assessments of the risk of soil and groundwater contamination have been carried out at current and former Group 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 and Garessio in Italy; Dagenham in the United

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Kingdom; Ujpest in Hungary; Prague in the Czech Republic; Beaucaire, Valernes, Limay, Rousset, Romainville, Neuville, Vitry, Tours and Toulouse in France; and on a number of sites divested to third parties and covered by contractual environmental guarantees granted by Sanofi.

Sanofi may also have potential liability for investigation and cleanup at several other sites. Sanofi has established provisions for the sites already identified and to cover contractual guarantees for environmental liabilities for sites that have been divested. In France specifically, Sanofi has 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.e to the consolidated financial statements. In 2015, Sanofi spent 63 million (including 0.4 million related to the held-for-exchange Animal Health business) on rehabilitating sites previously contaminated by soil or groundwater pollution.

Due to the changes in environmental regulations governing site remediation, Sanofi s 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 considered, 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 .

Sanofi has 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. During the year, a comprehensive review was carried out on the legacy of environmental pollution. In light of data collected during this review, the Group adjusted the provisions to approximately 720 million as of December 31, 2015 (including 12 million related to the held-for-exchange Animal Health business) versus 696 million as of December 31, 2014. 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. In accordance with Group standards, these provisions are reviewed twice a year and updated in light of new information, if applicable.

To our knowledge, the Group did not incur any liability in 2015 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 (55 in 2015) are carried out by the Group in order to assess compliance with our standards (which implies compliance with regulations) and to initiate corrective measures. Additionally, 11 specialized audits covering biosafety, and 133 prevention visits were carried out by our teams in 2015. Moreover, 63 specific visits were performed together with the experts representing the Group insurers.

Sanofi has implemented a worldwide master policy on health, safety and the 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, 78 rules (policies) have been drawn up in the key fields of HSE management, Good HSE Practices, safety in the workplace, process safety, industrial 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. The Group s COVALIS Committee is responsible for the hazard determination and classification of all active pharmaceutical ingredients and synthesis intermediates handled at Sanofi facilities. This covers all active ingredients handled in production at company sites or

in processes sub-contracted for manufacture. Any important issues involving raw materials or other substances that lack established occupational exposure limits may also be reviewed. The COVALIS committee determines the occupational exposure limits required within the Group. The Group s 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 the Group. 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 industrial 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 initial and routine medical program, focused on the potential occupational health risks linked to their duties.

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In addition, dedicated resources have been created to implement the E.U. 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, the Group 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: process or installation changes, as well as changes in production scale and transfers between industrial or research units.

Our laboratories that specialize in process safety testing, which 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 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

The main objectives of our environmental policy are to implement clean manufacturing techniques, minimize the use of natural resources and reduce the environmental impact of our activities. In order to optimize and improve our environmental performance, we have a strategy of continuous improvement practiced at all our sites through the annual implementation of HSE progress plans. We believe that this strategy clearly expresses the commitment of both management and individuals to health, safety and the environment. In 2015, seven of our European sites were included in the scope of the European CO_2 Emissions Credit Trading Scheme aimed at helping to reach the targets set by the Kyoto protocol.

Our recent efforts in terms of environmental protection have mainly targeted reductions in energy consumption, greenhouse gas emissions control, improvements in the performance of water treatment installations, reduction of volatile organic compound emissions, raw material savings and recycling, and reductions in waste materials or increases in the percentage being recycled. Measured against the benchmark year for

our targets (2010), direct and indirect emissions from our production and research facilities (excluding vehicle fleets) have fallen by 15.8% overall. We are targeting a 20% reduction in CO_2 emissions in 2020 vs. 2010 on a constant structure basis.

An internal committee of experts called ECOVAL assesses the environmental impact of the pharmaceutical agents found in products marketed by Sanofi. It has developed an environmental risk assessment methodology and runs programs to collect the necessary data for such assessments. Additional ecotoxicity assessments are being performed on certain substances which predate current regulations, in order to obtain information that was not gathered when they were launched (as regulatory requirements were different at that time) and evaluate environmental risks resulting from their use by patients.

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C. Organizational Structure

Significant subsidiaries

Sanofi is the holding company of a consolidated group consisting of approximately 400 subsidiaries. The table below sets forth our significant subsidiaries as of

December 31, 2015. For a 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 S.A.	09/24/1974	France	Pharmaceuticals	100%
Genzyme Corporation	11/21/1991	United States	Pharmaceuticals	100%
Hoechst GmbH	07/08/1974	Germany	Pharmaceuticals	100%
Merial, Inc.	08/01/1997	United States	Animal Health	100%
Merial S.A.S.	02/25/1941	France	Animal Health	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 U.S. LLC	06/28/2000	United States	Pharmaceuticals	100%
Sanofi-Aventis Participations SAS	02/25/2000	France	Pharmaceuticals	100%
Sanofi Pasteur	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%

Since 2009, we have transformed our Group 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.

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 immuno-oncology; and (ii) with BMS, relating to Plavix®. For further information, refer to Note C. to our consolidated financial statements, Principal Alliances .

Internal organization of activities

Sanofi and its subsidiaries form a group, organized around three activities: Pharmaceuticals, Vaccines and Animal Health.

On December 15, 2015, we announced that we had opened exclusive negotiations with Boehringer Ingelheim with a view to an asset swap. The proposed deal would see Sanofi exchange its Animal Health business (Merial) for Boehringer Ingelheim s Consumer Health Care business and a gross cash payment. Until final completion of the transaction, which is subject to execution of definitive agreements and thereafter to regulatory clearances, expected in the fourth quarter of 2016, we will continue to monitor the performance of the Animal health business (which remains an operating segment pursuant to IFRS 8) and to report the performance of that business at Group level.

Within the Group, responsibility for research and development (R&D) in their respective fields rests with Sanofi and Genzyme Corporation (Pharmaceuticals); Sanofi Pasteur and Sanofi Pasteur, Inc. (Vaccines); and Merial, Inc. and Merial S.A.S. (Animal Health). However, within the integrated R&D organization, the definition of strategic priorities and the coordination of R&D efforts are done globally. To fulfill this role, these companies subcontract R&D work 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. The licensee subsidiaries manufacture and distribute the majority of the Group s products, either directly or via local distribution entities.

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

- Pharmaceuticals: Sanofi, Aventis Pharma S.A., Sanofi Biotechnology S.A.S. (France), Sanofi-Aventis Deutschland GmbH (Germany) and Genzyme Corporation (U.S.);
- Vaccines: Sanofi Pasteur (France) and Sanofi Pasteur, Inc. (U.S.);
- Animal Health: Merial, Inc. (U.S.) and Merial S.A.S. (France).

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 S.A., Sanofi Chimie, Sanofi Winthrop Industrie, Sanofi, Merial SAS France 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;
- In Ireland: Genzyme Ireland Limited.

Financing and financial relationships between Group companies

The Sanofi parent company raises the bulk of the Group 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, the Sanofi parent company was carrying 92% of the Group s external financing and 85% of its surplus cash as of December 31, 2015.

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

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	58%
Research	14%
Offices	13%
Logistics	9%
Other	5%

* *Our Vaccines and Animal Health activities occupy offices and research, production and warehouse facilities. Those sites are allocated between the first four categories in the table above as appropriate.*

Breakdown of sites by ownership status

Leasehold	28%
Owned	72%

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 our Group, we are continuing to adapt the organization of our 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 the Group. The department focuses on customer needs and service quality, the sharing of lean 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.

We carry out our industrial production at 102 sites in 41 countries (including 40 sites in emerging markets):

- 74 sites for our Pharmaceuticals activity, including Genzyme;
- 12 sites for the industrial operations of Sanofi Pasteur in vaccines; and

- 16 sites for the Animal Health activities of Merial.

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In 2015, we produced the following quantities:

- Pharmaceuticals: 4,577 million units, comprising:
  - units manufactured and packaged: 3,089 million;
  - units packaged only: 260 million;
  - bulk products in unit equivalents: 463 million;
  - outsourced units: 765 million;
- Vaccines: 513 million containers (syringes and ampoules) filled, including outsourced production;
- Animal Health: 524 million doses of vaccines for all species other than avian, 92 billion doses of avian vaccines, and 76.5 million units of pharmaceutical products.

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.

Industrial Sites: Pharmaceuticals

Production of 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).

The sites where our major drugs, active ingredients, specialties and medical devices are manufactured are:

- France: Ambarès (Plavix®, Aprovel®, Depakine®), Aramon (irbesartan), Compiègne (Aubagio®, Lasix®, Imovane®), Le Trait (Lovenox®), Lisieux (Doliprane®), Lyon Gerland (Thymoglobulin®, Celsior®), Maisons-Alfort (Lovenox®), Sisteron (clopidogrel bisulfate, dronedarone, zolpidem tartrate), Tours (Stilnox®, Aprovel®, Xatral®), Vitry-sur-Seine (docetaxel, aflibercept);

Germany: Frankfurt: insulins (Lantus®, Apidra®, Lyxumia®, Toujeo®), oncology products (Taxotere®, Eloxatin®), medical devices (Click®STAR and Solo STAR®);

- Ireland: Waterford (Myozyme®, Lumizyme®, Cholestagel®, Thymoglobulin®, Renagel®, Renvela®, Cerezyme®);
- Italy: Scoppito (Tritace®, Amaryl®) and Anagni (Depakine®, Fasturtec®, Rifa antibiotic family);
- United Kingdom: Haverhill (sevelamer hydrochloride API (Renagel®), sevelamer carbonate API (Renvela®), Cerezyme®, Fabrazyme®, Thyrogen®, Myozyme®, etc), and Holmes Chapel (Nasacort®, Flutiform®);
- Hungary: Ujpest (irbesartan), Csanyikvölgy (Lovenox®);
- Japan: Kawagoe (Plavix®);
- United States: Kansas City (Allegra®, currently being transferred to Tours and Compiègne in France), and Chattanooga (Consumer Health Care products);
- Brazil: Suzano (Amaryl® and Novalgine®) and Campinas (generics);
- Mexico: Ocoyoacac (Flagyl®); and
- Singapore: Jurong (enoxaparin).

Genzyme manages 8 production sites and works with more than 15 subcontractors to manufacture 12 commercial products over a broad range of technological platforms.

Genzyme s sites are as follows:

- Belgium: Geel (A1 alpha glucosidase: Myozyme®/Lumizyme®);
- United States: Allston (Cerezyme®), Framingham Biologics (Fabrazyme®, Thyrogen®), Framingham Biosurgery (Seprafilm®, hyaluronic acid), Ridgefield (Synvisc®, Hectorol®, Mozobil®, Jonexa®, Kynamro®), Woburn (LeGoo®), Northborough and Lynnwood, Washington State (Leukine®).

Industrial Sites: Vaccines (Sanofi Pasteur)

The headquarters of our Vaccines division, Sanofi Pasteur, is located in Lyon, France. Sanofi Pasteur has 12 industrial sites in 8 countries:

- France: Marcy l Étoile, Val de Reuil and Neuville;
- United States: Swiftwater, Canton and Rockville;
- Canada: Toronto;

- India: Hyderabad (Shantha);
- China: Shenzhen;
- Argentina: Pilar;
- Mexico: Ocoyoacac; and
- Thailand: Chachoengsao.

Sanofi Pasteur also has its own R&D and production sites, either freehold or under finance lease with a purchase option exercisable on expiration of the lease.

Industrial Sites: Animal Health (Merial)

Merial has 16 industrial sites in nine different countries and numerous administrative offices including its headquarters in Lyon, France.

Merial s industrial sites are as follows:

- Brazil: Paulinia (avermectin-based pharmaceutical products, and vaccines against foot-and-mouth disease and rabies), and a production unit approved by the FDA and EMA for NexGard®;

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- China: Nanchang (live avian vaccines);
- France: Toulouse (Frontline® and clostridial vaccines), St-Priest LPA (vaccines), Lyon Gerland, Saint-Herblon (Coophavet), Lentilly (packaging);
- Italy: Noventa (inactivated avian vaccines);
- Netherlands: Lelystad (antigen against foot-and-mouth disease);
- United Kingdom: Pirbright (antigens and vaccines against foot-and-mouth disease);
- United States: two dedicated facilities for Merial s avian vaccines at Gainesville (Georgia) and Raleigh (North Carolina), a dedicated facility for mammalian viral and bacterial vaccines at Athens (Georgia), a dedicated facility for autogenous ruminant and swine vaccines at Worthington (Minnesota);
- Puerto Rico: a dedicated site at Barceloneta for production and packaging of Heartgard® and Heartgard® Plus; and
- New Zealand: Ancare facility, Auckland (pharmaceutical products, mainly for the ruminant market).

Research & Development sites

In Pharmaceuticals, research and development activities are conducted at 15 sites:

- six operational sites in France: Chilly/Longjumeau, Montpellier, Paris, Strasbourg, Toulouse and Vitry/ Alfortville;
- two sites in the rest of Europe (Germany and the Netherlands), the larger of which is in Frankfurt (Germany);
- five sites in the United States, the largest being the Bridgewater, Cambridge and Framingham sites; and
- two sites in Asia (a clinical research unit in Beijing, China and a unit in Japan).

Vaccines research and development sites are presented under Industrial Sites: Vaccines (Sanofi Pasteur) above.

In Animal Health, research and development activities are conducted at 13 sites. In addition, the Barceloneta site in Puerto Rico was acquired from Merck in December 2014.

D.3. Acquisitions, Capital Expenditures and Divestitures

The carrying amount of our property, plant and equipment at December 31, 2015 was 9,943 million. During 2015, we invested 1,318 million (see Note D.3. to our consolidated financial statements, included at Item 18 of this annual report), mainly in increasing capacity and improving productivity at our various production and R&D sites.

Our principal acquisitions, capital expenditures and divestitures in 2013, 2014 and 2015 are described in Notes D.1. (Impact of changes in the scope of consolidation), D.3. (Property, plant and equipment) and D.4. (Goodwill and other intangible assets) to our consolidated financial statements, included at Item 18 of this annual report.

As of December 31, 2015, our firm commitments in respect of future capital expenditures amounted to 436 million. The principal locations involved were: for the Pharmaceuticals segment, the industrial facilities at Frankfurt (Germany), Framingham and Allston (United States), Geel (Belgium), Waterford (Ireland), and Sisteron and Elbeuf (France); and for the Vaccines segment, the facilities at Swiftwater (United States) and Marcy l Étoile (France).

In the medium term and assuming no changes in the scope of consolidation, we expect to invest on average some 2 billion a year in property, plant and equipment. We believe that our own cash resources and the undrawn portion of our existing credit facilities will be sufficient to fund these expenditures.

Our principal ongoing investments are described below.

Pharmaceuticals

The Frankfurt facility, our principal site for the manufacture of diabetes treatments, will shortly be equipped with a second aseptic processing area that uses isolator technology to significantly improve the aseptic filling process and boost productivity. This investment will be operational later in 2016. At the end of 2014, we announced the investment of a further 200 million in sterile filling and manufacturing capacity for medical devices at our Frankfurt site.

The **Diabetes** industrial network has a solid base in emerging markets, both in Russia with the Orel site (now our second largest insulin pen production site after Frankfurt) and at the Beijing site in China which handles assembly and filling of SoloSTAR®, the pre-filled injection system for Lantus®. As part of the integration of Shantha (India) into our Injectables platform, the Indian site uses the Group manufacturing technology to handle filling and packaging for Insuman® insulin, initially for the local market and later for other emerging markets.

The pharmaceutical industrial operations of our **Consumer Health Care** (CHC) platform are spread across a network of ten sites. Global markets are supplied from our facilities at Origgio (Italy), Cologne (Germany) and Veresegyház (Hungary). Regional markets are supplied from our Suzano facility in Brazil, our Rzeszow facility in Poland and our ACE facility in Vietnam. Our facilities at Lisieux (France, production of Doliprane® for the French market), Hangzhou and Tangshan (China), Virginia (Australia), and the Chattem facility in Tennessee (United States), mainly supply their local markets. We have recently invested heavily in major

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projects intended to build a specialist CHC industrial network. This has included switching some CHC products from non-CHC facilities to the dedicated CHC network, transferring some liquid and effervescent formulations of CHC products to the Cologne site, and transforming the Origgio site into a facility dedicated to a single product family (Enterogermina®).

In 2014, a platform dedicated to **Biologics** was launched to develop synergies between Pharmaceuticals, Sanofi Pasteur, Sanofi Genzyme and our Biotherapeutics activities. This platform is helping us extend our footprint in biotechnologies by adopting a multi-disciplinary approach and improving capacity utilization. It also enables us to leverage our expertise in the production of biologics, from active ingredient through to integrated manufacturing, including both the medicine itself and associated medical devices.

Three dedicated biotechnology sites have been developed: Paris/Lyon (France), Frankfurt (Germany) and Boston (United States). Piloting this innovative technology, which relies on cell or microbiological culture or the development of viral vectors, calls for highly specific knowledge and expertise backed by dedicated production platforms to support global product launches.

The development of our **Emerging Markets** platform is built on a network of over 40 regional and local industrial sites in 25 countries, supporting growth in those markets.

At Sidi Abdellah in Algeria we are building a new facility that will become our largest industrial complex in Africa, mainly producing dry and liquid formulations. In July 2014, we took a substantial step in growing our Generics business in the Middle East by acquiring a significant stake in Globalpharma, the local pharmaceuticals subsidiary of Dubai Investments PJSC. The Globalpharma plant in Dubai was integrated into our industrial network during 2015. The main products manufactured there are anti-infective, cardiovascular and gastro-intestinal drugs.

In Vietnam, we have completed construction of our new facility in Ho Chi Minh City, which manufactures specialty pharmaceuticals and CHC products and is supporting the launch of Lactacyd® in Japan.

The Industrial Affairs Department has an ongoing policy of adapting our industrial facilities to market needs. As part of this process, we closed our facility at Fawdon (United Kingdom) in 2015, and plan to close our facility at Kansas City (United States) in 2016. We sold our facility at Quetigny (France) in 2015, and have reached agreement with a third party to sell our facility at Mirador (Argentina) in 2016.

The **Sanofi Genzyme** industrial network is predominantly located in the United States, where major investments are under way. The site at Allston (Massachusetts) has initiated

a major investment program in connection with the implementation of its compliance remediation workplan, which was approved by the FDA in January 2012.

Vaccines (Sanofi Pasteur)

Sanofi Pasteur s industrial operations are in a major investment phase, especially with the new dedicated dengue fever vaccine facility at Neuville (France), which was approved by the ANSM in 2014 and began production in 2015. Also in 2015, Sanofi Pasteur inaugurated a new building at Marcy L Étoile (France), dedicated mainly to production of the Haemophilus influenza type b (Hib) vaccine.

Animal Health (Merial)

Merial is adapting its industrial capacity to keep pace with the growing animal health market. In 2012, Merial acquired Newport Laboratories, which has an autogenous vaccine production facility at Worthington, Minnesota (United States). To support the future growth of avian and other vaccines in the Chinese market, Merial invested U.S.$70 million in a new site in the Nanchang high-tech development zone, which was inaugurated in October 2013. At the Paulinia site in Brazil, Merial is now manufacturing its new **NexGard®** product, with FDA approval and in compliance with European Union Good Manufacturing Practices (GMP). In September 2014, Merial began construction of a new facility that

will use new technologies to triple the current capacity of Paulinia.

In December 2014, Merial acquired the Merck manufacturing facility at Barceloneta (Puerto Rico), which is now operational. This acquisition will enable Merial to expand its industrial operations and capitalize on expertise in chewables production and technology. The site is already producing two of Merial s flagship products, Heartgard® and Heartgard® Plus.

Innovation and culture of industrial excellence

In 2015, Sanofi highlighted industrial innovation in its various facilities by organizing its seventh annual round of innovation trophies, centered on patient needs, industrial performance and citizen entrepreneurship.

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

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D.4. Office Space

As part of the rationalization of our office sites in the Paris region of France, we have since 2009 been carrying out a medium-term review of our office space master plan for the Greater Paris area. This review will result in all our Group support functions and operating divisions being housed in a smaller number of buildings (five in 2012, with relocation completed in 2015). All of those sites will meet environmental certification standards, and offer cost-effective space solutions.

As part of this process, a new campus site known as Campus Sanofi Val de Bièvre (CSVB) was delivered in early March 2015. Relocation to this state-of-the-art workspace was completed in July 2015. By providing dynamic workspaces, the new campus promotes more effective interaction between functions, symbolizing the transformation of the Group. The campus houses the world headquarters of our Industrial Affairs department, our French subsidiary, and global support functions.

A second Master Plan was initiated at the end of 2011; this plan defines the Group s medium-term office space requirements in the Lyon urban area, and is in the implementation phase. A first off-plan lease was signed in early 2013 covering some of the Pooled Services functions

and was delivered at the end of March 2015 by its owner, Plastic Omnium. Additional space was leased in the same complex in October 2015. A further lease was signed in June 2014 on premises that from 2017 will house our corporate functions in Lyon; this deal involves the sale of an existing freehold site and the off-plan reconstruction of the Group s first energy-positive building in France. Our Lyon Master Plan aims to rationalize sites along the same lines as the Paris Master Plan: buildings with environmental certification that offer both a reduction in overall occupancy costs and workspace consistent with the new Corporate Charter.

Two more Master Plans were initiated at the end of 2012 to define office space strategy, one in the Cambridge urban area (Massachusetts, USA) and the other in Frankfurt (Germany). The Cambridge plan went live in 2014 with the start of the preparatory phase, and is scheduled for delivery in 2018. Integrating the U.S. operations of Genzyme will provide opportunities for rationalizing office space in the city.

Further rationalization projects in other parts of the world were completed in 2015, including the installation of our Singapore regional headquarters in a new friendly building featuring dynamic workspaces and the relocation of our Indian subsidiary to a new building in Mumbai. We also sold a number of properties in locations including Mumbai (India), Labège (France) and Dagenham (United Kingdom).

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Item 5. Operating and Financial Review and Prospects

Item 5. Operating and Financial Review and Prospects

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

Our consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and with IFRS adopted by the European Union as of December 31, 2015.

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

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

2015 Overview

On April 2, 2015, Olivier Brandicourt took office as Chief Executive Officer of Sanofi, further to a unanimous decision by the Board of Directors on February 19, 2015.

During 2015, we accelerated our policy of research and development alliances and targeted acquisitions. In diabetes, we entered into collaboration agreements with Evotec, Verily (formerly Google Life Sciences), Hanmi Pharmaceuticals Co., Ltd and Lexicon Pharmaceuticals, Inc. In immuno-oncology, we entered into a new global collaboration with Regeneron to discover, develop and commercialize new antibody cancer treatments, alongside a further immuno-oncology collaboration with Evotec and Apeiron Biologics. In rare diseases, we acquired Caprelsa® (vandetanib) from Astra Zeneca. We also entered into a strategic collaboration agreement with Voyager Therapeutics for the discovery, development and commercialization of new adeno-associated virus (AAV) gene therapies to treat serious disorders of the central nervous system.

In July 2015, we announced our intention to change our business structure by creating five global business units (GBUs): General Medicines & Emerging Markets, Sanofi Genzyme (Specialty Care), Diabetes & Cardiovascular, Sanofi Pasteur (Vaccines), and Merial (Animal Health). This new structure is being implemented effective beginning January 2016. For more information, see Results of

Operations Year Ended December 31, 2015 Compared with Year Ended December 31, 2014 Presentation of net sales by business segment from 2016 onwards .

On November 6, 2015, we unveiled our new long-term strategy, which rests on four pillars: reshape the portfolio, deliver outstanding launches, sustain innovation in R&D and simplify the organization (see Item 4. Information on the Company B. Business Overview B.1. Strategy).

On December 15, 2015, we announced that we had entered into exclusive negotiations with Boehringer Ingelheim with a view to an asset swap. The proposed deal, which could complete in the fourth quarter of 2016 once the necessary regulatory clearance is obtained, would see Sanofi exchange its Animal Health business (Merial), valued at 11.4 billion, for Boehringer Ingelheim s Consumer Health Care business, valued a6.7 billion. The deal would also involve Boehringer Ingelheim making a gross cash payment of 4.7 billion to Sanofi. Sanofi s intent is to allocate part of the net proceeds from the exchange to our share repurchase program.

Following this announcement, the net profit or loss of the Animal Health business (Merial) is now presented in a separate line item in the consolidated income statement, Net income/(loss) of the held-for-exchange Animal Health business , in accordance with IFRS 5 (see Notes D.2.1. and D.36. to our consolidated financial statements, included at Item 18 of this annual report). Consequently, the net sales reported in the consolidated income statement do not include the net sales of the Animal Health business.

Until final completion of the transaction, expected in the fourth quarter of 2016, we will continue to monitor the performance of the Animal Health business (which remains an operating segment pursuant to IFRS 8), and to report the performance of that business at the Group level. In our analysis of our financial performance for the year ended December 31, 2015 we discuss our aggregate net sales, which combines our net sales as reported in the consolidated income statement with the net sales of the Animal Health business.

Net sales for the year ended December 31, 2015 were 34,542 million, 9.0% higher than in 2014.

Aggregate net sales[1] (including the Animal Health business) for the year ended December 31, 2015 amounted to 37,057 million, up 9.7% compared to 2014 (+2.2% at constant exchange rates, see definition at Presentation of Net Sales below), driven mainly by the performance of our Genzyme, Vaccines and Animal Health businesses, and by growth in Emerging Markets[2]. Successes for our research efforts during 2015 included, for our Pharmaceuticals

(1) Non-GAAP financial measure. For a definition, see Presentation of Net Sales below.

(2) World excluding United States, Canada, Western Europe, Japan, South Korea, Australia and New Zealand. Refer to Results of Operations Year Ended December 31, 2015 Compared with Year Ended December 31, 2014 Net Sales below.

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segment, the launches of Praluent® (hypercholesterolemia) in the United States and in some European Countries, and Toujeo® (diabetes) in the United States and Europe; and for our Vaccines business, the approval in Mexico, the Philippines and Brazil of Dengvaxia®, the world s first ever dengue fever vaccine.

Business net income[1] reached 7,371 million, 7.7% higher than in 2014, while business earnings per share[1] was 5.64, up 8.5% compared to 2014. Net income attributable to equity holders of Sanofi amounted to 4,287 million, 2.3% lower than in 2014. Basic earnings per share was 3.28, down 1.8% compared to 2014.

With respect to our financial position, we ended 2015 with our debt, net of cash and cash equivalents (see definition at Liquidity and Capital Resources below) at 7,254 million (2014: 7,171 million). Debt, net of cash and cash equivalents, is a financial indicator that is used by management to measure our overall net indebtedness and to manage our equity capital. In order to assess our

financing risk, we also use a gearing ratio , a non-GAAP financial measure that we define as the ratio of debt, net of cash and cash equivalents, to total equity. Our gearing ratio was 12.5% at the end of 2015 compared to 12.7% at the end of 2014. See Liquidity and Capital Resources below.

The Shareholders will be asked at the Annual General Meeting, to be held on May 4, 2016, to approve a dividend of 2.93 per share for the 2015 financial year, representing a payout of 52.0% of business net income.

Impacts from generic competition

Some of our flagship products continued to experience diminishing sales in 2015 due to generic competition. While we do not believe it is possible to state with certainty what level of net sales would have been achieved in the absence of generic competition, we are able to estimate the impact of generic competition had for each product.

A comparison of our consolidated net sales for the years ended December 31, 2015 and 2014 (see Results of Operations Year Ended December 31, 2015 Compared with Year Ended December 31, 2014) shows that in 2015, generic competition led to a loss of 256 million of net sales on a reported basis. The table below sets forth the impact by product:

(million)	2015	2014	Change on a reported basis	Change on a reported basis (%)
Product	**Reported**	**Reported**		
Aprovel® Western Europe	143	190	(47)	-24.7%
Lantus® Western Europe	898	871	27	+3.1%
Plavix® Western Europe	169	217	(48)	-22.1%
Renagel® /Renvela® Western Europe	111	133	(22)	-16.5%
Ambien® U.S.	74	74	-	0.0%
Lovenox® U.S.	77	130	(53)	-40.8%
Taxotere® U.S.	(1)	8	(9)	-100.0%

Allegra® Japan	180	178	2	+1.1%
Amaryl® Japan	46	54	(8)	-14.8%
Lantus® Japan	112	115	(3)	-2.6%
Myslee® Japan	121	125	(4)	-3.2%
Plavix® Japan	695	759	(64)	-8.4%
Taxotere® Japan	60	87	(27)	-31.0%
Total	**2,685**	**2,941**	**(256)**	**-8.7%**

(1) *Business net income and business earnings per share are non-GAAP financial measures which our management uses to monitor our operational performance, and which are defined under Business Net Income below.*

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We expect the decline caused by generic competition to continue in 2016, with a negative impact on net income. Products susceptible to the effects of such generic competition in 2016 include:

- those for which new generic competition can reasonably be expected in 2016 based on expiration dates, patents or other regulatory or commercial exclusivity: Renagel®/Renvela® in the United States; Lovenox® in Western Europe; Aprovel® in Japan;

- those which already faced generic competition in 2015, but whose sales can reasonably be expected to be subject to sales decline in 2016: Aprovel®, Lantus®, Plavix® and Renagel®/Renvela® in Western Europe; Ambien®, Lovenox® and Taxotere® in the United States; and Allegra®, Amaryl®, Myslee®, Lantus®, Plavix® and Taxotere® in Japan.

Specifically as regards Lantus® in the United States, in September 2015 Sanofi reached a settlement agreement with Eli Lilly and Company (Lilly) regarding the patents for Lantus SoloSTAR® (insulin glargine). The agreement resolves a U.S. patent infringement lawsuit regarding Lilly s pursuit of regulatory approval for a product that would compete with Lantus SoloSTAR®. Sanofi and Lilly agreed to end that lawsuit and to discontinue similar disputes worldwide. Under the agreement, Lilly will pay royalties to Sanofi in exchange for a license to certain Sanofi patents. In the U.S., Lilly will not sell its insulin glargine product before December 15, 2016. The settlement does not include the injectable solution formulation of Lantus® in vials, Toujeo®, or combination products (for further information see Item 8 Information on Legal or Arbitration Proceedings Lantus® and Lantus SoloSTAR® Patent Litigation).

In 2015, the consolidated net sales of these products in countries where generic competition currently exists or is expected in 2016 amounted to 4,411 million; this comprises 873 million in the United States (including 723 million in net sales of Renagel®/Renvela®); 2,230 million in Europe (including 909 million in net sales of Lovenox®); and 1,308 million in Japan (including 94 million in net sales of Aprovel®). The negative impact from generics entering the market on our 2016 net sales is likely to represent a substantial proportion of this amount, but the actual impact will depend on a number of factors such as the actual launch dates of generic products in 2016, the prices at which they are sold, and potential litigation outcomes.

Purchase Accounting Effects

Our results of operations and financial condition for the years ended December 31, 2015, 2014 and 2013 have been significantly affected by our August 2004 acquisition of Aventis, our April 2011 acquisition of Genzyme and certain subsequent transactions. See Critical accounting and reporting policies Business combinations below for an explanation of the impact of business combinations on our results of operations.

The Aventis business combination has given rise to significant amortization expenses (638 million in 2015, 874 million in 2014 and 1,199 million in 2013). The Genzyme business combination has given rise to significant amortization of intangible assets (890 million in 2015, 811 million in 2014 and 930 million in 2013) and impairment of intangible assets (expenses of 214 million in 2015, net reversal of 309 million in 2014 and expenses of 665 million in 2013).

In order to isolate the purchase accounting effects of all acquisitions and certain other items, we use a non-GAAP financial measure that we refer to as business net income . For a further discussion and definition of business net income , and business net income for the years ended December 31, 2015, 2014 and 2013, see Business Net Income below.

Sources of Revenues and Expenses

Revenue. Revenue arising from the sale of goods is presented in the income statement under Net sales . Net sales comprise revenue from sales of pharmaceutical products, human vaccines and active ingredients, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities. Returns, discounts, incentives and rebates described above are recognized in the period in which the underlying sales are recognized, as a reduction of sales revenue. See Note B.14. to our consolidated financial statements included at Item 18 of this annual report. We sell pharmaceutical products and vaccines directly, through alliances, and through licensees throughout the world. When we sell products directly, we record sales revenues as part of our consolidated net sales. When we sell products through alliances, the revenues reflected in our consolidated financial statements are based on the contractual arrangements governing those alliances. For more information about our alliances, see Financial Presentation of Alliances below. When our products are sold through licensees, we receive royalty income that we record in Other revenues . See Note C. to the consolidated financial statements included at Item 18 of this annual report.

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

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products that we have patented. When we pay royalties, we record them in cost of sales, and when we receive royalties, we record them in Other revenues as discussed above.

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

Segment Information

Operating Segments

In accordance with IFRS 8 Operating Segments, we have defined our operating segments as Pharmaceuticals , Human Vaccines (Vaccines) and Animal Health . All other activities are combined in a separate segment categorized as Other .

The Pharmaceuticals segment covers research, development, production and marketing of medicines, including those originating from Genzyme. The Sanofi pharmaceuticals portfolio consists of flagship products, plus a broad range of prescription medicines, generic medicines, and consumer health products. This segment also includes all associates and joint ventures whose activities are related to pharmaceuticals, in particular Regeneron and the entities majority owned by BMS. See Financial Presentation of Alliances below.

The Vaccines segment is wholly dedicated to vaccines, including research, development, production and marketing. This segment includes our Sanofi Pasteur MSD joint venture with Merck & Co., Inc. (Merck) in Europe.

Following the signature of the exclusivity agreement with Boehringer Ingelheim (see Note D.2.1. to our consolidated financial statements included at Item 18 of this annual report) and in accordance with IFRS 5 requirements on the presentation of discontinued operations, the net income/loss of the Animal Health business is presented in a separate line item in the consolidated income statements for 2015 and the prior periods reported. Until final completion of the transaction, expected in the fourth quarter of 2016, Sanofi will continue to monitor the performance of the Animal Health business. As of December 31, 2015, the Animal Health business remains an operating segment of the Group pursuant to IFRS 8.

The Animal Health segment comprises the research, development, production and marketing activities of Merial, which offers a complete range of medicines and vaccines for a wide variety of animal species.

The Other segment includes all activities that do not qualify as reportable segments under IFRS 8. This segment includes the effects of retained commitments in respect of divested activities.

Inter-segment transactions are not material.

Business Operating Income of Segments

We report segment results on the basis of Business Operating Income . This indicator is compliant with IFRS 8 and is used internally to measure operational performance and allocate resources.

Business Operating Income is derived from Operating income , adjusted as follows:

- the amounts reported in the line items Restructuring costs , Fair value remeasurement of contingent consideration liabilities , and Other gains and losses, and litigation are eliminated;

- amortization and impairment losses charged against intangible assets (other than software and other rights of an industrial or operational nature) are eliminated;

- the share of profits/losses of associates and joint ventures is added;

- net income attributable to non-controlling interests is deducted;

- other acquisition-related effects (primarily the workdown of acquired inventories remeasured at fair value at the acquisition date, and the impact of acquisitions on investments in associates and joint ventures) are eliminated;

- restructuring costs relating to associates and joint ventures are eliminated; and

- the non-recurring adjustment recognized in 2014 for the annual Branded Prescription Drug (BPD) Fee in the United States (following publication by the U.S. Internal Revenue Service in July 2014 of the final regulations on that fee) is also eliminated.

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The table below, presented in compliance with IFRS 8, shows a reconciliation between our Business Operating Income and our Income before tax and associates and joint ventures for the years ended December 31, 2015, 2014 and 2013:

(million)	2015	2014	2013
Business Operating Income[1]	**9,313**	**8,957**	**8,821**
Share of profit/(loss) of associates and joint ventures[2]	(169)	(146)	(89)
Net income attributable to non-controlling interests[3]	126	126	161
Amortization of intangible assets	(2,137)	(2,081)	(2,527)
Impairment of intangible assets	(767)	31	(1,387)
Fair value remeasurement of contingent consideration liabilities	53	(303)	314
Expenses arising from the impact of acquisitions on inventories[4]	-	-	(8)
Restructuring costs	(795)	(404)	(303)
Additional year expense related to US Branded Prescription Drug Fee[5]	-	(116)	-
Operating Income	**5,624**	**6,064**	**4,982**
Financial expense	(559)	(598)	(609)
Financial income	178	192	111
Income before tax and associates and joint ventures	**5,243**	**5,658**	**4,484**

(1) Excluding the Animal Health business, the net income/loss of which is presented in a separate line item, Net income/(loss) of the held-for-exchange Animal Health business , in the consolidated financial statements for 2015 and prior years (see Notes D.2.1. and D.36. to our consolidated financial statements included at Item 18 of this annual report). Until final completion of the transaction, expected at the end of 2016, the Animal Health business remains an operating segment of the Group pursuant to IFRS 8.

(2) Excluding (i) restructuring costs of associates and joint ventures and (ii) expenses arising from the impact of acquisitions on associates and joint ventures.

(3) Excluding (i) restructuring costs and (ii) other adjustments attributable to non-controlling interests.

(4) This line records the impact of the workdown of acquired inventories remeasured at fair value at the acquisition date.

(5) Annual fee related to 2013 sales: the IRS reform of July 2014 altered the date on which the liability is recognized, such that the expense recognized during 2014 was based on both 2013 and 2014 sales.

Business Net Income

In addition to net income, we use a non-GAAP financial measure that we refer to as business net income to evaluate our Group s performance. Business net income, which is defined below, represents the aggregate business operating income of all of our operating segments, less net

financial expenses and the relevant income tax effects. We believe that this non-GAAP financial measure allows investors to understand the performance of our Group because it segregates the results of operations of our current business activities, as opposed to reflecting the impact of past transactions such as acquisitions.

Our management uses business net income to manage and to evaluate our performance, and we believe it is appropriate to disclose this non-GAAP financial measure, as a supplement to our IFRS reporting, in order to assist investors in analyzing the factors and trends affecting our business performance. Our management also intends to use business net income as the basis for proposing the dividend policy for the Group. Accordingly, management believes that an

investor s understanding of trends in our dividend policy is enhanced by disclosing business net income.

We have also decided to report business earnings per share . Business earnings per share is a specific non-GAAP financial measure, which we define as business net income divided by the weighted average number of shares outstanding. Our management intends to give earnings guidance based on business earnings per share. We also present business earnings per share on a diluted basis.

Business net income is defined as Net income attributable to equity holders of Sanofi determined under IFRS, excluding:

- amortization and impairment losses charged against intangible assets (other than software and other rights of an industrial or operational nature);
- fair value remeasurements of contingent consideration liabilities related to business acquisitions;
- other impacts associated with acquisitions (including impacts of acquisitions on associates and joint ventures);

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- restructuring costs[1];
- other gains and losses (including gains and losses on major disposals of non-current assets[1]);
- costs of provisions associated with litigation[1];
- tax effects related to the items listed above as well as effects of major tax disputes;
- the 3% tax on the distribution of dividends to Sanofi shareholders;
- the additional expense relating to the annual U.S. Branded Prescription Drug Fee, booked in 2014 following publication in July 2014 of the final U.S. IRS regulation on this issue;
- those Animal Health income statement items that are not included in business net income[2]; and
- the portion attributable to non-controlling interests of the items listed above.

The following table reconciles our business net income to Net income attributable to equity holders of Sanofi for the years ended December 31, 2015, 2014 and 2013:

(million)	2015[1]	2014[1]	2013[1]
Business net income	**7,371**	**6,847**	**6,686**
Amortization of intangible assets	(2,137)	(2,081)	(2,527)
Impairment of intangible assets	(767)	31	(1,387)
Fair value remeasurement of contingent consideration liabilities	53	(303)	314
Expenses arising from the impact of acquisitions on inventories	-	-	(8)
Restructuring costs	(795)	(404)	(303)
Other gains and losses, and litigation[2]	-	35	-
Additional year expense related to US Branded Prescription Drug Fee[3]	-	(116)	-
Tax effects on the items listed above, comprising:	1,331	928	1,341
amortization of intangible assets	*757*	*564*	*801*
impairment of intangible assets	*262*	*(18)*	*527*
fair value remeasurement of contingent consideration liabilities	*39*	*254*	*(85)*
expenses arising from the impact of acquisitions on inventories	-	-	*2*

restructuring costs	*273*	*141*	*96*
other gains and losses, and litigation	*-*	*(13)*	*-*
Other tax items	(111)	(110)	(109)
Share of items listed above attributable to non-controlling interests	25	8	4
Restructuring costs and expenses arising from the impact of acquisitions on associates and joint ventures	(191)	(198)	(50)
Animal Health items[4]	(492)	(247)	(245)
Net income attributable to equity holders of Sanofi	**4,287**	**4,390**	**3,716**

(1) The Animal Health business is reported separately in accordance with IFRS 5.

(2) Profit related to the acquisition of Alnylam shares in 2014, reported in the line item Financial Income .

(3) Annual fee related to 2013 sales: the IRS reform of July 2014 altered the date on which the liability is recognized, such that the expense recognized during 2014 was based on both 2013 and 2014 sales.

(4) Includes the following items: impact of the discontinuation of depreciation and impairment of property, plant & equipment with effect from the start date of IFRS 5 application; impact of the amortization and impairment of intangible assets until the start date of IFRS 5 application; costs incurred as a result of the divestment; and the tax effect of those items.

(1) Presented in the income statement line items Restructuring costs , and Other gains and losses, and litigation , as defined in Note B.20. to our consolidated financial statements.

(2) Includes the following items: impact of the discontinuation of depreciation and impairment of property, plant & equipment with effect from the start date of IFRS 5 application (Non-Current Assets Held for Sale and Discontinued Operations); impact of the amortization and impairment of intangible assets until the start date of IFRS 5 application; costs incurred as a result of the divestment; and the tax effect of those items.

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The following table sets forth the calculation of our business net income for the years ended December 31, 2015, 2014 and 2013:

(million)	2015	2014	2013
Business operating income[1]	**9,313**	**8,957**	**8,821**
Business operating income of the Animal Health business[2]	635	492	502
Aggregate financial income and expenses (including the held-for-exchange Animal Health business)	(390)	(447)	(503)
Aggregate income tax expense (including the held-for-exchange Animal Health business)	(2,187)	(2,155)	(2,134)
Business net income	**7,371**	**6,847**	**6,686**

(1) Business operating income from continuing operations.

(2) See Results of Operations Year Ended December 31, 2015 Compared with Year Ended December 31, 2014 Segment results and at Results of Operations Year Ended December 31, 2014 Compared with Year Ended December 31, 2013 Segment results below

The most significant reconciliation items between our business net income and Net income attributable to equity holders of Sanofi relate to the purchase accounting effect of our acquisitions, particularly the amortization and impairment of intangible assets (other than software). We believe that excluding these non-cash charges enhances an investor s understanding of our underlying economic performance because we do not consider that the excluded charges reflect the combined entity s ongoing operating performance. Rather, we believe that each of the excluded charges reflects the decision to acquire the businesses concerned.

The purchase-accounting effects on net income primarily relate to:

- charges related to the amortization and impairment of intangible assets (other than software and other rights of an industrial or operational nature), net of tax and non-controlling interests;
- charges to cost of sales resulting from the workdown of acquired inventories remeasured at fair value, net of tax; and
- charges related to the impairment of goodwill.

We believe (subject to the limitations described below) that disclosing business net income enhances the comparability of our operating performance, for the following reasons:

- the elimination of charges related to the purchase accounting effect of our acquisitions (particularly amortization and impairment of finite-lived intangible assets other than software and other rights of an industrial or operational nature) enhances the comparability of our ongoing operating performance relative to our peers in the pharmaceutical industry that carry these intangible assets (principally patents and trademarks) at low book values either because they are the result of in-house research and development that has already been expensed in prior periods or because they were acquired through business combinations that were accounted for as poolings-of-interest;
- the elimination of selected items, such as the increase in cost of sales arising from the workdown of inventories remeasured at fair value, gains and losses on disposals of non-current assets and costs and provisions associated with major litigation, improves comparability from one period to the next; and

- the elimination of restructuring costs relating to the implementation of our transformation strategy enhances comparability because these costs are directly, and only, incurred in connection with transformation processes such as the rationalization of our research and development structures.

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

There are material limitations associated with the use of business net income as compared to the use of IFRS net income attributable to equity holders of Sanofi in evaluating our performance, as described below:

- The results presented by business net income cannot be achieved without incurring the following costs that the measure excludes:

Amortization of intangible assets. Business net income excludes the amortization charges related to intangible assets (other than software and other rights of an industrial or operational nature). Most of these amortization charges relate to intangible assets that we have acquired. Although amortization is a non-cash charge, it is important for investors to consider it because it represents an allocation in each reporting period of a portion of the purchase price that we paid for certain intangible assets that we have acquired

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through acquisitions. For example, in connection with our acquisition of Aventis in 2004, we paid an aggregate of 31,279 million for these amortizable intangible assets (which, in general, were to be amortized over their useful lives, representing an average amortization period of eight years) and 5,007 million for in-progress research & development. In connection with our acquisition of Genzyme in April 2011, we paid an aggregate of 7,873 million for amortizable intangible assets (average amortization period of eight and a half years) and 2,148 million for in-progress research & development. A large part of our revenues could not be generated without owning acquired intangible assets.

Restructuring costs. Business net income does not reflect restructuring costs even though it does reflect the benefits of the optimization of our activities, such as our research and development activities, much of which we could not achieve in the absence of restructuring costs.

- In addition, the results presented by business net income are intended to represent the Group s underlying performance, but items such as gains and losses on disposals and provisions associated with major litigation may recur in future years.

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

In determining the level of future dividend payments, and in analyzing dividend policy on the basis of business net income, our management intends to take into account the fact that many of the adjustments reflected in business net income have no effect on the underlying amount of cash available to pay dividends. However, although the adjustments relating to the elimination of the effect of the purchase accounting treatment of the Aventis acquisition and other acquisitions represent non-cash charges, the adjustments relating to restructuring costs represent significant cash charges.

This Item 5 contains a discussion and analysis of business net income on the basis of consolidated financial data. Because our business net income is not a standardized measure, it may not be comparable with the non-GAAP financial measures of other companies using the same or a similar non-GAAP financial measure.

Presentation of Net Sales

In the discussion below, we present our consolidated net sales for 2015, 2014 and 2013. We analyze our net sales among various categories, including by business, product

and geographical region. We refer to our consolidated net sales as **reported sales**.

In addition to reported sales, we analyze non-GAAP financial measures designed to (i) include net sales from our Animal Health business in the analysis of the Group s performance and (ii) isolate the impact on our net sales of currency exchange rates and changes in Group structure.

Following the announcement of exclusive negotiations with Boehringer Ingelheim regarding the divestment of our Animal Health business (Merial), the net profit or loss of that business is now presented in a separate line item in the consolidated income statement, Net income/(loss) of the held-for-exchange Animal Health business , in accordance with IFRS 5 (see Note D.36. to our consolidated financial statements included at Item 18 of this annual report). Consequently, the net sales reported in our consolidated income statement do not include the net sales of the Animal Health business.

Until final completion of the transaction, expected in the fourth quarter of 2016, we will continue to monitor the performance of the Animal Health business (which remains an operating segment pursuant to IFRS 8), and to report the performance of that business at Group level. In our analysis of our financial performance for the year ended December 31, 2015 we discuss our **aggregate net sales**, which combines our net sales as reported in the consolidated income statement with the net sales of the Animal Health business, because we believe it provides comparability of our sales performance with prior periods and such sales will continue to be significant in future periods until the transaction is completed. Aggregate net sales is a non-GAAP financial measure.

When we refer to changes in our **net sales at constant exchange rates** (CER), we exclude the effect of exchange rates by recalculating net sales for the relevant period using the exchange rates that were used for the previous period. See Note B.2. to our consolidated financial statements for further information relating to the manner in which we translate into euros transactions recorded in other currencies.

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

- by including sales from an entity or with respect to product rights acquired in the current period for a portion of the previous period equal to the portion of the current period during which we owned them, based on sales information we receive from the party from whom we made the acquisition;

- similarly, by excluding sales for a portion of the previous period when we have sold an entity or rights to a product in the current period; and

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· for a change in consolidation method, by recalculating the previous period on the basis of the method used for the current period.

A reconciliation of (i) our reported net sales to our net sales at constant exchange rates and (ii) our reported net sales to our aggregate net sales and our aggregate net sales at constant exchange rates is provided at Results of Operations Year Ended December 31, 2015 Compared with Year Ended December 31, 2014 Net Sales and at Results of Operations Year Ended December 31, 2014 Compared with Year Ended December 31, 2013 Net Sales below.

Financial Presentation of Alliances

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

The financial impact of the alliances on the Company s income statement is described in Results of Operations Year Ended December 31, 2015 Compared with Year Ended December 31, 2014 and Year Ended December 31, 2014 Compared with Year Ended December 31, 2013 , in particular in Net sales , Other Revenues , Share of Profit/Loss of Associates and Joint Ventures and Net Income Attributable to Non-Controlling Interests .

Alliance Arrangements with Regeneron

Our relationship with Regeneron began in 2003 with an agreement for the co-development of the anti-angiogenic agent Zaltrap®. We expanded our relationship in 2007 with the signature of an Investment Agreement and created a strategic R&D collaboration on fully human monoclonal antibodies. In 2015, the parties further expanded the relationship with the creation of a collaboration for antibodies in the field of immuno-oncology.

Collaboration agreement on Zaltrap® (aflibercept)

Zaltrap® (aflibercept) is a solution administered by intravenous perfusion, used in association with 5-fluorouracil, leucovorin and irinotecan (FOLFIRI) as a treatment for metastatic colorectal cancer that is resistant to or has progressed following an oxaliplatin-containing regimen.

In the United States, Zaltrap® is a registered trademark of Regeneron. The product was approved by the U.S. Food and Drug Administration (FDA) in August 2012, and has been marketed in the United States since that date. Zaltrap® was approved by the European Commission in February 2013, and has been marketed in that territory since then.

The collaboration agreement signed by Sanofi and Regeneron in September 2003 on the development and commercialization of Zaltrap® (aflibercept) was amended and restated in February 2015. That amendment ended Regeneron s obligation to reimburse 50% of the development costs funded by Sanofi. As of December 31, 2014, the balance of outstanding development costs was 0.8 billion.

Collaboration agreement on the discovery, development and commercialization of human therapeutic antibodies

In November 2007, Sanofi and Regeneron signed new agreements (amended in November 2009 and further amended in 2015 in connection with the immuno-oncology agreements described below) for the discovery, development and commercialization of fully human therapeutic antibodies. Under the 2009 amended agreements Sanofi committed to funding the discovery and pre-clinical development of fully human therapeutic antibodies by up to $160 million per year through 2017. Sanofi has an option to develop and commercialize antibodies discovered by Regeneron pursuant to this collaboration. Following the signature in July 2015 of the immuno-oncology collaboration agreement described below, $75 million (spread over three years) was reallocated to that new agreement.

If the option is exercised, Sanofi co-develops the antibody with Regeneron and is responsible for funding. Sanofi and Regeneron share co-promotion rights and profits on sales of the co-developed antibodies. On receipt of the first positive Phase III trial results for any such antibody, the subsequent Phase III costs for that antibody are split 80% Sanofi, 20% Regeneron. Amounts received from Regeneron under those arrangements are recognized by Sanofi as a reduction in the line item Research and development expenses . Once a product begins to be commercialized, and provided that the share of quarterly results under the agreement represents a profit, Sanofi is entitled to an additional profit-share (capped at 10% of Regeneron s share of quarterly profits) until Regeneron has paid 50% of the cumulative development costs incurred by the parties in the collaboration. In addition, Sanofi may be required to make milestone payments based on cumulative sales of all antibodies. As of December 31, 2015, the aggregate development costs incurred by both parties were 3.9 billion (including 2.6 billion funded 100% by Sanofi and 1.3 billion funded 80% by Sanofi and 20% by Regeneron).

On the earlier of (i) 24 months before the launch date or (ii) the first positive Phase III trial result Sanofi and Regeneron will share the commercial expenses of the antibodies jointly developed under the license agreement. Sanofi recognizes all the sales of those antibodies. Profits and losses arising from commercial operations in the United States are split 50/50. Outside the United States,

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Sanofi is entitled to between 55% and 65% of profits depending on sales of the antibodies, and bears 55% of any losses. The share of profits and losses attributable to Regeneron under the agreement is recognized in the line items *Other operating income* or *Other operating expenses*, which are components of operating income. In addition, Regeneron is entitled to receive payments of up to $250 million contingent on the attainment of specified levels of sales outside the United States.

If Sanofi opts not to exercise its license option for an antibody, Sanofi would receive a royalty from Regeneron on sales of that antibody.

Collaboration agreement on the discovery, development and commercialization of antibodies in the field of immuno-oncology

On July 28, 2015, Sanofi and Regeneron announced a new global collaboration to discover, develop and commercialize new antibody cancer treatments in the emerging field of immuno-oncology. As part of the agreement, the two companies will jointly develop a programmed cell death protein 1 (PD-1) inhibitor antibody currently in Phase I testing, and plan to initiate clinical trials in 2016 with new therapeutic candidates based on ongoing, innovative preclinical programs. Sanofi has made an upfront payment of $640 million to Regeneron. The companies will invest approximately $1 billion from discovery through proof of concept (POC) development (usually a Phase IIa study) of monotherapy and novel combinations of immuno-oncology antibody candidates to be funded 25% by Regeneron ($250 million) and 75% by Sanofi ($750 million). Under the terms of the discovery program, Sanofi is entitled to an additional profit-share (capped at 10% of Regeneron s share of quarterly profits) until the progressive payments from Regeneron reach 50% of clinical development costs initially funded by Sanofi.

Sanofi and Regeneron have also committed to equally fund no more than $650 million (or $325 million per company) for development of REGN2810, a PD-1 inhibitor antibody. In addition, Sanofi will make a one-time milestone payment of $375 million to Regeneron in the event that sales of a PD-1 product and any other collaboration antibody sold for use in combination with a PD-1 product were to exceed, in the aggregate, $2 billion in any consecutive 12-month period. Finally, the two companies agreed to reallocate $75 million (spread over three years) to immuno-oncology antibody research and development from Sanofi s $160 million annual contribution to their existing antibody collaboration, which otherwise continues as announced in November 2009. Beyond the committed funding, additional funding will be allocated as programs enter post-POC development.

Investor Agreement

In January 2014, Sanofi and Regeneron amended the investor agreement that has existed between the two

companies since 2007 (the Amended Investor Agreement). Under the terms of the Amended Investor Agreement, Sanofi retains the right to acquire up to 30% of Regeneron s capital stock (consisting of the outstanding shares of common stock and the shares of Class A stock). Having passed the threshold of 20% ownership of the capital stock, Sanofi exercised its right under the Amended Investor Agreement to designate an independent director, who has been appointed to the Board of Directors of Regeneron. The interest held by Sanofi in Regeneron has been consolidated by the equity method since the start of April 2014. In December 2015, Sanofi disclosed its intent to purchase, directly or through its subsidiaries, additional shares of Regeneron Common Stock to maintain and opportunistically increase its beneficial ownership without exceeding the maximum allowed under the Amended Investor Agreement entered into in January 2014 (30% of Shares of Then Outstanding Common Stock, as defined therein). Sanofi made no commitments concerning the price and availability of shares of Common Stock, the timing, or any other factors considered relevant to Sanofi. On December 31, 2015, Sanofi had an equity interest of 22.1% in Regeneron. On the conditions set out in the Amended Investor Agreement entered into in January 2014, Sanofi s right to designate a Regeneron board member is contingent on Sanofi maintaining its percentage share of Regeneron s outstanding capital stock (measured on a quarterly basis) at a level no lower than the highest percentage level previously achieved, with the maximum requirement capped at 25%.

In November 2015, the Independent Designee (as defined in the Amended Investor Agreement) designated by Sanofi as an independent director, resigned from the Regeneron Board of Directors. Sanofi intends to designate a successor pursuant to the Amended Investor Agreement.

The Amended Investor Agreement also gives Sanofi the right to receive certain reasonable information as may be agreed upon by the parties and which will facilitate Sanofi s ability to account for their investment in the Company using the equity method of accounting under International Financial Reporting Standards.

Alliance Arrangements with Bristol-Myers Squibb (BMS)

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

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

Under the terms of this amended agreement, which took effect on January 1, 2013, BMS returned to Sanofi its rights

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to Plavix® and Avapro®/Avalide® in all markets worldwide with the exception of Plavix® in the United States and Puerto Rico, giving Sanofi sole control and freedom to operate commercially in respect of those products. In exchange, starting January 1, 2013 through December 31, 2018 BMS receives royalty payments on Sanofi s sales of branded and unbranded Plavix® and Avapro®/Avalide® worldwide (except for Plavix® in the United States and Puerto Rico), and will also receive a terminal payment of $200 million from Sanofi in December 2018, part of which will be used to buy out the non-controlling interests. Rights to Plavix® in the United States and Puerto Rico remain unchanged and continue to be governed by the terms of the original alliance agreements until December 10, 2019.

In all of the territories managed by Sanofi (including the United States and Puerto Rico for Avapro®/Avalide®) as defined in the new agreement, Sanofi recognizes in its consolidated financial statements the revenue and expenses generated by its own operations. The share of profits reverting to BMS subsidiaries is presented within *Net income attributable to non-controlling interests* in the income statement.

In the territory managed by BMS (United States and Puerto Rico for Plavix®), Sanofi recognizes its share of profits and losses within the line item *Share of profit/(loss) of associates and joint ventures* .

Impact of Exchange Rates

We report our consolidated financial statements in euros. Because we earn a significant portion of our revenues in countries where the euro is not the local currency, our results of operations can be significantly affected by exchange rate movements between the euro and other currencies, primarily the U.S. dollar and, to a lesser extent, the Japanese yen, and currencies in emerging countries. We experience these effects even though certain of these countries do not account for a large portion of our net sales. In 2015, we earned 35.5% of our net sales (36.2% of our aggregate net sales) in the United States. An increase in the value of the U.S. dollar against the euro has a positive impact on both our revenues and our operating income. A decrease in the value of the U.S. dollar against the euro has a negative impact on our revenues, which is not offset by an equal reduction in our costs and therefore negatively affects our operating income. A variation in the value of the U.S. dollar has a particularly significant impact on our operating income, which is higher in the United States than elsewhere,

and on the contribution to net income of our collaborations with Regeneron and BMS in the United States (see Financial Presentation of Alliances above).

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

Divestments

There were no material divestments in 2015 and 2014.

In 2013, Sanofi sold its U.S. commercial rights of five pharmaceutical products to Covis Pharmaceuticals, Inc. The gain on this sale amounted to 165 million.

Acquisitions

- The impact of acquisitions in 2015 on our consolidated financial statements is not material.

- The principal acquisitions during 2014 are described below:

In 2014, Sanofi acquired 7 million shares of Regeneron. As of December 31, 2014, Sanofi held 22.3% of the company s share capital (versus 15.9% on December 31, 2013). The acquisition price amounted to 1,629 million. See Note D.1.1. to our consolidated financial statements included at Item 18 of this annual report.

The impact of other acquisitions in 2014 on our consolidated financial statements is not material.

- The principal acquisitions during 2013 are described below:

In March 2013, Sanofi acquired Genfar S.A. (Genfar), a Colombian pharmaceutical company that is a significant player in Colombia and other countries in Latin America. Genfar is the second-largest generics manufacturer in Colombia by sales, with annual sales around 100 million.

In June 2013, Merial announced the completion of its acquisition of the animal health division of the Indian company Dosch Pharmaceuticals Private Limited, which markets 86 animal health products and 50 specialities for ruminants, poultry and companion animals.

Other than Genfar, the impact of these acquisitions on our consolidated financial statements is not material.

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Results of Operations

Year Ended December 31, 2015 Compared with Year Ended December 31, 2014

The consolidated income statements for the years ended December 31, 2015 and December 31, 2014 are presented below:

(under IFRS)		**as % of**		**as % of**
(million)	**2015[1]**	**net sales**	**2014[1]**	**net sales**
Net sales	**34,542**	**100.0%**	**31,694**	**100.0%**
Other revenues	319	0.9%	305	1.0%
Cost of sales	(10,919)	(31.6%)	(10,230)	(32.3%)
Gross profit	**23,942**	**69.3%**	**21,769**	**68.7%**
Research & development expenses	(5,082)	(14.7%)	(4,667)	(14.7%)
Selling & general expenses	(9,382)	(27.2%)	(8,425)	(26.6%)
Other operating income	254		301	
Other operating expenses	(462)		(157)	
Amortization of intangible assets	(2,137)		(2,081)	
Impairment of intangible assets	(767)		31	
Fair value remeasurement of contingent consideration liabilities	53		(303)	
Restructuring costs	(795)		(404)	
Other gains and losses, and litigation	-		-	
Operating income	**5,624**	**16.3%**	**6,064**	**19.1%**
Financial expenses	(559)		(598)	
Financial income	178		192	
Income before tax and associates and joint ventures	**5,243**	**15.2%**	**5,658**	**17.9%**
Income tax expense	(709)		(1,214)	
Share of profit/(loss) of associates and joint ventures	(22)		(52)	
Net income excluding the held-for-exchange Animal Health business[1]	**4,512**	**13.1%**	**4,392**	**13.9%**
Net income/(loss) of the held-for-exchange Animal Health business	(124)		117	
Net income	**4,388**	**12.7%**	**4,509**	**14.2%**
Net income attributable to non-controlling interests	101		119	
Net income attributable to equity holders of Sanofi	**4,287**	**12.4%**	**4,390**	**13.9%**
Average number of shares outstanding (million)	1,306.2		1,315.8	
Average number of shares outstanding after dilution (million)	1,320.7		1,331.1	
Basic earnings per share (in euros)	3.28		3.34	
Basic earnings per share excluding the held-for-exchange Animal Health business (in euros)	3.38		3.25	
Diluted earnings per share (in euros)	3.25		3.30	
Diluted earnings per share excluding the held-for-exchange Animal Health business(in euros)	3.34		3.21	

(1) The results of the Animal Health business are presented separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations); refer to Notes D.2.1. and D.36. to our consolidated financial statements included at Item 18 of this annual report.

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Net Sales

Net sales for the year ended December 31, 2015 were 34,542 million, 9.0% higher than in 2014. Exchange rate movements had a favorable effect of 7.4 percentage points. At constant exchange rates, net sales rose by 1.6% year-on-year.

The following table sets forth a reconciliation of our reported net sales for the years ended December 31, 2015 and December 31, 2014 to our net sales at constant exchange rates:

(million)	2015	2014	Change
Net sales	**34,542**	**31,694**	**+9.0%**
Effect of exchange rates	(2,334)		
Net sales at constant exchange rates (CER)	**32,208**	**31,694**	**+1.6%**

Net Sales by business

Our net sales comprise the net sales generated by our Pharmaceuticals and Human Vaccines (Vaccines) segments, in accordance with IFRS 5.

Following the announcement of exclusive negotiations with Boehringer Ingelheim regarding the divestment of our Animal Health business (Merial), the net profit or loss of that business is now presented in a separate line item in the consolidated income statement, Net income/(loss) of the held-for-exchange Animal Health business , in accordance with IFRS 5 (see Notes D.2.1. and D.36. to our consolidated financial statements included at Item 18 of this annual report). Consequently, the net sales reported in our consolidated income statement do not include the net sales of the Animal Health business.

Until final completion of the transaction, expected in the fourth quarter of 2016, we will continue to monitor the

performance of the Animal Health business (which remains an operating segment pursuant to IFRS 8), and to report the performance of that business at the Group level. In our analysis of our financial performance for the year ended December 31, 2015 we discuss our aggregate net sales, which combines our net sales as reported in the consolidated income statement with the net sales of the Animal Health business. Aggregate net sales is a non-GAAP financial measure.

Aggregate net sales for the year were 37,057 million, 9.7% higher than in 2014. Exchange rate movements had a favorable effect of 7.5 percentage points, mainly reflecting the appreciation of the U.S. dollar and the Chinese yuan renminbi against the euro, which more than compensated for the unfavorable effects of the Russian rouble and Brazilian real. At constant exchange rates, aggregate net sales rose by 2.2% year-on-year.

The following table sets forth a reconciliation of our net sales for the years ended December 31, 2015 and December 31, 2014 to our aggregate net sales at constant exchange rates:

(million)	2015	2014	Change
Net sales[1]	**34,542**	**31,694**	**+9.0%**
Net sales of the Animal Health business[2]	2,515	2,076	+21.1%
Aggregate net sales	**37,057**	**33,770**	**+9.7%**
Effect of exchange rates	(2,549)		
Aggregate net sales at constant exchange rates (CER)	**34,508**	**33,770**	**+2.2%**

(1) In accordance with the presentation requirements of IFRS 5, the consolidated income statement line item Net sales does not include the net sales of the Animal Health business.

(2) Presented in a separate income statement line item Net income/(loss) of the held-for-exchange Animal Health business , in accordance with IFRS 5.

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The following table sets forth our 2015 and 2014 net sales by operating segment, along with our aggregate net sales including the net sales of the Animal Health business (which remains an operating segment pursuant to IFRS 8).

(million)	2015	2014	Change	Change at constant exchange rates
Pharmaceuticals	29,799	27,720	+7.5%	+0.8%
Vaccines	4,743	3,974	+19.4%	+7.3%
Net sales[1]	**34,542**	**31,694**	**+9.0%**	**+1.6%**
Animal Health[2]	2,515	2,076	+21.1%	+10.8%
Aggregate net sales	**37,057**	**33,770**	**+9.7%**	**+2.2%**

(1) In accordance with the presentation requirements of IFRS 5, the consolidated income statement line item Net sales does not include the net sales of the Animal Health business.

(2) Presented in a separate income statement line item Net income/(loss) of the held-for-exchange Animal Health business , in accordance with IFRS 5.

Net Sales by Product Pharmaceuticals segment

In 2015, net sales for the Pharmaceuticals segment were 29,799 million, up 7.5% on a reported basis and 0.8% at constant exchange rates (CER). The year-on-year increase of 2,079 million includes favorable exchange rate effects of 1,854 million, along with the following main effects at constant exchange rates:

- growth in net sales for Genzyme (up 768 million), Generics (up 138 million), and Consumer Health Care (up 92 million);
- lower net sales for the Diabetes division (down 496 million) and for established prescription products (down 259 million).

Our flagship Pharmaceuticals segment products are discussed below.

The following table presents 2015 and 2014 net sales for the Pharmaceuticals segment by product:

(million)	Indication	2015	2014	Change on	Change at

Product		Reported	Reported	a reported basis	constant exchange rates
Lantus®	Diabetes	6,390	6,344	+0.7%	-10.8%
Amaryl®	Diabetes	393	360	+9.2%	+1.7%
Apidra®	Diabetes	376	336	+11.9%	+4.8%
Toujeo®	Diabetes	164	-	-	-
Insuman®	Diabetes	141	137	+2.9%	+2.9%
Blood glucose monitoring (BGM)	Diabetes	63	64	-1.6%	-1.6%
Lyxumia®	Diabetes	38	27	+40.7%	+37.0%
Afrezza®	Diabetes	7	-	-	-
Other diabetes products		8	5	+60,0 %	+60,0 %
Total: Diabetes		**7,580**	**7,273**	**+4.2%**	**-6.8%**
Jevtana®	Prostate cancer	321	273	+17.6%	+9.5%
Thymoglobulin®	Organ rejection	256	217	+18.0%	+6.0%
Eloxatin®	Colorectal cancer	227	210	+8.1%	-0.5%
Taxotere®	Breast, lung, prostate, stomach, and head & neck cancer	222	266	-16.5%	-22.2%
Mozobil®	Hematologic malignancies	143	111	+28.8%	+16.2%
Zaltrap®	Colorectal cancer	77	69	+11.6%	+5.8%
Other oncology products		258	255	+1.2%	-10.6%
Total: Oncology		**1,504**	**1,401**	**+7.4%**	**-1.9%**

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(*million*)		2015	2014	Change on a reported	Change at constant
Product	**Indication**	**Reported**	**Reported**	**basis**	**exchange rates**
Cerezyme®	Gaucher disease	757	715	+5.9%	+1.3%
Cerdelga®	Gaucher disease	66	4	-	-
Myozyme® /Lumizyme®	Pompe disease	650	542	+19.9%	+12.4%
Fabrazyme®	Fabry disease	592	460	+28.7%	+17.2%
Aldurazyme®	Mucopolysaccharidosis	195	172	+13.4%	+8.7%
Other rare diseases products		290	244	+18.9%	+8.6%
Sub-total: Rare diseases		**2,550**	**2,137**	**+19.3%**	**+11.4%**
Aubagio®	Multiple sclerosis	871	433	+101.2%	+77.8%
Lemtrada®	Multiple sclerosis	243	34	+614.7%	+550.0%
Sub-total: Multiple sclerosis		**1,114**	**467**	**+138.5%**	**+112.2%**
Total: Genzyme		**3,664**	**2,604**	**+40.7%**	**+29.5%**
Plavix®	Atherothrombosis	1,929	1,862	+3.6%	-4.1%
Lovenox®	Thrombosis	1,719	1,699	+1.2%	-0.5%
Renagel® /Renvela®	Hyperphosphatemia	935	684	+36.7%	+18.9%
Aprovel® /CoAprovel®	Hypertension	762	727	+4.8%	-3.7%
Allegra®	Allergic rhinitis, urticaria	194	192	+1.0%	-3.6%
Myslee® /Ambien®/Stilnox®	Sleep disorders	306	306	0.0%	-6.2%
Synvisc® /Synvisc-One®	Arthritis	413	352	+17.3%	+2.3%
Multaq®	Atrial fibrillation	341	290	+17.6%	+0.7%
Depakine®	Epilepsy	422	395	+6.8%	+2.8%
Tritace®	Hypertension	274	281	-2.5%	-3.9%
Lasix®	Edema, hypertension	162	164	-1.2%	-3.7%
Targocid®	Bacterial infections	160	162	-1.2%	-4.3%
Orudis®	Rheumatoid arthritis, osteoarthritis	156	160	-2.5%	+3.8%
Cordarone®	Arrhythmia	130	129	+0.8%	-0.8%
Xatral®	Benign prostatic hypertrophy	95	94	+1.1%	-3.2%
Actonel®	Osteoporosis, Paget s disease	23	82	-72.0%	-70.7%
Auvi-Q® /Allerject®	Severe allergies, anaphylaxis	(5)	72	-106.9%	-113.9%
Other prescription products		3,617	3,649	-0.9%	-3.0%
Total: established prescription products		**11,633**	**11,300**	**+2.9%**	**-2.3%**
Praluent®	Hypercholesterolemia	9	-	-	-
Consumer Health Care		**3,492**	**3,337**	**+4.6%**	**+2.8%**
Generics		**1,917**	**1,805**	**+6.2%**	**+7.6%**
Total: Pharmaceuticals		**29,799**	**27,720**	**+7.5%**	**+0.8%**

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Diabetes division

Net sales for the **Diabetes** division were 7,580 million, down 6.8% CER, mainly due to lower sales of Lantus® in the United States. In the United States, Diabetes division net sales totaled 4,316 million, down 17.3% CER. Outside the United States, the division posted 8.9% net sales growth CER, to 3,264 million. The effects of a strong performance in Emerging Markets[1] (+16.4% CER, at 1,627 million) were attenuated by slower sales growth in Western Europe (+2.9% CER, at 1,189 million), mainly on the entry of a biosimilar of insulin glargine into the market in the second half of the year.

Net sales for the **glargine franchise** (Lantus® and Toujeo®) fell by 8.5% CER to 6,554 million.

Net sales of **Lantus®** were 10.8% lower CER in 2015, at 6,390 million. This decline in net sales of Lantus® during 2015 reflected higher volumes (+4.6%), but also a generally unfavorable price effect (-15.4% CER), primarily in the United States. Net sales in the United States decreased by 20.5% CER to 4,023 million, due mainly to three factors: slower growth in the basal insulins market, further rises in the level of rebates compared with 2014, and the fact that a higher proportion of sales passed through governmental channels such as Medicaid. In Emerging Markets, sales increased by 17.3% CER to 1,137 million, driven by growth in China, the Middle East and Latin America. In Western Europe, where a biosimilar of Lantus® was launched in the second half of 2015, net sales growth was modest (+1.8% CER).

Toujeo®, a new-generation basal insulin which saw its first launches in 2015 (late March in the United States, from April onwards in Western Europe, and subsequently in Japan and Canada), posted net sales of 164 million, including 137 million in the United States.

For 2016, we anticipate a generally favorable trend in prescription rates for the glargine franchise. In the medium to long term, trends in Lantus® volumes will depend on various factors such as the number of new rival products reaching the market (including biosimilars in Emerging Markets) and the level of volume growth for Toujeo®. Specifically as regards Lantus® in the United States, in September 2015 we reached an out-of-court settlement with Lilly, who agreed not to sell their insulin glargine before December 15, 2016 (see Impacts from generic competition above).

We expect that the high level of rebates in the United States will perpetuate an unfavorable price effect on sales of Lantus® in 2016. Over the longer term, we are unable to predict price effects in the diabetes market, which will be dictated by the impact of new rival products on the price of diabetes treatments across all regions.

Net sales of **Apidra®** totaled 376 million in 2015, up 4.8% CER, reflecting a strong performance in Emerging Markets (+23.3% CER, at 89 million) but lower sales in the United States (-7.6% CER, at 145 million).

Net sales of **Amaryl®** rose by 1.7% CER to 393 million. On the upside, Emerging Markets performed well (+7.6% CER, at 319 million), but sales were affected by generic competition in Japan (-18.5% CER, at 46 million).

Based on latest market trends, we forecast that overall net sales for the Diabetes division will decline at an average annualized rate in a range from 4% to 8% CER over the period from 2015 through 2018. However, actual net sales may differ from these forecasts given the many assumptions on which our projections are based.

For comments regarding Afrezza®, refer to Item 4. Information on the Company B.2. Main Pharmaceutical Products a) Diabetes Solutions Afrezza® .

Oncology business

Net sales for the **Oncology** business were 1,504 million, down 1.9% CER. Good performances from Jevtana® and Mozobil® were offset by the impact of generic versions of Taxotere® in Japan.

Net sales of **Jevtana®** totaled 321 million in 2015, up 9.5% CER, driven by a strong performance in the United States (+16.5% CER, at 127 million) and by sales in Japan (+533.3% CER, at 20 million) where the product was launched in September 2014.

Net sales of **Thymoglobulin®** rose by 6.0% CER to 256 million, as sales advanced in the United States (+12.0% CER, at 145 million) but fell in Emerging Markets (-5.1% CER, at 56 million).

Taxotere® saw net sales fall sharply by 22.2% CER, to 222 million. The product is facing competition from generics in Emerging Markets (-7.7% CER, at 142 million) and in Japan (-34.5% CER, at 60 million).

Eloxatin® net sales decreased by 0.5% CER to 227 million, hit by a sharp decline in U.S. sales (-68.2% CER, at 9 million) but boosted by growth in Emerging Markets (+14.6% CER, at 130 million), especially in China.

Net sales of **Mozobil®** reached 143 million, up 16.2% CER, mainly on sales growth in the United States (+11.3% CER, at 83 million).

Zaltrap® (aflibercept, developed in collaboration with Regeneron) recorded net sales of 77 million, up 5.8% CER. A surge in sales in Western Europe (+32.4% CER, at

(1) World excluding United States, Canada, Western Europe, Japan, South Korea, Australia and New Zealand.

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49 million) following recent launches more than offset lower sales in the United States (-37.0% CER, at 21 million).

Genzyme business

The **Genzyme** business generated net sales of 3,664 million, up 29.5% CER, driven by a solid performance from Aubagio® and the ongoing launch of Lemtrada®.

In Gaucher disease, net sales of **Cerezyme®** advanced by 1.3% CER to 757 million, as strong growth in Emerging Markets (+10.3% CER, at 263 million) more than compensated for lower sales in the United States (-9.1% CER, at 201 million) due to the launch of Cerdelga® in September 2014. **Cerdelga®** reported net sales of 66 million, of which 60 million were generated in the United States.

Net sales of **Myozyme®/Lumizyme®** rose by 12.4% CER to 650 million, driven by further growth in patient numbers in the United States (+20.4% CER, at 205 million) and Emerging Markets (+18.3% CER, at 112 million).

Fabrazyme® achieved net sales growth of 17.2% CER, to 592 million. The product reported growth in all regions on a rise in the number of patients treated, with notable performances in the United States (+14.3% CER, at 305 million), Western Europe (+19.1% CER, at 133 million) and Emerging Markets (+25.4% CER, at 71 million).

The Multiple Sclerosis franchise generated net sales of 1,114 million, up 112.2% CER year-on-year. Net sales of **Aubagio®** surged by 77.8% CER in 2015 to 871 million. In the United States, net sales reached 618 million, up 59.2% CER. In Western Europe, the product continued to extend its geographical reach, and full-year net sales rose by 130.1% CER at 192 million. Net sales of **Lemtrada®** amounted to 243 million (+550.0% CER), including 89 million in Western Europe (mainly in Germany and the United Kingdom) and 128 million in the United States, where the product was launched at the end of 2014.

Established prescription products

Net sales of **Plavix®** declined by 4.1% CER to 1,929 million, impacted by generic competition in Western Europe (-22.6% CER, at 169 million) and also, from June 2015, in Japan (-12.5% CER, at 695 million). In Emerging Markets, Plavix® reported net sales growth of 9.2% CER to 1,006 million, driven by China (+13.1% CER, at 660 million). Sales of Plavix® in the United States and Puerto Rico are handled by BMS under the terms of the Sanofi-BMS alliance (see Financial presentation of alliances Alliance Arrangements with Bristol-Myers Squibb above).

Full-year net sales of **Lovenox®** were virtually unchanged in 2015, slipping just 0.5% CER to 1,719 million. Net sales in Western Europe also saw little change year-on-year, rising by 0.4% CER to 909 million. Lower net sales in the United States due to generic competition (-50.8% CER, at

77 million) were offset by a good performance in Emerging Markets (+8.8% CER, at 638 million), especially in Latin America and Africa. Sales of the generic version of Lovenox® launched by Sanofi in 2012 are recorded by our Generics business (see below).

Net sales of **Renagel®/Renvela®** rose by 18.9% CER to 935 million on a strong performance in the United States (+30.8% CER, at 723 million), reflecting reduced competition from Impax which for a few months beginning April 2014 had the right to sell a limited number of authorized generics of Renvela®. In Western Europe, sales fell year-on-year (-17.3% CER, at 111 million) as a result of competition from generics. We are still anticipating possible approvals of generics in the United States in 2016.

Aprovel®/Avapro® reported a drop in net sales of 3.7% CER to 762 million, mainly as a result of competition from generics in Western Europe, where sales fell by 25.3% CER to 143 million. Net sales in Emerging Markets rose by 8.2% CER to 465 million, mainly on a good performance in China.

Net sales of Auvi-Q®/Allerject® (epinephrine auto-injectors) fell by 113.9% CER to negative 5 million (versus positive 72 million in 2014) due to the voluntary recall in October 2015 of all batches of the product marketed in the United States and Canada. This recall had a negative effect of 122 million on net sales, largely as a result of the reversal of all sales of the product since the start of 2015. It was discovered that the product could potentially have inaccurate dosage delivery, which may include failure to deliver the drug. Sanofi has ultimately decided to return all U.S. and Canadian rights to Auvi-Q® to the developer of Auvi-Q®.

We have no comments on sales of our other established prescription products.

Praluent®

Praluent® reported net sales of 9 million, mainly in the United States where the product was launched in July 2015.

Consumer Health Care business

Net sales for the **Consumer Health Care** business rose by 2.8% CER in 2015 to 3,492 million. The main growth drivers were the United States (+6.1% CER, at 902 million) largely due to a strong performance from Allegra® OTC following the launch of a new formulation, and Australia/New Zealand (+18.5% CER, at 191 million).

Net sales in Emerging Markets reached 1,672 million, up 1.6% CER, as lower sales in Brazil and Eurasia/Middle East were more than offset by growth in Central and Eastern Europe, Asia and Africa. In Western Europe, net sales fell by 1.8% CER to 668 million, as French sales of Doliprane® fell following two price cuts in January 2015 and November 2015. In the Rest of the World region, net sales rose by 15.9% CER to 250 million, reflecting good performances in Australia/New Zealand.

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The following table breaks down our 2015 and 2014 net sales for the Consumer Health Care business by product:

(million)	2015	2014	Change on a reported basis	Change at constant exchange rates
Product	**Reported**	**Reported**		
Allegra®	424	350	+21.1%	+8.0%
Doliprane®	303	310	-2.3%	-2.3%
Essentiale®	196	235	-16.6%	-6.4%
Enterogermina®	161	156	+3.2%	1.3%
Nasacort®	122	114	+7.0%	-8.8%
No Spa®	88	109	-19.3%	-5.5%
Lactacyd®	114	104	+9.6%	+10.6%
Maalox®	97	98	-1.0%	+4.1%
Dorflex®	81	90	-10.0%	+6.7%
Magné B6®	82	88	-6.8%	+9.1%
Other products	1,824	1,683	+8.4%	+4.2%
Total: Consumer Health Care	**3,492**	**3,337**	**+4.6%**	**+2.8%**

Generics business

The **Generics** business recorded 2015 net sales of 1,917 million, up 7.6% (CER).

In Emerging Markets, the Generics business generated net sales of 1,094 million, a rise of 5.2% CER, driven by Eurasia/Middle East and Venezuela. Net sales in Western Europe increased by 4.1% CER to 569 million, boosted by a good performance in Germany. In the United States, net

sales advanced by 15.4% CER to 171 million, mainly due to increased sales of the authorized generic of Lovenox®. In the Rest of the World region, net sales rose by 90.7% CER to 83 million, due mainly to the performance in Japan of the authorized generic of Allegra® and of the authorized generic of Plavix® launched by Sanofi and our partner Nichi-Iko Pharmaceuticals Co., Ltd at the end of the second quarter of 2015.

The following table presents the 2015 net sales of our Pharmaceutical segment products by region:

(*million*)	Western Europe[1]	Change at constant exchange rates	United States	Change at constant exchange rates	Emerging Markets[2]	Change at constant exchange rates	Rest of the world[3]	Change at constant exchange rates
Product	**Reported**		**Reported**		**Reported**		**Reported**	
Lantus®	898	+1.8%	4,023	-20.5%	1,137	+17.3%	332	+1.3%
Amaryl®	16	-15.8%	2	-50.0%	319	+7.6%	56	-16.1%
Apidra®	104	+6.1%	145	-7.6%	89	+23.3%	38	+8.8%
Toujeo®	14	-	137	-	9	-	4	-
Insuman®	76	-8.5%	2	+100.0%	63	+20.4%	-	-
Blood glucose monitoring (BGM)	59	+1.7%	-	-	2	-33.3%	2	-33.3%
Lyxumia®	22	+40.0%	-	-	7	+75.0%	9	+12.5%
Afrezza®	-	-	7	-	-	-	-	-
Other diabetes products	-	-	-	-	1	0.0%	7	+75.0%
Total: Diabetes	**1,189**	**+2.9%**	**4,316**	**-17.3%**	**1,627**	**+16.4%**	**448**	**+0.9%**
Jevtana®	135	-5.6%	127	+16.5%	33	+3.0%	26	+257.1%
Thymoglobulin®	36	+9.4%	145	+12.0%	56	-5.1%	19	0.0%
Eloxatin®	4	-20.0%	9	-68.2%	130	+14.6%	84	0.0%
Taxotere®	6	-60.0%	(1)	-112.5%	142	-7.7%	75	-30.0%
Mozobil®	38	+8.8%	83	+11.3%	15	+45.4%	7	+75.0%
Zaltrap®	49	+32.4%	21	-37.0%	7	+40.0%	-	-
Other oncology products	51	-9.1%	162	-10.6%	23	-24.1%	22	+5.0%
Total: Oncology	**319**	**-1.6%**	**546**	**-3.2%**	**406**	**+0.5%**	**233**	**-3.5%**

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(million)	Western Europe[1]	Change at constant exchange rates	United States	Change at constant exchange rates	Emerging Markets[2]	Change at constant exchange rates	Rest of the world[3]	Change at constant exchange rates
Product	**Reported**		**Reported**		**Reported**		**Reported**	
Cerezyme®	245	+0.8%	201	-9.1%	263	+10.3%	48	-2.2%
Cerdelga®	6	-	60	-	-	-	-	-
Myozyme® /Lumizyme®	289	+5.2%	205	+20.4%	112	+18.3%	44	+18.9%
Fabrazyme®	133	+19.1%	305	+14.3%	71	+25.4%	83	+16.2%
Aldurazyme®	70	+6.3%	40	0.0%	63	+20.4%	22	0.0%
Other rare diseases products	46	+9.3%	114	+9.0%	40	+25.8%	90	+1.2%
Sub-total Rare diseases	**789**	**+7.0%**	**925**	**+14.5%**	**549**	**+15.9%**	**287**	**+7.5%**
Aubagio®	192	+130.1%	618	+59.2%	29	+190.0%	32	+121.4%
Lemtrada®	89	+210.7%	128	-	12	+500,0%	14	+600.0%
Sub-total Multiple sclerosis	**281**	**+150.5%**	**746**	**+91.2%**	**41**	**+241.7%**	**46**	**+181.3%**
Total: Genzyme	**1,070**	**+26.0%**	**1,671**	**+39.5%**	**590**	**+21.4%**	**333**	**+17.8%**
Plavix®	169	-22.6%	1*	0.0%	1,006	+9.2%	753	-12.6%
Lovenox®	909	+0.4%	77	-50.8%	638	+8.8%	95	+3.3%
Renagel® /Renvela®	111	-17.3%	723	+30.8%	77	+12.3%	24	+4.5%
Aprovel® /CoAprovel®	143	-25.3%	15*	-33.3%	465	+8.2%	139	-3.8%
Allegra®	10	-10.0%	-	-	1	-50.0%	183	-2.8%
Myslee® /Ambien®/Stilnox®	38	-5.0%	74	-16.2%	63	+8.8%	131	-7.4%
Synvisc® /Synvisc-One®	29	+3.6%	322	-1.5%	49	+23.1%	13	+18.2%
Multaq®	41	-6.8%	287	+2.1%	10	+12.5%	3	-33.3%
Depakine®	141	-1.4%	-	-	267	+6.3%	14	-12.5%
Tritace®	118	-7.9%	-	-	151	+2.1%	5	-44.4%
Lasix®	75	-5.1%	3	-33.3%	58	+7.8%	26	-15.6%
Targocid®	80	-6.0%	-	-	72	0.0%	8	-22.2%
Orudis®	17	-6.0%	-	-	135	+5.8%	4	+33.3%
Cordarone®	23	-4.2%	-	-	75	+7.1%	32	-14.3%
Xatral®	36	-5.3%	-	-	54	-3.8%	5	+25.0%
Actonel®	1	-94.1%	-	-	15	-51.4%	7	-80.0%
Auvi-Q® /Allerject®	3	+50.0%	(6)	-118.0%	-	-	(2)	-122.2%
Other prescription products	1,533	-1.9%	314	-23.0%	1,414	+3.5%	356	-12.9%
Total: established prescription products	**3,477**	**-5.3%**	**1,810**	**-5.7%**	**4,550**	**+5.9%**	**1,796**	**-11.4%**
Praluent®	1	-	9	-	-	-	(1)	-
Consumer Health Care	**668**	**-1.8%**	**902**	**+6.1%**	**1,672**	**+1.6%**	**250**	**15.9%**
Generics	**569**	**+4.1%**	**171**	**+15.4%**	**1,094**	**+5.2%**	**83**	**+90.7%**
Total: Pharmaceuticals	**7,293**	**+0.9%**	**9,425**	**-4.8%**	**9,939**	**+7.1%**	**3,142**	**-3.3%**

(1) France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark.

(2) World excluding United States, Canada, Western Europe, Japan, South Korea, Australia and New Zealand.

(3) Japan, South Korea, Canada, Australia and New Zealand.

** Sales of active ingredient to the entity majority-owned by BMS in the United States.*

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Net Sales Human Vaccines (Vaccines) segment

In 2015, net sales for the Vaccines segment were 4,743 million, up 19.4% on a reported basis and 7.3% at constant exchange rates (CER). Year-on-year growth was driven by sales of Polio/Pertussis/Hib vaccines in Emerging Markets, and in the United States by sales of Menactra® and the performance of VaxServe (a Sanofi Pasteur company that distributes vaccines in the United States).

The table below sets forth 2015 and 2014 net sales of our Vaccines segment by product range:

(million)	2015 Reported	2014 Reported	Change on a reported basis	Change at constant exchange rates
Polio/Pertussis/Hib Vaccines (*including Pentacel® and Pentaxim®*)	1,348	1,154	+16.8%	+8.1%
Influenza Vaccines (*including Vaxigrip® and Fluzone®*)	1,322	1,178	+12.2%	+2.0%
Meningitis/Pneumonia Vaccines (*including Menactra®*)	614	454	+35.2%	+16.7%
Adult Booster Vaccines (*including Adacel®*)	496	398	+24.6%	+10.1%
Travel and Other Endemics Vaccines	375	377	-0.5%	-6.9%
VaxServe	481	314	+53.2%	+28.7%
Other Vaccines	107	99	+8.1%	-8.1%
Total: Vaccines	**4,743**	**3,974**	**+19.4%**	**+7.3%**

Net sales of **Polio/Pertussis/Hib** vaccines rose by 8.1% CER to 1,348 million, boosted by the performances of Pentaxim® and Hexaxim®. Net sales in Emerging Markets grew strongly by 32.8% CER to 791 million, due to sales of Pentaxim® and polio vaccines in China. The Shan5 pentavalent pediatric vaccines generated net sales of 33 million, mainly to world healthcare organizations. In the United States, sales declined by 20.2% CER to 393 million, due to lower sales of Pentacel® caused by manufacturing delays.

Net sales of **Influenza** vaccines rose by 2.0% CER to 1,322 million. Sales were strong in the United States (+11.8% CER, at 896 million), reinforcing Sanofi Pasteur s differentiation strategy in influenza vaccines. In Emerging Markets, sales declined by 15.0% CER to 302 million, due mainly to shipment delays in Brazil and Mexico.

Net sales of **Meningitis/Pneumonia** vaccines reached 614 million, up 16.7% CER. Menactra® generated net sales of 563 million, up 18.2% CER, driven by public-sector sales in the United States.

Adult booster vaccines net sales increased by 10.1% CER to 496 million, as strong performances in the United States

(+9.8% CER, at 360 million) and Emerging Markets (+35.4% CER, at 65 million) more than offset lower sales in Western Europe (-13.6% CER, at 51 million) due to the timing of shipments.

Net sales of **Travel and Other Endemics** vaccines declined by 6.9% CER to 375 million.

VaxServe, a Sanofi Pasteur company that distributes vaccines in the United States, posted net sales growth of 28.7% CER to 481 million.

Net sales of **Other Vaccines** declined by 8.1% CER to 107 million.

In addition to the Vaccines activity reflected in our consolidated net sales, sales generated by Sanofi Pasteur MSD, our joint venture with Merck in Europe, fell by 2.8% on a reported basis in 2015 to 824 million. The main factors were a decline in sales of Gardasil® (-11.7% on a reported basis) and Adult Booster vaccines (-16.5% on a reported basis), partly offset by a good performance from hepatitis A vaccines. Sales generated by Sanofi Pasteur MSD are not included in our consolidated net sales.

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The following table presents the 2015 net sales of our Vaccines segment by product range and by region:

(*million*)	Western Europe[1] Reported	Change at constant exchange rates	United States Reported	Change at constant exchange rates	Emerging Markets[2] Reported	Change at constant exchange rates	Rest of the world[3] Reported	Change at constant exchange rates
Polio/Pertussis/Hib Vaccines								
(*inc. Pentacel® and Pentaxim®*)	36	+50.0%	393	-20.2%	791	+32.8%	128	-16.4%
Influenza Vaccines								
(*inc. Vaxigrip® and Fluzone®*)	89	-4.3%	896	+11.8%	302	-15.0%	35	-2.7%
Meningitis/Pneumonia Vaccines								
(*inc. Menactra®*)	2	-33.3%	496	+15.0%	108	+29.3%	8	-11.1%
Adult Booster Vaccines								
(*inc. Adacel®*)	51	-13.6%	360	+9.8%	65	+35.4%	20	+26.7%
Travel and Other Endemics Vaccines	22	+4.8%	111	-2.1%	188	-11.2%	54	-3.6%
VaxServe	-	-	481	+28.7%	-	-	-	-
Other Vaccines	3	-25.0%	84	-10.0%	7	-25.0%	13	+42.9%
Total: Vaccines	**203**	**-0.5%**	**2,821**	**+7.2%**	**1,461**	**+11.9%**	**258**	**-7.8%**

(1) *France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark. Net sales in Europe generated by Sanofi Pasteur MSD (our joint venture between Sanofi and Merck) are not included in our consolidated net sales.*

(2) *World excluding United States, Canada, Western Europe, Japan, South Korea, Australia and New Zealand.*

(3) *Japan, South Korea, Canada, Australia and New Zealand.*

Net Sales Animal Health segment

Following the announcement of exclusive negotiations with Boehringer Ingelheim regarding the divestment of our Animal Health business (Merial), the net profit or loss of that business is now presented in a separate line item in the consolidated income statement, Net income/(loss) of the held-for-exchange Animal Health business , in accordance with IFRS 5 (see Notes D.2.1. and D.36. to our consolidated financial statements included at Item 18 of this annual report). Consequently, the net sales reported in our consolidated income statement do not include the net sales of the Animal Health business.

Until final completion of the transaction, which is subject to execution of definitive agreements and thereafter to regulatory clearances, expected in the fourth quarter of 2016, we will continue to monitor the performance of the Animal Health business (which remains an operating segment), and to report the performance of that business at Group level.

Net sales for the Animal Health segment in 2015 amounted to 2,515 million, up 21.1% on a reported basis and 10.8% CER.

The following table presents the 2015 and 2014 net sales of our Animal Health segment[1] by product range:

(million)	2015	2014	Change	Change at constant exchange rates
Companion animals	1,629	1,281	+27.2%	+13.1%
Production animals	886	795	+11.4%	+7.0%
Total: Animal Health[1]	**2,515**	**2,076**	**+21.1%**	**+10.8%**
Of which vaccines	*804*	*720*	*+11.7%*	*+5.7%*
Of which fipronil-based products	*627*	*597*	*+5.0%*	*-4.5%*
Of which avermectin-based products	*498*	*398*	*+25.1%*	*+11.1%*
Of which other products	*586*	*361*	*+62.3%*	*+46.0%*

(1) Presented in the income statement line item Net income/(loss) of the held-for-exchange Animal Health business , in accordance with IFRS 5.

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Net sales for the **Companion Animals** franchise rose by 13.1% CER to 1,629 million, reflecting the resilience of the **fipronil**-based products (-4.5% CER, at 627 million) in the face of competition and the success of **NexGard®**, a new product launched in 2014 that generated 288 million in net sales in 2015 (+122.1% CER).

Sales of **Production Animals** franchise products rose by 7.0% CER to 886 million, driven by growth in products for ruminants in the United States and avian products in Emerging Markets.

The following table presents the 2015 sales of our Animal Health segment by product range and by region:

(million)	Western Europe[1]	Change at constant exchange rates	United States	Change at constant exchange rates	Emerging Markets[2]	Change at constant exchange rates	Rest of The World[3]	Change at constant exchange rates
Product	**Reported**		**Reported**		**Reported**		**Reported**	
Vaccines	187	+0.5%	195	+5.2%	361	+5.7%	61	+28.9%
Fipronil-based products	183	-0.6%	301	-8.5%	110	+7.8%	33	-26.2%
Avermectin-based products	49	-10.9%	320	+18.2%	58	+11.3%	71	+4.6%
Other products	111	+15.1%	344	+53.5%	85	+36.5%	46	+161.1%
Total: Animal Health	**530**	**+1.6%**	**1,160**	**+15.0%**	**614**	**+10.1%**	**211**	**+20.0%**

(1) France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark.

(2) World excluding United States, Canada, Western Europe, Japan, South Korea, Australia and New Zealand.

(3) Japan, South Korea, Canada, Australia and New Zealand.

Net Sales and Aggregate Net Sales by Geographical Region

We divide our sales geographically into four regions: the United States, Emerging Markets, Western Europe and the Rest of the World. The following table presents our 2015 and 2014 net sales by region:

(million)	**2015**	**2014**	**Change on**	**Change at**
	Reported	**Reported**		

			a reported basis	constant exchange rates
United States	12,246	10,500	+16.6%	-2.2%
Emerging Markets[1]	11,400	10,469	+8.9%	+7.7%
Of which Eastern Europe and Turkey	*2,366*	*2,484*	*-4.8%*	*+5.1%*
Of which Asia (excl. Pacific region)	*3,536*	*2,724*	*+29.8%*	*+13.3%*
Of which Latin America	*3,047*	*3,113*	*-2.1%*	*+3.8%*
Of which Africa & Middle-East	*2,222*	*2,006*	*+10.8%*	*+6.8%*
Western Europe[2]	7,496	7,351	+2.0%	+0.9%
Rest of the World[3]	3,400	3,374	+0.8%	-3.6%
Of which Japan	*2,034*	*2,083*	-2.4%	-7,2%
Total net sales	**34,542**	**31,694**	**+9,0%**	**+1,6%**

(1) World excluding United States, Canada, Western Europe, Japan, South Korea, Australia and New Zealand.

(2) France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark.

(3) Japan, South Korea, Canada, Australia and New Zealand.

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The following table presents our 2015 and 2014 aggregate net sales (including the Animal Health business) by region:

(million)	**2015**	**2014**	**Change**	**Change at constant exchange rates**
United States	13,406	11,339	+18.2%	-1.0%
Emerging Markets[1]	12,014	11,022	+9.0%	+7.8%
Of which Eastern Europe and Turkey	*2,429*	*2,541*	*-4.4%*	*+5.4%*
Of which Asia (excl. Pacific region)	*3,732*	*2,881*	*+29.5%*	*+13.2%*
Of which Latin America	*3,305*	*3,363*	*-1.7%*	*+4.0%*
Of which Africa & Middle-East	*2,319*	*2,095*	*+10.7%*	*+6.8%*
Western Europe[2]	8,026	7,865	+2.0%	+0.9%
Rest of the World[3]	3,611	3,544	+1.9%	-2.5%
Of which Japan	2,082	2,119	-1.7%	-6.6%
Total aggregate net sales	**37,057**	**33,770**	**+9.7%**	**+2.2%**

(1) World excluding United States, Canada, Western Europe, Japan, South Korea, Australia and New Zealand.

(2) France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark.

(3) Japan, South Korea, Canada, Australia and New Zealand.

In the United States, net sales declined by 2.2% CER to 12,246 million. Aggregate net sales declined by 1.0% CER to 13,406 million, reflecting reduced sales for the Diabetes division (-17.3% CER), though the effect was partly offset by solid performances by Genzyme (+39.5% CER), Vaccines (+7.2% CER) and Animal Health (+15.0% CER).

In Emerging Markets, net sales reached 11,400 million, up 7.7% CER. Aggregate net sales reached 12,014 million, up 7.8% CER, driven by Diabetes (+16.4% CER), Genzyme (+21.4% CER), Vaccines (+11.9% CER) and Animal Health (+10.1% CER).

Aggregate net sales in Latin America advanced by 4.0% CER to 3,305 million. Growth was boosted by a favorable sequence of purchases in the local market in Venezuela (+22.2% CER, at 457 million), but hampered by Brazil (-6.2% CER, at 1,112 million) due to lower influenza vaccine sales. In Asia, aggregate net sales rose by 13.2% CER to 3,732 million. Aggregate net sales in China reached 2,218 million, up 19.5% CER, reflecting good performances in Diabetes and Vaccines (on strong sales of polio vaccines), and also in established prescription products (especially Plavix®). The Eastern Europe/Turkey region saw aggregate net sales rise by 5.4% CER to 2,429 million, mainly in Diabetes, Generics and Vaccines. Growth in Turkey reached 15.7% CER (to 461 million), while aggregate net sales in Russia declined by 2.8% CER to

596 million due to adverse economic conditions.

Net sales in Western Europe rose by 0.9% CER to 7,496 million. Aggregate net sales rose by 0.9% CER to 8,026 million. The effects of ongoing generic competition for Plavix® and Aprovel® were more than compensated for by

the performances of the Genzyme business (+26.0% CER) and the Diabetes division (+2.9% CER).

In the Rest of the World region, net sales amounted to 3,400 million, down 3.6% CER. Aggregate net sales amounted to 3,611 million, down 2.5% CER. Lower sales of established prescription products (-11.4% CER) and in Vaccines (-7.8% CER) were not fully offset by positive performances from Genzyme, Generics, Consumer Health Care and Animal Health. In Japan, aggregate net sales totaled 2,082 million (-6.6% CER) due to the adverse impact of competition from generics of Taxotere®, Myslee® and Amaryl® combined with lower polio vaccine sales, partly compensated for by good performances in Generics and Animal Health.

Presentation of net sales by business from 2016 onwards

With effect from January 2016, we are streamlining our organization and rolling out our new structure, based on five Global Business Units (GBUs): General Medicines & Emerging Markets, Sanofi Genzyme (Specialty Care), Diabetes & Cardiovascular, Sanofi Pasteur (Vaccines), and Merial (Animal Health). To help investors better understand the net sales figures that we will report under this new structure from 2016 onwards, the tables below present net sales by GBU and geographical region for 2015 and 2014.

Details of our five new GBUs are as follows:

The General Medicines & Emerging Markets GBU brings together our established prescription products (except Multaq®, which has been reclassified to the Diabetes & Cardiovascular GBU); our Consumer Health Care and

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Generics businesses, the scope of which is unchanged; and the Emerging Markets net sales (and only those net sales) of our Diabetes & Cardiovascular and Sanofi Genzyme businesses.

The Sanofi Genzyme GBU combines the net sales of our Oncology, Multiple Sclerosis and Rare Diseases business generated anywhere in the world other than in Emerging Markets.

The Diabetes & Cardiovascular GBU brings together the net sales of our Diabetes business generated anywhere in the world other than Emerging Markets, and the net sales of our Cardiovascular business (comprising sales of Praluent® and Multaq®) generated anywhere in the world other than in Emerging Markets.

The sum total of the net sales of those three GBUs corresponds to the net sales of our Pharmaceuticals segment.

The Vaccines and Animal Health GBUs correspond to our existing Vaccines and Animal Health segments.

We are also making the following changes to geographical regions, starting January 2016:

- the new Europe zone will include both Western Europe and Eastern Europe (excluding Eurasia);
- the Emerging Markets zone will exclude mature countries in Eastern Europe, but retain the Eurasian countries; and
- the Rest of the World zone will now also include Puerto Rico, formerly included in the United States zone.

Following the announcement on December 15, 2015 that we had opened exclusive negotiations with Boehringer Ingelheim with a view to the divestment of our Animal Health business (Merial), Merial s contribution to our net income is now presented in a separate line item, Net income/(loss) of the held-for-exchange Animal Health business , in accordance with IFRS 5 (see Notes D.2.1. and D.36. to our consolidated financial statements included at Item 18 of our annual report). Consequently, the net sales reported in our consolidated income statement do not include the net sales of the Animal Health business (see Net sales by business segment above).

In our analysis of our financial performance for the year ended December 31, 2015 we discuss our aggregate net sales (a non-GAAP financial measure), which combines our net sales as reported in the consolidated income statement with the net sales of the Animal Health business.

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The following table presents our 2015 and 2014 aggregate net sales by Global Business Unit:

(million)	2015	2014	Change	Change at constant exchange rates
Total Established Prescription Products[1]	11,292	11,010	+2.6%	-2.4%
Consumer Health Care	3,492	3,337	+4.6%	+2.8%
Generics	1,917	1,805	+6.2%	+7.6%
Total Emerging Markets[7] Diabetes & Cardiovascular	1,413	1,168	+21.0%	+16.5%
Total Emerging Markets[7] Sanofi Genzyme	893	777	+14.9%	+12.7%
General Medicines & Emerging Markets GBU[7]	**19,007**	**18,097**	**+5.0%**	**+1.4%**
Total Oncology[2]	1,120	1,040	+7.7%	-2.5%
Total Multiple Sclerosis[3]	1,080	456	+136.8%	+109.9%
Total Rare Diseases[4]	2,075	1,732	+19.8%	+9.7%
Sanofi Genzyme GBU[8]	**4,275**	**3 228**	**+32.4%**	**+19.9%**
Total Diabetes[5]	6,173	6,110	+1.0%	-11.3%
Total Cardiovascular[6]	344	285	+20.7%	+3.5%
Diabetes & Cardiovascular GBU[8]	**6,517**	**6,395**	**+1.9%**	**-10.6%**
Total Pharmaceuticals	**29,799**	**27,720**	**+7.5%**	**+0.8%**
Vaccines GBU	**4,743**	**3,974**	**+19.4%**	**+7.3%**
Total net sales	**34,542**	**31,694**	**+9.0%**	**+1.6%**
Animal Health GBU	**2,515**	**2,076**	**+21.1%**	**+10.8%**
Total aggregate net sales	**37,057**	**33,770**	**+9.7%**	**+2.2%**

(1) Plavix®, Lovenox®, Renagel®/Renvela®, Aprovel®, Allegra®, Stilnox®/Ambien®/Myslee® , Synvisc®/Synvisc-One®, Depakine®, Tritace®, Lasix®, Targocid®, Orudis®, Cordarone®, Xatral® and other prescription products.

(2) Taxotere®, Jevtana®, Eloxatin®, Thymoglobulin®, Mozobil®, Zaltrap® and other oncology products.

(3) Aubagio® and Lemtrada®.

(4) Cerezyme®, Cerdelga®, Myozyme®, Fabrazyme®, Aldurazyme® and other rare diseases products.

(5) Lantus®, Apidra®, Amaryl®, Insuman®, Lyxumia®, Afrezza®, Toujeo® and other diabetes products.

(6) Praluent® and Multaq®.

(7) World excluding United States, Canada, Western & Eastern Europe (apart from Russia, Ukraine, Georgia, Belarus, Armenia and Turkey), Japan, South Korea, Australia, New Zealand and Puerto Rico.

(8) Excluding Emerging Markets.

The table below shows the allocation of our 2015 and 2014 net sales to our new geographical regions:

(million)	**2015 Reported**	**2014 Reported**	**Change on a reported basis**	**Change at constant exchange rates**
United States	12,246	10,500	+16.6%	-2.2%
Emerging Markets[1]	10,072	9,240	+9.0%	+7.8%
Of which Latin America	*3,047*	*3,113*	*-2.1%*	*+3.8%*
Of which Asia (excluding South Asia)	*3,101*	*2,375*	*+30.6%*	*+13.9%*
Of which Africa, Middle-East and South Asia	*2,657*	*2,354*	*+12.9%*	*+7.1%*
Of which Eurasia[2]	*1,132*	*1,324*	*-14.5%*	*+4.0%*
Europe[3]	8,729	8,511	+2.6%	+1.6%
Rest of the World[4]	3,495	3,443	+1.5%	-3.3%
Of which Japan	*2,034*	*2,083*	*-2.4%*	*-7.2%*
Total net sales	**34,542**	**31,694**	**+9.0%**	**+1.6%**

(1) World excluding United States, Canada, Western & Eastern Europe (apart from Eurasia), Japan, South Korea, Australia, New Zealand and Puerto Rico.
(2) Russia, Ukraine, Georgia, Belarus, Armenia and Turkey.
(3) Western Europe and Eastern Europe except Eurasia.
(4) Japan, South Korea, Canada, Australia, New Zealand and Puerto Rico.

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The table below shows the allocation of our 2015 and 2014 aggregate net sales to our new geographical regions:

(million)	2015	2014	Change	Change at constant exchange rates
United States	13,406	11,339	+18.2%	-1.0%
Emerging Markets[1]	10,646	9,757	+9.1%	+8.0%
Of which Latin America	*3,305*	*3,363*	*-1.7%*	*+4.0%*
Of which Asia (excluding South Asia)	*3,288*	*2,529*	*+30.0%*	*+13.7%*
Of which Africa, Middle-East and South Asia	*2,763*	*2,449*	*+12.8%*	*+7.2%*
Of which Eurasia[2]	*1,156*	*1,344*	*-14.0%*	*+4.7%*
Europe[3]	9,299	9,062	+2.6%	+1.6%
Rest of the World[4]	3,706	3,612	+2.6%	-2.1%
Of which Japan	*2,082*	*2,119*	*-1.7%*	*-6.6%*
Total aggregate net sales	**37,057**	**33,770**	**+9.7%**	**+2.2%**

(1) World excluding United States, Canada, Western & Eastern Europe (apart from Eurasia), Japan, South Korea, Australia, New Zealand and Puerto Rico.

(2) Russia, Ukraine, Georgia, Belarus, Armenia and Turkey.

(3) Western Europe and Eastern Europe except Eurasia.

(4) Japan, South Korea, Canada, Australia, New Zealand and Puerto Rico.

Other Revenues

Other revenues, which mainly comprise royalties under licensing agreements contracted in connection with continuing operations, amounted to 319 million (compared with 305 million in 2014).

Aggregate other revenues (including the Animal Health business) were up 6.2% at 360 million (versus 339 million in 2014) reflecting: (i) favorable currency effects and (ii) a decline in royalties received from Amgen on sales of Enbrel® in the United States.

Gross Profit

Gross profit reached 23,942 million in 2015 (69.3% of net sales), versus 21,769 million in 2014 (68.7% of net sales).

Aggregate gross profit (including the Animal Health business) was 25,613 million in 2015 (69.1% of aggregate net sales), versus 23,080 million in 2014 (68.3% of aggregate net sales). This represents a year-on-year increase of 11.0%, and equates to an improvement of 0.8 of a percentage point in the gross margin ratio based on aggregate net sales.

The gross margin ratio for the Pharmaceuticals segment was 0.4 of a percentage point higher at 71.5%. The main factor was an improvement in the ratio of cost of sales to net sales, due largely to the favorable effect of exchange rates. Other factors included a positive impact from the Genzyme business and a negative impact from the Diabetes division in the United States.

The gross margin ratio for the Vaccines segment rose by 3.9 percentage points to 55.7%, reflecting a more favorable product mix and favorable exchange rate effects.

The gross margin ratio for the Animal Health segment increased by 3.2 percentage points to 66.4%, mainly as a result of favorable exchange rate effects.

Research and Development Expenses

Research and development (R&D) expenses amounted to 5,082 million in 2015, compared with 4,667 million in 2014.

Aggregate R&D expenses (including the Animal Health business) totaled 5,259 million in 2015 (versus 4,824 million in 2014) and represented 14.2% of aggregate net sales (versus 14.3% in 2014). The overall year-on-year increase of 435 million (9.0%) included 356 million for the Pharmaceuticals segment (+8.5%), 59 million for the Vaccines segment (+12.0%) and 20 million for the Animal Health segment (+12.7%).

The majority of this increase was attributable to the adverse impact of exchange rates. At constant exchange rates, aggregate R&D expenses rose only modestly, reflecting increased expenditure on dupilumab and Praluent® and the initiation of the new alliance with Regeneron in immuno-oncology in the second half of 2015.

Selling and General Expenses

Selling and general expenses totaled 9,382 million in 2015, compared with 8,425 million in 2014.

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Aggregate selling and general expenses (including the Animal Health business) reached 10,247 million (27.7% of aggregate net sales), compared with 8,991 million in 2014 (26.6% of aggregate net sales). This represents a year-on-year rise of 1,256 million (14.0%).

By segment, the year on-year increase was 964 million (+12.5%) for Pharmaceuticals, 112 million (+18.2%) for Vaccines and 183 million (+26.8%) for Animal Health. In addition to unfavorable exchange rate effects, the overall increase also reflects investment in new product launches in the Genzyme business (multiple sclerosis), Diabetes, Animal Health, and Cardiovascular (Praluent®).

Other Operating Income and Expenses

In 2015, other operating income totaled 254 million (versus 301 million in 2014), and other operating expenses 462 million (versus 157 million in 2014).

On an aggregate basis (including the Animal Health business), other operating income and expenses represented an overall net expense of 203 million in 2015, compared with overall net income of 164 million in 2014. This year-on-year adverse movement of 367 million was attributable mainly to the operating foreign exchange loss on our Venezuelan operations, which reached 240 million in 2015 compared with 47 million in 2014 (see Note D.26. to our consolidated financial statements included at Item 18 of this annual report).

This item also included gains on disposal amounting to 145 million in 2015 on an aggregate basis (versus 229 million in 2014), mainly on intangible assets in the United States.

Amortization of Intangible Assets

Amortization charged against intangible assets totaled 2,137 million in 2015, versus 2,081 million in 2014.

This overall year-on-year increase of 56 million reflects a number of factors: (i) an increase in amortization charged against the intangible assets recognized on the acquisition of Genzyme (890 million in 2015, versus 811 million in 2014), due to new product launches and unfavorable exchange rate effects; (ii) the amortization in full, in December 2015, of a priority review voucher acquired in May 2015 for $245 million and used for the filing of a new drug application with the FDA for LixiLan; and (iii) a reduction in amortization charged against the intangible assets recognized on the acquisition of Aventis (637 million in 2015, versus 874 million in 2014) as some products reached the end of their life cycles.

Impairment of Intangible Assets

In 2015, this line item showed impairment losses of 767 million against intangible assets, versus a net reversal of 31 million in 2014.

In 2015, this line item includes (i) a net impairment loss of 340 million on research projects in the Pharmaceuticals and Vaccines segments, primarily Synvisc-One® in osteoarthritis of the hip and the rotavirus vaccine project (Shantha); and (ii) impairment losses of 427 million taken against rights relating to a number of marketed products in the Pharmaceuticals segment, mainly Afrezza® in the United States (following termination of the license and collaboration agreement with MannKind Corporation) and Auvi-Q®/Allerject® in the United States and Canada (following the voluntary recall of this product in the fourth quarter of 2015).

The 2014 figure includes a gain of 356 million arising because the impairment loss taken in 2013 against Lemtrada® (alemtuzumab) was reversed following approval of the product by the FDA in November 2014. It also includes the negative effects of (i) a net impairment loss of 203 million arising from various research projects in Pharmaceuticals and Vaccines, in particular the discontinuation of collaborative development programs with Alopexx (SAR 279 356) and Kalobios (*Pseudomonas aeruginosa* vaccine), and from revised commercial prospects

(especially for the rotavirus vaccine project); and (ii) the impairment losses of 123 million taken against rights to a number of marketed products in the Pharmaceuticals and Vaccines segments (mainly Consumer Health Care assets in the Emerging Markets region).

Fair Value Remeasurement of Contingent Consideration Liabilities

Fair value remeasurements of contingent consideration liabilities recognized on acquisitions in accordance with the revised IFRS 3 represented a net gain of 53 million in 2015, versus a net expense of 303 million in 2014.

These remeasurements mainly relate to the contingent consideration payable to Bayer as a result of an acquisition made by Genzyme prior to the latter s acquisition by Sanofi, and to the contingent value rights (CVRs) issued by Sanofi in connection with the Genzyme acquisition (see Note D.18. to our consolidated financial statements included at Item 18 of this annual report).

Restructuring Costs

Restructuring costs amounted to 795 million in 2015, compared with 404 million in 2014.

In 2015, restructuring costs related mainly to (i) employee-related expenses arising from headcount adjustment plans in the United States and the rest of the world; (ii) the reorganization of the Group s R&D activities, especially in France following signature of the agreement with Evotec; and (iii) impairment losses taken against industrial assets in Europe. In 2014, these costs mainly comprised employee-related expenses arising from headcount adjustment plans in

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France and the rest of Europe. See Note D.27. to our consolidated financial statements included at Item 18 of this annual report.

Other Gains and Losses, and Litigation

Nothing was recognized on this line in either 2015 or 2014.

Operating Income

Operating income totaled 5,624 million for 2015, compared with 6,064 million for 2014. The year-on-year decline of 7.3% was attributable mainly to the higher levels of research and development expenses, selling and general expenses, impairment of intangible assets and restructuring costs, which were not wholly offset by the growth in net sales and gross profit.

Financial Income and Expenses

Net financial expenses for 2015 were 381 million, compared with 406 million for 2014. Aggregate net financial expenses (including the Animal Health business) were 390 million in 2015, against 412 million in 2014, a decrease of 22 million.

On an aggregate basis (including the Animal Health business), financial expenses directly related to our debt, net of cash and cash equivalents (see definition in Consolidated Balance sheet and debt below) amounted to 281 million in 2015, versus 293 million in 2014, reflecting a slight reduction in the cost of our debt.

Interest expenses relating to post-employment benefit obligations, on an aggregate basis including the Animal Health business, amounted to 115 million in 2015 and 142 million in 2014.

Income before Tax and Associates and Joint Ventures

Income before tax and associates and joint ventures amounted to 5,243 million in 2015, versus 5,658 million in 2014, a fall of 7.3%.

Income Tax Expense

Income tax expense represented 709 million in 2015, versus 1,214 million in 2014, giving an effective tax rate (based on consolidated net income) of 13.5% in 2015, versus 21.5% in 2014 (see Note D.30. to our consolidated financial statements included at Item 18 of this annual report).

The level of income tax expense was significantly impacted by the positive tax effects arising on the amortization and impairment of intangible assets (1,019 million in 2015, versus 546 million in 2014) and on restructuring costs (273 million in 2015, versus 141 million in 2014). In addition, the tax effect of the fair value remeasurement of

contingent consideration liabilities represented a gain of 39 million in 2015, compared with a gain of 254 million in 2014. Overall, these effects reduced our income tax expense by 403 million.

The effective tax rate based on our business net income is calculated on the basis of business operating income minus net financial expenses and before the share of profit/loss of associates and joint ventures and net income attributable to non-controlling interests, but after adding back the business operating income of the Animal Health business (before the share of profit/loss of associates and joint ventures and net income attributable to non-controlling interests for that business) and after subtracting net financial expenses for that business. This effective tax rate was 23.0% in 2015 and 24.0% in 2014. The main impacts on this tax rate are the geographical mix of the results from Group entities, the tax

effects of the elimination of intragroup margin on inventory, and settlements of recent proceedings involving the tax authorities in various countries that had a positive effect in 2014. In 2015, there was also a favorable effect as a result of changes in the taxation of dividends in France following a ruling by the Court of Justice of the European Union and the resulting amendments to the 2015 Finance Act.

Share of Profit/Loss of Associates and Joint Ventures

Associates and joint ventures contributed a net loss of 22 million in 2015, versus a net loss of 52 million in 2014.

Beginning April 2014, this line item includes our share of the profits and losses of Regeneron (impact: losses of 54 million in 2015, and 126 million in 2014), including the impact of the fair value remeasurement of our share of the acquired intangible assets of Regeneron. It also includes our share of after-tax profits from territories managed by BMS under the Plavix® and Avapro® alliance (36 million in 2015, versus 31 million in 2014), plus immaterial amounts for our share of profits and losses from other associates and joint ventures.

Net Income Excluding the Held-For-Exchange Animal Health Business

Net income excluding the held-for-exchange Animal Health business amounted to 4,512 million in 2015, versus 4,392 million in 2014.

Net Income/(Loss) of the Held-For-Exchange Animal Health Business

In accordance with IFRS 5, the net income or loss of the Animal Health business is presented in a separate line item, Net income/(loss) of the held-for-exchange Animal Health business (see Notes D.2.1. and D.36. to our consolidated financial statements included at Item 18 of this annual report). This business reported a net loss of 124 million in

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2015, compared with net income of 117 million in 2014. In 2015, this line item includes income tax expense of 149 million arising from taxable temporary differences relating to holdings in subsidiaries, because it has become probable that those differences will reverse.

Net Income

Net income amounted to 4,388 million in 2015, compared with 4,509 million in 2014.

Net Income Attributable to Non-Controlling Interests

Net income attributable to non-controlling interests was 101 million in 2015, versus 119 million in 2014. This line mainly comprises the share of pre-tax profits paid to BMS from territories managed by Sanofi (94 million, versus 109 million in 2014). The year-on-year decrease was directly related to competition from generics of clopidogrel (active ingredient of Plavix®) and irbesartan (active ingredient of Aprovel®) in Europe.

Net Income Attributable to Equity Holders of Sanofi

Net income attributable to equity holders of Sanofi amounted to 4,287 million, versus 4,390 million in 2014.

Basic earnings per share for 2015 was 3.28, 1.8% lower than the 2014 figure of 3.34, based on an average number of shares outstanding of 1,306.2 million in 2015 (1,315.8 million in 2014). Diluted earnings per share for 2015 was 3.25, 1.5% lower than the 2014 figure of 3.30), based on an average number of shares outstanding after dilution of 1,320.7 million in 2015 and 1,331.1 million in 2014.

Segment results

We report segment results on the basis of Business Operating Income . This indicator, adopted in compliance with IFRS 8, is used internally to measure operational performance and to allocate resources. See Segment information above for the definition of business operating income and a reconciliation to Income before tax and associates and joint ventures.

Business Operating Income

Business operating income amounted to 9,313 million in 2015, 4.0% higher than in 2014 (8,957 million) and represented 27.0% of net sales, versus 28.3% in 2014.

Business operating income for 2015 and 2014 is set forth below:

(million)	2015	2014	Change
Pharmaceuticals	8,013	8,018	-0.1%
Vaccines	1,414	994	+42.3%
Other	(114)	(55)	-107.3%
Business operating income[1]	**9,313**	**8,957**	**+4.0%**
Animal Health business[2]	635	492	+29.1%

Total: aggregated basis[3]	**9,948**	**9,449**	**+5.3%**

(1) Business operating income from continuing operations.

(2) The net income/(loss) of the Animal Health business is presented in a separate income statement line item, Net income/(loss) of the held-for-exchange Animal Health business , in accordance with IFRS 5. Until final completion of the transaction, the Animal Health business remains an operating segment of the Group pursuant to IFRS 8 (see Notes D.2.1. and D.36. to our consolidated financial statements included at Item 18 of this annual report).

(3) Non-GAAP financial measure.

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The following table presents our segment results for the year ended December 31, 2015:

(million)	Pharmaceuticals	Vaccines	Other	Total Group	Animal Health[1]	Total: aggregated basis[2]
Net sales	**29,799**	**4,743**	**-**	**34,542**	**2,515**	**37,057**
Other revenues	288	31	-	319	41	360
Cost of sales	(8,788)	(2,131)	-	(10,919)	(885)	(11,804)
Research and development expenses	(4,530)	(552)	-	(5,082)	(177)	(5,259)
Selling and general expenses	(8,656)	(726)	-	(9,382)	(865)	(10,247)
Other operating income and expenses	(121)	27	(114)	(208)	5	(203)
Share of profit/(loss) of associates and joint ventures	146	23	-	169	1	170
Net income attributable to non-controlling interests	(125)	(1)	-	(126)	-	(126)
Business operating income	**8,013**	**1,414**	**(114)**	**9,313**	**635**	**9,948**

(1) The net income/loss of the Animal Health business is presented in a separate income statements line item, Net income/(loss) of the held-for-exchange Animal Health business for 2015 and prior years, in accordance with IFRS 5. Until final completion of the transaction, the Animal Health business remains an operating segment of the Group pursuant to IFRS 8 (see Notes D.2.1. and D.36. to our consolidated financial statements included at Item 18 of this annual report).

(2) Non-GAAP financial measure which includes the Animal Health business.

The following table presents our segment results for the year ended December 31, 2014:

(million)	Pharmaceuticals	Vaccines	Other	Total Group	Animal Health[1]	Total: aggregated basis[2]
Net sales	**27,720**	**3,974**		**31,694**	**2,076**	**33,770**
Other revenues	272	33	-	305	34	339
Cost of sales	(8,282)	(1,948)	-	(10,230)	(799)	(11,029)
Research and development expenses	(4,174)	(493)	-	(4,667)	(157)	(4,824)
Selling and general expenses	(7,692)	(614)	(3)	(8,309)	(682)	(8,991)
Other operating income and expenses	194	2	(52)	144	20	164
Share of profit/(loss) of associates and joint ventures	106	40	-	146	1	147
Net income attributable to non-controlling interests	(126)	-	-	(126)	(1)	(127)
Business operating income	**8,018**	**994**	**(55)**	**8,957**	**492**	**9,449**

(1) The net income/loss of the Animal Health business is presented in a separate income statement line item, Net income/(loss) of the held-for-exchange Animal Health business for 2015 and prior years, in accordance with IFRS 5. Until final completion of the transaction, the Animal Health business remains an operating segment of the Group pursuant to IFRS 8 (see Notes D.2.1. and D.36. to our consolidated financial statements included at Item 18 of this annual

report).

(2) Non-GAAP financial measure which includes the Animal Health business.

Business Net Income

Business net income is a non-GAAP financial measure that we use to evaluate our Group s performance. See Business Net Income above for the definition of business net income and a reconciliation to Net income attributable to equity holders of Sanofi.

Business net income totaled 7,371 million in 2015, versus 6,847 million in 2014, an increase of 7.7%; it represented 21.3% of net sales in 2015 (19.9% of aggregate net sales) versus 21.6% of net sales in 2014 (20.3% of aggregate net sales).

Business Earnings Per Share

We also report business earnings per share, a non-GAAP financial measure which we define as business net income divided by the weighted average number of shares outstanding (see Business Net Income above).

Business earnings per share was 5.64 in 2015, 8.5% higher than the 2014 figure of 5.20, based on an average number of shares outstanding of 1,306.2 million in 2015 and 1,315.8 million in 2014.

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Year Ended December 31, 2014 Compared with Year Ended December 31, 2013

The consolidated income statements for the years ended December 31, 2014 and December 31, 2013 break down as follows:

(under IFRS)		**as % of**		**as % of**
(million)	**2014[1]**	**net sales**	**2013[1]**	**net sales**
Net sales	**31,694**	**100.0%**	**30,966**	**100.0%**
Other revenues	305	1.0%	325	1.0%
Cost of sales	(10,230)	(32.3%)	(10,302)	(33.2%)
Gross profit	**21,769**	**68.7%**	**20,989**	**67.8%**
Research & development expenses	(4,667)	(14.7%)	(4,605)	(14.9%)
Selling & general expenses	(8,425)	(26.6%)	(7,950)	(25.7%)
Other operating income	301		691	
Other operating expenses	(157)		(240)	
Amortization of intangible assets	(2,081)		(2,527)	
Impairment of intangible assets	31		(1,387)	
Fair value remeasurement of contingent consideration liabilities	(303)		314	
Restructuring costs	(404)		(303)	
Other gains and losses, and litigation	-		-	
Operating income	**6,064**	**19.1%**	**4,982**	**16.1%**
Financial expenses	(598)		(609)	
Financial income	192		111	
Income before tax and associates and joint ventures	**5,658**	**17.9%**	**4,484**	**14.5%**
Income tax expense	(1,214)		(726)	
Share of profit/(loss) of associates and joint ventures	(52)		39	
Net income excluding the held-for-exchange Animal Health business[1]	**4,392**	**13.9%**	**3,797**	**12.3%**
Net income/(loss) of the held-for-exchange Animal Health business	117		77	
Net income	**4,509**	**14.2%**	**3,874**	**12.5%**
Net income attributable to non-controlling interests	119		158	
Net income attributable to equity holders of Sanofi	**4,390**	**13.9%**	**3,716**	**12.0%**
Average number of shares outstanding (million)	1,315.8		1,323.1	
Average number of shares outstanding after dilution (million)	1,331.1		1,339.1	
Basic earnings per share (in euros)	3.34		2.81	
Basic earnings per share excluding the held-for-exchange Animal Health business (in euros)	3.25		2.75	
Diluted earnings per share (in euros)	3.30		2.77	
Diluted earnings per share excluding the held-for-exchange Animal Health business(in euros)	3.21		2.72	

(1) The results of the Animal Health business are presented separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations); refer to Notes D.2.1. and D.36. to our consolidated financial statements included at Item 18 of this annual report.

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Net Sales

Net sales for the year ended December 31, 2014 amounted to 31,694 million, 2.4% higher than in 2013. Exchange rate movements had an unfavorable effect of 2.4 percentage points, mainly reflecting the depreciation of the Japanese yen, the Russian rouble, the Brazilian real and the Argentine peso against the euro. At constant exchange rates, net sales rose by 4.8% year-on-year.

The following table sets forth a reconciliation of our reported net sales for the years ended December 31, 2014 and December 31, 2013 to our net sales at constant exchange rates:

(million)	2014	2013	Change
Net sales	**31,694**	**30,966**	**+2.4%**
Effect of exchange rates	750		
Net sales at constant exchange rates (CER)	**32,444**	**30,966**	**+4.8%**

Net Sales by business

Our net sales comprise the net sales generated by our Pharmaceuticals and Human Vaccines (Vaccines) segments, in accordance with IFRS 5.

Following the announcement of exclusive negotiations with Boehringer Ingelheim regarding the divestment of our Animal Health business (Merial), the net profit or loss of that business is now presented in a separate line item in the consolidated income statement, Net income/(loss) of the held-for-exchange Animal Health business , in accordance with IFRS 5 (see Note D.36. to our consolidated financial statements included at Item 18 of this annual report). Consequently, the net sales reported in our consolidated income statement do not include the net sales of the Animal Health business.

Until final completion of the transaction, expected in the fourth quarter of 2016, we will continue to monitor the

performance of the Animal Health business (which remains an operating segment pursuant to IFRS 8), and to report the performance of that business at Group level. In our analysis of our financial performance for the year ended December 31, 2014 we discuss our aggregate net sales, which combines our net sales as reported in the consolidated income statement with the net sales of the Animal Health business. Aggregate net sales is a non-GAAP financial measure.

Aggregate net sales for the year were 33,770 million, 2.5% higher than in 2013. Exchange rate movements had an unfavorable effect of 2.4 percentage points mainly reflecting the depreciation of the Japanese yen, the Russian rouble, the Brazilian real and the Argentine peso against the euro. At constant exchange rates, aggregate net sales rose by 4.9% year-on-year.

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The following table sets forth a reconciliation of our net sales for the years ended December 31, 2014 and December 31, 2013 to our aggregate net sales at constant exchange rates:

(million)	2014	2013	Change
Net sales[1]	**31,694**	**30,966**	**+2.4%**
Net sales of the Animal Health business[2]	2,076	1,985	+7.2%
Aggregate net sales	**33,770**	**32,951**	**+2.5%**
Effect of exchange rates	792		
Aggregate net sales at constant exchange rates (CER)	**34,562**	**32,951**	**+4.9%**

(1) In accordance with the presentation requirements of IFRS 5, the consolidated income statement line item Net sales does not include the net sales of the Animal Health business.

(2) Presented in a separate income statement line item Net income/(loss) of the held-for-exchange Animal Health business , in accordance with IFRS 5.

The following table breaks down our 2014 and 2013 net sales by operating segment, along with our aggregate net sales including the net sales of the Animal Health business (which remains an operating segment pursuant to IFRS 8).

(million)	2014	2013	Change	Change at constant exchange rates
Pharmaceuticals	27,720	27,250	+1.7%	+4.4%
Vaccines	3,974	3,716	+6.9%	+7.2%
Net sales[1]	**31,694**	**30,966**	**+2.4%**	**+4.8%**
Animal Health[2]	2,076	1,985	+4.6%	+6.7%
Aggregate net sales	**33,770**	**32,951**	**+2.5%**	**+4.9%**

(1) In accordance with the presentation requirements of IFRS 5, the consolidated income statement line item Net sales does not include the net sales of the Animal Health business.

(2) Presented in a separate income statement line item Net income/(loss) of the held-for-exchange Animal Health business , in accordance with IFRS 5.

Net Sales by Product Pharmaceuticals segment

In 2014, net sales for the Pharmaceuticals segment were 27,720 million, up 1.7% on a reported basis and 4.4% CER. The year-on-year increase of 470 million included unfavorable exchange rates effects of 739 million, along with the following effects at constant exchange rates:

- a positive performance from our growth platforms (1,873 million), mainly for the Diabetes division and our Genzyme and Consumer Health Care businesses (excluding the impact of changes in scope of consolidation in Consumer Health Care);
- a recovery in sales for our Generics operations in Brazil (309 million), by comparison with 2013 when we experienced temporary difficulties with our distribution channels in that country;

- negative effects totaling 973 million, including the residual impact of generic competition (primarily for Aprovel®, Allegra® and Taxotere®) and lower sales of other prescription products.

Our flagship Pharmaceuticals segment products are discussed below.

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The following table presents our 2014 and 2013 net sales for the Pharmaceuticals segment by product:

(million)		2014	2013	Change on a reported	Change at constant
Product	**Indication**	**Reported**	**Reported**	**basis**	**exchange rates**
Lantus®	Diabetes	6,344	5,715	+11.0%	+12.1%
Amaryl®	Diabetes	360	375	-4.0%	+0.3%
Apidra®	Diabetes	336	288	+16.7%	+19.1%
Insuman®	Diabetes	137	132	+3.8%	+6.8%
Blood glucose monitoring (BGM)	Diabetes	64	48	+33.3%	+33.3%
Lyxumia®	Diabetes	27	9	+200.0%	+211.1%
Other diabetes products		5	1	-	-
Total: Diabetes	**Diabetes**	**7,273**	**6,568**	**+10.7%**	**+12.1%**
Jevtana®	Prostate cancer	273	231	+18.2%	+19.5%
Taxotere®	Breast, lung, prostate, stomach, and head & neck cancer	266	409	-35.0%	-31.5%
Thymoglobulin®	Organ rejection	217	198	+9.6%	+11.1%
Eloxatin®	Colorectal cancer	210	221	-5.0%	-2.7%
Mozobil®	Hematologic malignancies	111	101	+9.9%	+9.9%
Zaltrap®	Colorectal cancer	69	53	+30.2%	+30.2%
Other oncology products		255	252	+1.2%	+2.4%
Total: Oncology		**1,401**	**1,465**	**-4.4%**	**-2.5%**
Cerezyme®	Gaucher disease	715	688	+3.9%	+8.3%
Myozyme® /Lumizyme®	Pompe disease	542	500	+8.4%	+9.8%
Fabrazyme®	Fabry disease	460	383	+20.1%	+23.0%
Aldurazyme®	Mucopolysaccharidosis	172	159	+8.2%	+11.3%
Cerdelga®	Gaucher disease	4	-	-	-
Other rare diseases products		244	244	0.0%	+2.9%
Sub-total: Rare diseases		**2,137**	**1,974**	**+8.3%**	**+11.2%**
Aubagio®	Multiple sclerosis	433	166	+160.8%	+160.8%
Lemtrada®	Multiple sclerosis	34	2	-	-
Sub-total: Multiple sclerosis		**467**	**168**	**+178.0%**	**+178.0%**
Total: Genzyme		**2,604**	**2,142**	**+21.6%**	**+24.3%**
Plavix®	Atherothrombosis	1,862	1,857	+0.3%	+4.7%
Lovenox®	Thrombosis	1,699	1,703	-0.2%	+2.1%
Aprovel® /CoAprovel®	Hypertension	727	882	-17.6%	-16.6%
Renagel® /Renvela®	Hyperphosphatemia	684	750	-8.8%	-8.7%
Depakine®	Epilepsy	395	405	-2.5%	+0.5%
Synvisc® /Synvisc-One®	Arthritis	352	371	-5.1%	-4.6%
Myslee® /Ambien®/Stilnox®	Sleep disorders	306	391	-21.7%	-18.4%

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(million)		2014	2013	Change on a reported basis	Change at constant exchange rates
Product	**Indication**	**Reported**	**Reported**		
Multaq®	Atrial fibrillation	290	269	+7.8%	+7.8%
Tritace®	Hypertension	281	307	-8.5%	-5.9%
Allegra®	Allergic rhinitis, urticaria	192	406	-52.7%	-48.3%
Lasix®	Edema, hypertension	164	172	-4.7%	-0.6%
Targocid®	Bacterial infections	162	166	-2.4%	-0.6%
Orudis®	Rheumatoid arthritis, osteoarthritis	160	144	+11.1%	+17.4%
Cordarone®	Arrhythmia	129	141	-8.5%	-2.8%
Xatral®	Benign prostatic hypertrophy	94	101	-6.9%	-5.0%
Actonel®	Osteoporosis, Paget s disease	82	100	-18.0%	-14.0%
Auvi-Q® /Allerject®	Severe allergies, anaphylaxis	72	60	+20.0%	+21.7%
Other prescription products		3,649	4,221	-13.6%	-11.2%
Total: established prescription products		**11,300**	**12,446**	**-9.2%**	**-6.7%**
Consumer Health Care		**3,337**	**3,004**	**+11.1%**	**+16.5%**
Generics		**1,805**	**1,625**	**+11.1%**	**+16.2%**
Total: Pharmaceuticals		**27,720**	**27,250**	**+1.7%**	**+4.4%**

Diabetes division

Net sales for the **Diabetes** division were 7,273 million, up 12.1% CER, driven by double-digit growth for Lantus® and Apidra®.

Lantus® increased its net sales by 12.1% (CER) to 6,344 million in 2014 due to strong performances in the United States (+12.4% CER, at 4,225 million), where Lantus® SoloSTAR® accounted for 62% of full-year sales, and in Emerging Markets (+18.2% CER), especially in China (+33.6% CER), the Africa/Middle East region (+17.3% CER) and in Eastern Europe (+15.9% CER). Western Europe turned in a good performance as net sales rose by 7.7% CER to 871 million.

The product s sales growth during 2014 reflected both an increase in volume and a generally favorable price effect. In volume terms, sales of Lantus® increased across all geographical areas in 2014 (by 4.8% overall). In the medium to long term, volume growth will depend on various factors. See Results of Operations Year Ended December 31, 2015 Compared with Year Ended December 31, 2014 .

Price effects on sales of Lantus® were favorable overall in 2014 (+7.3% CER); the biggest effect was felt in the United States. However, we encountered a tougher pricing

environment in the U.S. basal insulins market in the second half of 2014, which was reflected in mounting price pressure from payers. During that period, we conducted negotiations with payers in the United States, securing favorable positions for Lantus® in the formularies of the key payers. To maintain those positions, we had to significantly increase the level of discounts offered in order to match the substantial rebates offered by our competitors.

We cannot predict the long-term price effects in the diabetes market, as these will depend on the impact of new rival products on the pricing of diabetes treatments across all geographic areas. See Results of Operations Year Ended December 31, 2015 Compared with Year Ended December 31, 2014 .

Net sales of **Apidra®** totaled 336 million in 2014, up 19.1% CER, driven by a strong performance in the United States (+16.1% CER, at 131 million) and in Emerging Markets (+27.9% CER, at 73 million).

Net sales of **Amaryl®** were flat year-on-year (+0.3% CER, at 360 million), reflecting the effect of generic competition in Japan (-27.2% CER, at 54 million), but also a good performance in Emerging Markets (+9.2% CER, at 275 million).

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Blood glucose monitoring systems posted a surge in net sales of 33.3% CER to 64 million, largely as a result of recent launches of MyStar Extra® in Western Europe.

Lyxumia®, which continued to be rolled out worldwide during 2014, generated sales of 27 million. In Germany, the product was withdrawn from the market in April 2014 due to a negative outcome on the pricing level set by the authorities.

Oncology business

Net sales for the **Oncology** business were 1,401 million, down 2.5% CER.

Jevtana® reported net sales of 273 million in 2014, up 19.5% CER, boosted by recent launches in Western Europe where sales rose by 28.2% CER to 142 million.

Net sales of **Taxotere®** fell sharply, by 31.5% CER, to 266 million. The product faced competition from generics in Emerging Markets (-24.1% CER, at 143 million), the United States (-81.0% CER, at 8 million) and in Japan (-28.2% CER, at 87 million).

Sales of **Eloxatin®** were 210 million, down 2.7% CER, mainly as a result of competition from generics in the United States.

Sales of **Mozobil®** rose by 9.9% CER to 111 million.

Net sales of **Zaltrap®** (aflibercept, developed in collaboration with Regeneron) totaled 69 million, up 30.2% CER, on the back of recent launches in Western Europe (+146.7%, at 37 million) that more than compensated for lower sales in the United States (-25.0% CER, at 27 million).

Genzyme business

The **Genzyme** business generated net sales of 2,604 million, up 24.3% CER, driven by strong growth in sales of Aubagio® and Fabrazyme®.

Cerezyme® increased its net sales by 8.3% CER to 715 million, driven by Emerging Markets (+14.4% CER, at 242 million) and Western Europe (+6.7% CER, at 241 million).

Net sales of **Myozyme®/Lumizyme®** rose by 9.8% CER to 542 million, reflecting the product s performance in Emerging Markets (+42.3% CER, at 93 million).

Fabrazyme® reported strong net sales growth of 23.0% CER, to 460 million. Net sales were up 13.8% CER in the United States (at 223 million), 26.4% CER in Western Europe (at 110 million), and 50.0% CER in Emerging Markets (at 59 million).

In multiple sclerosis, **Aubagio®** recorded net sales of 433 million during 2014, including 326 million in the United States (where the product was launched in October 2012)

and 83 million in Western Europe (where launches began at the end of 2013). Sales of **Lemtrada®** were 34 million, of which 28 million was generated in Western Europe.

Established prescription products

Net sales of **Plavix®** were up 4.7% CER at 1,862 million. Growth was driven by Japan (+10.0% CER, at 759 million) and Emerging Markets (+9.3% CER, at 825 million), especially China (+18.0% CER, at 498 million). However, the effects were mitigated by generic competition in Western Europe (-15.6% CER, at 217 million). Sales of Plavix® in the United States and Puerto Rico are handled by BMS under the terms of the Sanofi-BMS alliance (see Financial presentation of alliances Alliance Arrangements with Bristol-Myers Squibb above).

Lovenox® posted net sales growth of 2.1% CER in 2014, to 1,699 million. Lower net sales in the United States, where sales of the branded product fell by 30.5% CER to 130 million in the face of generic competition, were offset by good performances in Western Europe (+4.3% CER, at 898 million) and in Emerging Markets (+10.2% CER, at 581 million), especially in China and Latin America. Sales of the generic version of Lovenox® launched by Sanofi in 2012 are recorded by our Generics business (see below).

Aprovel®/CoAprovel® reported a drop in net sales of 16.6% CER to 727 million, mainly as a result of competition from generics in Western Europe, where sales were 43.8% lower at 190 million. Net sales in Emerging Markets were relatively stable year-on-year, rising by 2.3% CER to 389 million.

Net sales of **Renagel®/Renvela®** fell by 8.7% CER to 684 million due to lower sales in the United States (-13.6% CER, at 464 million), reflecting the effects of the agreement whereby Sanofi granted Impax the right to sell a limited number of authorized generics of Renvela® from April 2014.

Allegra® posted a fall in prescription net sales (-48.3% CER, at 192 million), affected by competition from generics in Japan (-30.0% CER, at 178 million) and by the reclassification of sales of the product in some countries of Emerging Markets to our Consumer Health Care business. On a constant structure basis and CER, Emerging Markets net sales were stable year-on-year, but CER they were down 98.3% at 2 million. Net sales of Allegra® OTC in the United States and in Japan are also recorded by our Consumer Health Care business.

Net sales of **Stilnox® / Ambien® / Myslee®** fell by 18.4% CER to 306 million, reflecting competition from generics of Myslee® (-29.2% CER, at 125 million).

Synvisc®/Synvisc-One® posted net sales of 352 million, down 4.6% CER, on lower sales in the United States (-7.5% CER, at 274 million).

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Net sales of **Multaq®** increased by 7.8% CER to 290 million, driven by sales in the United States (+8.8% CER, at 235 million).

Auvi-Q®/Allerject® recorded net sales of 72 million (+21.7% CER), including 61 million in the United States where the product was launched in January 2013.

We have no comments on our other prescription products.

Consumer Health Care business

In 2014, net sales for the **Consumer Health Care** business segment were 3,337 million, up 11.1% on a reported basis and 16.5% CER.

Some products that were accounted for as prescription products in 2013 (combined net sales: 273 million) were reclassified in 2014 to Consumer Health Care. Excluding the effects of this category change, Consumer Health Care net sales rose by 1.8% in 2014 (or by 6.8% CER), driven by growth in Emerging Markets and in the United States, where the Nasacort® Allergy 24H OTC nasal spray has been on the market since February 2014.

The following table breaks down our 2014 and 2013 net sales for the Consumer Health Care business by product:

(million)	2014	2013	Change on a reported basis	Change at constant exchange rates
Product	**Reported**	**Reported**		
Doliprane®	310	290	+6.9%	+7.2%
Allegra®	350	264	+32.6%	+37.1%
Essentiale®	235	207	+13.5%	+27.1%
Enterogermina®	156	130	+20.0%	+24.6%
Nasacort®	114	1	-	-
No Spa®	109	117	-6.8%	+6.0%
Lactacyd®	104	105	-1.0%	+5.7%
Maalox®	98	94	+4.3%	+9.6%
Dorflex®	90	93	-3.2%	+6.5%
Other products	1,771	1,703	+4.0%	+8.5%
Total: Consumer Health Care	**3,337**	**3,004**	**+11.1%**	**+16.5%**

Generics business

The **Generics** business reported net sales of 1,805 million in 2014, up 16.2% CER, reflecting a recovery in sales in Brazil by comparison with 2013 when sales were adversely affected by temporary difficulties in our distribution channels in that country. Excluding Brazil, Generics net sales fell by 2.8% year-on-year CER.

In Emerging Markets, the Generics business generated net sales of 1,106 million, up 38.8% CER (or 2.7% excluding Brazil). In the United States, net sales fell by 31.3% CER to 123 million, reflecting a decline in sales of authorized generics of Lovenox® and Taxotere®.

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The following table presents 2014 net sales of our Pharmaceutical segment products by region:

(*million*)	Western Europe[1]	Change at constant exchange rates	United States	Change at constant exchange rates	Emerging Markets[2]	Change at constant exchange rates	Rest of the world[3]	Change at constant exchange rates
Product	**Reported**		**Reported**		**Reported**		**Reported**	
Lantus®	871	+7.7%	4,225	+12.4%	934	+18.2%	314	+3.1%
Amaryl®	19	-13.6%	4	+100.0%	275	+9.2%	62	-24.4%
Apidra®	98	+16.7%	131	+16.1%	73	+27.9%	34	+19.4%
Insuman®	82	-8.9%	1	0.0%	54	+38.1%	-	-100.0%
Blood glucose monitoring (BGM)	58	+28.9%	-	-	3	+200.0%	3	+50.0%
Lyxumia®	15	+150.0%	-	-	4	-	8	+200.0%
Other diabetes products	-	-	-	-	1	0.0%	4	-
Total: Diabetes	**1,143**	**+8.3%**	**4,361**	**+12.6%**	**1,344**	**+17.9%**	**425**	**+1.3%**
Jevtana®	142	+28.2%	91	+5.8%	33	+16.1%	7	+100.0%
Taxotere®	15	-31.8%	8	-81.0%	143	-24.1%	100	-27.4%
Thymoglobulin®	32	+3.2%	108	+5.9%	59	+27.1%	18	+11.8%
Eloxatin®	5	-16.7%	22	+5.3%	103	-1.9%	80	-4.5%
Mozobil®	34	+3.1%	62	+8.9%	11	+22.2%	4	+50.0%
Zaltrap®	37	+146.7%	27	-25.0%	5	+150.0%	-	-
Other oncology products	55	0.0%	151	+1.3%	29	0.0%	20	+21.1%
Total: Oncology	**320**	**+17.4%**	**469**	**-4.9%**	**383**	**-6.3%**	**229**	**-11.5%**
Cerezyme®	241	+6.7%	186	+4.5%	242	+14.4%	46	0.0%
Myozyme® /Lumizyme®	270	-1.8%	142	+14.6%	93	+42.3%	37	+18.8%
Fabrazyme®	110	+26.4%	223	+13.8%	59	+50.0%	68	+28.6%
Aldurazyme®	64	+6.7%	33	+13.8%	54	+13.7%	21	+15.8%
Cerdelga®	-	-	4	-	-	-	-	-
Other rare diseases products	43	+7.7%	89	-10.1%	31	+23.1%	81	+10.0%
Sub-total Rare diseases	**728**	**+5.8%**	**677**	**+8.0%**	**479**	**+23.1%**	**253**	**+14.0%**
Aubagio®	83	+600.0%	326	+112.5%	10	+550.0%	14	-
Lemtrada®	28	-	2	-	2	-	2	-
Sub-total Multiple sclerosis	**111**	**+692.9%**	**328**	**+113.8%**	**12**	**+650.0%**	**16**	**-**
Total: Genzyme	**839**	**+19.6%**	**1,005**	**+28.7%**	**491**	**+26.0%**	**269**	**+20.8%**
Plavix®	217	-15.6%	1*	-80.0%	825	+9.3%	819	+7.2%
Lovenox®	898	+4.3%	130	-30.5%	581	+10.2%	90	-2.0%
Aprovel® /CoAprovel®	190	-43.8%	18*	+5.9%	389	+2.3%	130	-5.8%
Renagel® /Renvela®	133	-0.8%	464	-13.6%	65	+9.4%	22	+9.1%
Depakine®	139	0.0%	-	-	240	+1.2%	16	-5.9%
Synvisc® /Synvisc-One®	28	+12.0%	274	-7.5%	39	+24.2%	11	-29.4%
Myslee® /Ambien®/Stilnox®	40	-2.4%	74	-17.0%	57	0.0%	135	-27.9%
Multaq®	44	+2.3%	235	+8.8%	8	0.0%	3	+50.0%
Tritace®	127	-6.6%	-	-	145	-3.8%	9	-21.4%

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(million)	Western Europe(1)	Change at constant exchange rates	United States	Change at constant exchange rates	Emerging Markets(2)	Change at constant exchange rates	Rest of the world(3)	Change at constant exchange rates
Product	**Reported**		**Reported**		**Reported**		**Reported**	
Allegra®	10	0.0%	-	-	2	-98.3%	180	-29.8%
Lasix®	78	+4.0%	3	0.0%	51	+12.2%	32	-22.2%
Targocid®	84	+5.1%	-	-	69	-2.7%	9	-23.1%
Orudis®	20	-16.7%	-	-	137	+23.9%	3	+33.3%
Cordarone®	24	-4.0%	-	-	70	+2.7%	35	-11.6%
Xatral®	38	-2.6%	-	-100.0%	52	0.0%	4	-20.0%
Actonel®	17	-22.7%	-	-	35	-7.5%	30	-15.8%
Auvi-Q® /Allerject®	2	-33.3%	61	+21.6%	-	-	9	+50.0%
Other prescription products	1,547	-6.2%	344	-29.8%	1,370	-7.9%	388	-19.7%
Total: established prescription products	**3,636**	**-6.8%**	**1,604**	**-15.2%**	**4,135**	**-1.4%**	**1,925**	**-9.6%**
Consumer Health Care	**676**	**+1.7%**	**708**	**+15.4%**	**1,739**	**+28.7%**	**214**	**-12.4%**
Generics	**533**	**+4.3%**	**123**	**-31.3%**	**1,106**	**+38.8%**	**43**	**+27.8%**
Total: Pharmaceuticals	**7,147**	**-0.1%**	**8,270**	**+5.6%**	**9,198**	**+11.1%**	**3,105**	**-6.9%**

(1) France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark.

(2) World excluding United States, Canada, Western Europe, Japan, South Korea, Australia and New Zealand.

(3) Japan, South Korea, Canada, Australia and New Zealand.
** Sales of active ingredient to the entity majority-owned by BMS in the United States.*

Net Sales Human Vaccines (Vaccines) segment

In 2014, net sales for the Vaccines segment were 3,974 million, up 6.9% on a reported basis and 7.2% CER.

The following table presents the 2014 and 2013 net sales of our Vaccines segment by product range:

(million)	2014 Reported	2013 Reported	Change on a reported	Change at constant exchange rates

			basis	
Polio/Pertussis/Hib Vaccines (*including Pentacel® and Pentaxim®*)	1,154	1,148	+0.5%	+1.9%
Influenza Vaccines (*including Vaxigrip® and Fluzone®*)	1,178	929	+26.8%	+25.2%
Meningitis/Pneumonia Vaccines (*including Menactra®*)	454	496	-8.5%	-7.5%
Adult Booster Vaccines (*including Adacel®*)	398	391	+1.8%	+2.0%
Travel and Other Endemics Vaccines	377	382	-1.3%	+1.6%
Other Vaccines	413	370	+11.6%	+9.7%
Total: Vaccines	**3,974**	**3,716**	**+6.9%**	**+7.2%**

Polio/Pertussis/Hib vaccines reported net sales up 1.9% CER, at 1,154 million. This reflected a good performance in the United States (411 million, up 46.9% CER) as shipments of Pentacel® recovered following the supply limitations experienced in 2013. On the downside, negative factors included (i) lower net sales in Japan (-23.5% CER, at 127 million) due to the end of the 2013 catch-up vaccination campaigns that followed the launch of Imovax® and (ii) a fall

in net sales in Emerging Markets (-7.9% CER, at 573 million) due mainly to Pentaxim® and Imovax® in China.

Net sales of **Influenza** vaccines were up 25.2% CER at 1,178 million, helped by a strong performance in the United States (+25.7% at 694 million) as the differentiated vaccine strategy paid off, and also in Emerging Markets (+28.9% CER, at 354 million) on the back of seasonal influenza in Latin America.

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Meningitis/Pneumonia vaccines posted net sales of 454 million, down 7.5% CER, hindered by a poor performance in Emerging Markets (-32.8% CER, at 82 million) due mainly to a drop in sales of Menactra® in the Middle East.

Net sales of **Adult Booster** vaccines rose by 2.0% CER to 398 million. Net sales of **Travel and Other Endemics** vaccines were up 1.6% CER at 377 million.

Other Vaccines saw net sales rise by 9.7% CER to 413 million, reflecting the growth of VaxServe, a Sanofi

Pasteur company that distributes vaccines in the United States.

In addition to the Vaccines activity reflected in our consolidated net sales, sales generated by Sanofi Pasteur MSD, our joint venture with Merck in Europe, reached 848 million in 2014, down 3.3% (on a reported basis). Sales generated by Sanofi Pasteur MSD are not included in our consolidated net sales. Sales of Gardasil® were down 15.4% on a reported basis, at 186 million. Zostavax®, launched at the end of 2012, posted 50.6% growth in net sales to 77 million (versus 51 million in 2013).

The following table presents the 2014 net sales of our Vaccines segment by product range and by region:

(million)	Western Europe[1] Reported	Change at constant exchange rates	United States Reported	Change at constant exchange rates	Emerging Markets[2] Reported	Change at constant exchange rates	Rest of the world[3] Reported	Change at constant exchange rates
Polio/Pertussis/Hib Vaccines								
(*inc. Pentacel® and Pentaxim®*)	24	-31.4%	411	+46.9%	573	-7.9%	146	-22.5%
Influenza Vaccines								
(*inc. Vaxigrip® and Fluzone®*)	93	+12.0%	694	+25.7%	354	+28.9%	37	+18.2%
Meningitis/Pneumonia Vaccines								
(*inc. Menactra®*)	3	-40.0%	360	+2.3%	82	-32.8%	9	-9.1%
Adult Booster Vaccines								
(*inc. Adacel®*)	59	-1.7%	276	+2.6%	48	+6.5%	15	-5.9%
Travel and Other Endemics Vaccines	21	+16.7%	95	-2.1%	206	0.0%	55	+9.3%
Other Vaccines	4	+33.3%	394	+11.8%	8	-18.2%	7	-44.4%
Total: Vaccines	**204**	**0.0%**	**2,230**	**+17.1%**	**1,271**	**-0.8%**	**269**	**-12.5%**

(1) France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark. Net sales in Europe generated by Sanofi Pasteur MSD (the joint venture between Sanofi and Merck) are not consolidated.

(2) World excluding United States, Canada, Western Europe, Japan, South Korea, Australia and New Zealand.

(3) Japan, South Korea, Canada, Australia and New Zealand.

Net Sales Animal Health segment

Following the announcement of exclusive negotiations with Boehringer Ingelheim regarding the divestment of our Animal Health business (Merial), the net profit or loss of that business is now presented in a separate line item in the consolidated income statement, Net income/(loss) of the held-for-exchange Animal Health business , in accordance with IFRS 5 (see Notes D.2.1. and D.36. to our consolidated financial statements included at Item 18 of this annual report). Consequently, the net sales reported in our consolidated income statement do not include the net sales of the Animal Health business.

Until final completion of the transaction, expected in the fourth quarter of 2016 once regulatory clearances have been obtained, we will continue to monitor the performance of the Animal Health business (which remains an operating segment), and to report the performance of that business at Group level.

Net sales for the Animal Health segment in 2014 amounted to 2,076 million, up 4.6% on a reported basis and 6.7% CER.

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The following table presents the 2014 and 2013 net sales of our Animal Health[(1)] segment by product range:

(million)	2014	2013	Change	Change at constant exchange rates
Companion animals	1,281	1,195	+7.2%	+8.8%
Production animals	795	790	+0.6%	+3.5%
Total: Animal Health[(1)]	**2,076**	**1,985**	**+4.6%**	**+6.7%**
Of which fipronil-based products	*597*	*611*	*-2.3%*	*-0.2%*
Of which vaccines	*720*	*727*	*-1.0%*	*+1.2%*
Of which avermectin-based products	*398*	*413*	*-3.6%*	*-1.7%*
Of which other products	*361*	*234*	*+54.3%*	*+56.4%*

(1) Presented in the income statement line item Net income/(loss) of the held-for-exchange Animal Health business , in accordance with IFRS 5.

Net sales for the **Companion Animals** franchise rose by 8.8% CER to 1,281 million, reflecting the resilience of the **fipronil**- based products (-0.2% CER, at 597 million) in the face of competition and the success of **NexGard®**, a new product launched in 2014 that generated 113 million in net sales.

Net sales for the **Production Animals** franchise rose by 3.5% CER to 795 million, driven by growth in products for ruminants in the United States.

The following table presents 2014 net sales of our Animal Health segment by product range and by region:

(million)	Western Europe[(1)]	Change at constant exchange rates	United States	Change at constant exchange rates	Emerging Markets[(2)]	Change at constant exchange rates	Rest of The World[(3)]	Change at constant exchange rates
Product	**Reported**		**Reported**		**Reported**		**Reported**	
Fipronil-based products	181	+1.1%	272	-4.5%	102	+12.2%	42	-4.3%
Vaccines	185	+1.1%	155	+2.0%	335	+3.5%	45	-14.8%
Avermectin-based products	55	-6.9%	225	+0.9%	53	+1.8%	65	-8.1%
Other products	93	+10.6%	187	+129.6%	63	+25.9%	18	+28.6%
Total: Animal Health	**514**	**+1.8%**	**839**	**+13.0%**	**553**	**+7.1%**	**170**	**-6.3%**

(1) France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark.

(2) World excluding United States, Canada, Western Europe, Japan, South Korea, Australia and New Zealand.

(3) Japan, South Korea, Canada, Australia and New Zealand.

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Net Sales and Aggregate Net Sales by Geographical Region

We divide our sales geographically into four regions: the United States, Emerging Markets, Western Europe and the Rest of the World. The following table presents our 2014 and 2013 net sales by region:

(million)	2014 Reported	2013 Reported	Change on a reported basis	Change at constant exchange rates
Emerging Markets[1]	10,469	10,095	+3.7%	+9.8%
Of which Eastern Europe and Turkey	*2,484*	*2,623*	*-5.3%*	*+4.7%*
Of which Asia (excl. Pacific region)	*2,724*	*2,577*	*+5.7%*	*+7.0%*
Of which Latin America	*3,113*	*2,752*	*+13.1%*	*+22.7%*
Of which Africa & Middle-East	*2,006*	*2,012*	*-0.3%*	*+2.3%*
United States	10,500	9,686	+8.4%	+7.8%
Western Europe[2]	7,351	7,329	+0.3%	-0.1%
Rest of the World[3]	3,374	3,856	-12.5%	-6.7%
Of which Japan	*2,083*	*2,465*	-15.5%	-8.6%
Total net sales	**31,694**	**30,966**	**+2.4%**	**+4.8%**

(1) World excluding United States, Canada, Western Europe, Japan, South Korea, Australia and New Zealand.

(2) France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark.

(3) Japan, South Korea, Canada, Australia and New Zealand.

The following table presents our 2014 and 2013 aggregate net sales (including the Animal Health business) by region:

(million)	2014	2013	Change	Change at constant exchange rates
Emerging Markets[1]	11,022	10,642	+3.6%	+9.6%
Of which Eastern Europe and Turkey	*2,541*	*2,673*	*-4.9%*	*+5.0%*
Of which Asia (excl. Pacific region)	*2,881*	*2,726*	*+5.7%*	*+7.0%*

Of which Latin America	*3,363*	*3,013*	*+11.6%*	*+21.1%*
Of which Africa & Middle-East	*2,095*	*2,099*	*+2.5%*	*-0.2%*
United States	11,339	10,433	+8.7%	+8.2%
Western Europe[2]	7,865	7,831	+0.4%	0.0%
Rest of the World[3]	3,544	4,045	-12.4%	-6.7%
Of which Japan	*2,119*	*2,507*	*-15.5%*	*-8.6%*
Total aggregate net sales	**33,770**	**32,951**	**+2.5%**	**+4.9%**

(1) World excluding United States, Canada, Western Europe, Japan, South Korea, Australia and New Zealand.

(2) France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark.

(3) Japan, South Korea, Canada, Australia and New Zealand.

In Emerging Markets, net sales reached 10,469 million, up 9.8% CER. Aggregate net sales reached 11,022 million, up 9.6% CER, driven by Diabetes (+17.4% CER), Genzyme (+26.7% CER), Consumer Health Care (+28.4% CER) and Generics (+38.8% CER). Aggregate net sales in Latin

America surged by 21.1% CER, largely as a result of the effect of the recovery in generics sales on our performance in Brazil (+34.8% CER); excluding generics, aggregate net sales in Brazil advanced by 6.9% CER, reflecting the performance of the Consumer Health Care, Genzyme and

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Vaccines businesses. In China, aggregate net sales were up 8.8% CER at 1,603 million, reflecting strong performances in Diabetes and Consumer Health Care but also lower vaccine sales due mainly to delays in shipments of Pentaxim®. Russia posted aggregate net sales of 813 million, up 7.1% CER, propelled by Consumer Health Care and Diabetes.

In the United States, net sales rose by 7.8% CER to 10,500 million. Aggregate net sales rose by 8.2% CER to 11,339 million on fine performances in Diabetes (+12.6% CER), Genzyme (+28.7% CER) and Vaccines (+17.1% CER). Other growth drivers included Consumer Health Care (+15.4% CER), boosted by the switch of Nasacort® to the OTC market, and the launch of the new animal health product NexGard®. These factors more than compensated for declining sales for Generics (-31.3% CER), Oncology (-4.9% CER), and established prescription products (-15.2% CER).

Net sales in Western Europe were stable at 7,351 million. Aggregate net sales in Western Europe were stable at 7,865 million. Positive factors included the performances of Genzyme (+19.6% CER) and Diabetes (+8.3% CER), and the recent launches of Jevtana® and Zaltrap® in Oncology. The main negative factor was competition from generics of Aprovel® (-43.8% CER).

In the Rest of the World, net sales were 3,374 million, down 6.7% CER. Aggregate net sales were 3,544 million, down 6.7% CER. In Japan, aggregate net sales came to 2,119 million (-8.6% CER), reflecting the impact of generic competition on sales of Allegra® (-30.0% CER) and Myslee® (-29.2% CER) and lower sales of the Imovax® vaccine.

Other Revenues

Other revenues, which mainly comprise royalties under licensing agreements contracted in connection with continuing operations, fell by 6.1% to 305 million (compared with 325 million in 2013).

Aggregate other revenues (including the Animal Health business) fell by 4.5% to 339 million (compared with 355 million in 2013). The year-on-year change was mainly due to the decline in royalties received from Amgen on Enbrel® in the United States during 2013 due to contract termination.

Gross Profit

Gross profit amounted to 21,769 million (68.7% of net sales), versus 22,989 million in 2013 (67.8% of net sales).

Aggregate gross profit (including the Animal Health business) amounted to 23,080 million in 2014 (68.3% of aggregate net sales), versus 22,323 million in 2013 (67.7% of aggregate net sales). This represented a year-on-year increase of 3.4%, and an improvement of 0.6 of a percentage point in the gross margin ratio.

The gross margin ratio for the Pharmaceuticals segment was 1.3 percentage points higher at 71.1%, reflecting on the downside a dip in royalty revenue (0.1 of a percentage point), but on the upside an improvement in the ratio of cost of sales to net sales (1.4 percentage points) due largely to the recovery in generics sales in Brazil, a stronger industrial performance by Genzyme and favorable price effects on net sales of Lantus®.

The gross margin ratio for the Vaccines segment was 1.2 percentage points lower at 51.8%, reflecting a less favorable product mix.

The gross margin ratio for the Animal Health segment was 3.6 percentage points lower at 63.2%, also due to a less favorable product mix.

Research and Development Expenses

Research & development expenses (R&D) amounted to 4,667 million in 2014 (versus 4,605 million in 2013).

Aggregate R&D expenses (including the Animal Health business) amounted to 4,824 million in 2014 (versus 4,770 million in 2013) and represented 14.3% of aggregate net sales (versus 14.5% in 2013). Overall, aggregate R&D expenses increased by 54 million (+1.1%) year-on-year.

In the Pharmaceuticals segment, R&D expenses increased by 87 million (+2.1%), driven by investment in the advanced development pipeline (mainly monoclonal antibodies).

R&D expenses for the Vaccines segment fell by 25 million (-4.8%), largely due to the end of the Phase III clinical trials of the dengue fever vaccine.

In the Animal Health segment, R&D expenses were 8 million (-4.8%) lower than in 2013.

Selling and General Expenses

Selling and general expenses totaled 8,425 million, versus 7,950 million in 2013, an increase of 6.0%.

Aggregate selling and general expenses (including the Animal Health business) totaled 8,991 million, versus 8,603 million in 2013, an increase of 388 million (+4.5%). They represented 26.6% of aggregate net sales, versus 26.1% in 2013.

In the Pharmaceuticals segment, selling and general expenses rose by 330 million (+4.5%) due to promotional spend in the Genzyme (multiple sclerosis and rare diseases) and Consumer Health Care businesses.

In the Vaccines segment, selling and general expenses were 26 million (+4.4%) higher due to increased promotional spend.

Selling and general expenses in the Animal Health segment increased by 29 million (+4.4%) as a result of higher promotional spend on NexGard®.

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Other Operating Income and Expenses

In 2014, other operating income totaled 301 million (versus 691 million in 2013), and other operating expenses 157 million (versus 240 million in 2013).

Overall, aggregate other operating income and expenses (including the Animal Health business) represented net income of 164 million in 2014, versus net income of 450 million in 2013. This year-on-year decrease of 286 million was mainly attributable to a 165 million gain recognized in 2013 on the sale to Covis Pharma of commercial rights to five pharmaceutical products in the United States, and also to a fall in revenues from the alliance with Warner Chilcott on Actonel®.

This line item also includes a net operating foreign exchange loss of 102 million, versus 64 million in 2013.

Amortization of Intangible Assets

Amortization charged against intangible assets totaled 2,081 million in 2014, versus 2,527 million in 2013. The year-on-year decrease of 446 million was mainly due to a reduction in amortization charged against intangible assets recognized on the acquisitions of Aventis (874 million in 2014, versus 1,199 million in 2013) and of Genzyme (811 million in 2014, versus 930 million in 2013) as some pharmaceutical products reached the end of their life cycles (in particular Actonel®, Lovenox® and Renagel®/Renvela®).

Impairment of Intangible Assets

In 2014, this line item showed a net reversal of impairment losses against intangible assets of 31 million, versus a net expense of 1,387 million in 2013. The 2014 figure included a gain of 356 million arising because the impairment loss taken in 2013 against Lemtrada® (alemtuzumab) was reversed following approval of the product by the FDA in November 2014. It also included the negative effects of (i) a net impairment loss of 203 million arising from various research projects in Pharmaceuticals and Vaccines, in particular the discontinuation of collaborative development programs with Alopexx (SAR 279 356) and Kalobios (*Pseudomonas aeruginosa* vaccine), and from revised commercial prospects (especially for the rotavirus vaccine project; and (ii) the impairment losses of 122 million taken against rights to a number of marketed products in the Pharmaceuticals and Vaccines segments (mainly Consumer Health Care assets in the Emerging Markets region).

The impairment losses recognized in 2013 related primarily to (i) Lemtrada® (alemtuzumab) in the United States, following the refusal by the FDA to approve the U.S. marketing application for this product in its then current form (612 million); (ii) the discontinuation of the iniparib R&D project in non-small cell lung cancer and ovarian cancer (384 million); and (iii) the discontinuation of the

project on fedratinib, a selective JAK2 inhibitor in the treatment of polycythemia vera (170 million).

Fair Value Remeasurement of Contingent Consideration Liabilities

Fair value remeasurements of contingent consideration liabilities recognized on acquisitions in accordance with the revised IFRS 3 represented a net expense of 303 million in 2014, versus a net gain of 314 million in 2013. This item mainly relates to the contingent consideration payable to Bayer as a result of an acquisition made by Genzyme prior to the latter s acquisition by Sanofi and to the contingent value rights (CVRs) issued by Sanofi in connection with the Genzyme acquisition (see Note D.18. to our consolidated financial statements included at Item 18 of this annual report). In 2013, these remeasurements also related to contingent consideration that arose on the acquisition of TargeGen but that was cancelled following discontinuation of the fedratinib project.

Restructuring Costs

Restructuring costs amounted to 404 million in 2014, versus 303 million in 2013, and related primarily to measures associated with the major transformation program that we initiated in 2009 to adapt our structures to the challenges of the future. In both 2014 and 2013, these costs mainly comprised employee-related expenses arising from headcount adjustment plans in France and the rest of Europe.

Other Gains and Losses, and Litigation

Nothing was recognized on this line in either 2014 or 2013.

Operating Income

Operating income totaled 6,064 million for 2014, versus 4,982 million for 2013, an improvement of 21.7% attributable mainly to lower charges for amortization and impairment of intangible assets.

Financial Income and Expenses

Net financial expenses for 2014 were 406 million, versus 498 million for 2013. Aggregate net financial expenses (including the Animal Health business) for 2014 were 412 million, versus 503 million for 2013, a decrease of 91 million.

On an aggregate basis (including the Animal Health business), financial expenses directly related to our debt, net of cash and cash equivalents (see definition in Consolidated Balance sheet and debt below) amounted to 293 million in 2014, versus 317 million in 2013, mainly reflecting a slight fall in the average level of net debt during 2014.

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Net gains on disposals of non-current financial assets totaled 68 million (versus 42 million in 2013), and mainly related to divestments by Genzyme.

Net financial expenses for 2014 also included a gain of 35 million arising on the acquisition of shares in Alnylam in February 2014.

Income before Tax and Associates and Joint Ventures

Income before tax and associates and joint ventures amounted to 5,658 million in 2014, versus 4,484 million in 2013, an increase of 26.2%.

Income Tax Expense

Income tax expense represented 1,214 million in 2014, versus 726 million in 2013, giving an effective tax rate (based on consolidated net income) of 21.5% in 2014 compared with 16.2% in 2013 (see Note D.30. to our consolidated financial statements included at Item 18 of this annual report).

The level of income tax expense was significantly impacted by the positive tax effects arising on the amortization and impairment of intangible assets (546 million in 2014, versus 1,328 million in 2013) and on restructuring costs (141 million in 2014, versus 96 million in 2013). In addition, the tax effect of the fair value remeasurement of contingent consideration liabilities represented a benefit of 254 million in 2014, compared with an expense of 85 million in 2013. Overall, these effects increased our income tax expense by 413 million.

The effective tax rate based on our business net income is calculated on the basis of business operating income minus net financial expenses and before the share of profit/loss of associates and joint ventures and net income attributable to non-controlling interests, but after adding back the business operating income of the Animal Health business (before the share of profit/loss of associates and joint ventures and net income attributable to non-controlling interests for that business) and after subtracting net financial expenses for that business. This effective tax rate was 24.0% in both 2014 and 2013. The tax rate is mainly impacted by the geographical mix of the results from Group entities, the tax effects of the elimination of intragroup margin on inventory, and settlements and recent proceedings involving the tax authorities in various countries that had a positive effect in both 2013 and 2014.

Share of Profit/Loss of Associates and Joint Ventures

Associates and joint ventures contributed a net loss of 52 million in 2014, versus net income of 39 million in 2013.

Since April 2014, this line item has included our share of the profits and losses of Regeneron (impact: expense of 126 million), including the impact of the fair value remeasurement of our share of the acquired intangible assets of Regeneron. It also includes our share of after-tax profits from territories managed by BMS under the Plavix® and Avapro® alliance (31 million in 2014, versus 25 million in 2013), plus immaterial amounts for our share of profits and losses from other associates and joint ventures.

Net Income Excluding the Held-For-Exchange Animal Health Business

Net income excluding the held-for-exchange Animal Health business amounted to 4,392 million in 2014, versus 3,797 million in 2013.

Net Income/(Loss) of the Held-For-Exchange Animal Health Business

In accordance with IFRS 5, the net income or loss of the Animal Health business is presented in a separate line item, Net income/(loss) of the held-for-exchange Animal Health business (see Notes D.2.1. and D.36. to our consolidated financial statements included at Item 18 of this annual report). This business reported net income of 117 million in 2014, compared with net income of 77 million in 2013.

Net Income

Net income amounted to 4,509 million in 2014, versus 3,874 million in 2013.

Net Income Attributable to Non-Controlling Interests

Net income attributable to non-controlling interests was 119 million in 2014, versus 158 million in 2013. This line mainly comprises the share of pre-tax profits paid to BMS from territories managed by Sanofi (109 million, versus 141 million in 2013). The year-on-year decrease was directly related to competition from generics of clopidogrel (active ingredient of Plavix®) and irbesartan (active ingredient of Aprovel®) in Europe.

Net Income Attributable to Equity Holders of Sanofi

Net income attributable to equity holders of Sanofi amounted to 4,390 million, versus 3,716 million in 2013.

Basic earnings per share for 2014 was 3.34, 18.9% higher than the 2013 figure of 2.81, based on an average number of shares outstanding of 1,315.8 million in 2014 (1,323.1 million in 2013). Diluted earnings per share for 2014 was 3.30 (versus 2.77 in 2013), based on an average number of shares outstanding after dilution of 1,331.1 million in 2014 and 1,339.1 million in 2013.

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Segment results

We report segment results on the basis of Business Operating Income . This indicator, adopted in compliance with IFRS 8, is used internally to measure operational performance and to allocate resources. See Segment information above for the definition of business operating income and a reconciliation to Income before tax and associates and joint ventures.

Business Operating Income

Business operating income amounted to 8,957 million in 2014, 1.5% higher than in 2013 (8,821 million) and represented 28.3% of net sales, versus 28.5% in 2013.

Business operating income for 2014 and 2013 is set forth below:

(million)	2014	2013	Change
Pharmaceuticals	8,018	7,886	+1.7%
Vaccines	994	909	+9.4%
Other	(55)	26	-
Business operating income[1]	**8,957**	**8,821**	**+1.5%**
Animal Health business[2]	492	502	-2.0%
Total: aggregated basis[3]	**9,449**	**9,323**	**+1.4%**

(1) Business operating income of continuing operations.

(2) The net income/(loss) of the Animal Health business is presented in a separate income statement line item, Net income/(loss) of the held-for-exchange Animal Health business , in accordance with IFRS 5. Until final completion of the transaction, the Animal Health business remains an operating segment of the Group pursuant to IFRS 8 (see Notes D.2.1. and D.36. to our consolidated financial statements included at Item 18 of this annual report).

(3) Non-GAAP financial measure.

The following table presents our segment results for the year ended December 31, 2014.

(million)	Pharmaceuticals	Vaccines	Other	Total Group	Animal Health[1]	Total: aggregated basis[2]
Net sales	**27,720**	**3,974**	**-**	**31,694**	**2,076**	**33,770**

Other revenues	272	33	-	305	34	339
Cost of sales	(8,282)	(1,948)	-	(10,230)	(799)	(11,029)
Research and development expenses	(4,174)	(493)	-	(4,667)	(157)	(4,824)
Selling and general expenses	(7,692)	(614)	(3)	(8,309)	(682)	(8,991)
Other operating income and expenses	194	2	(52)	144	20	164
Share of profit/(loss) of associates and joint ventures	106	40	-	146	1	147
Net income attributable to non-controlling interests	(126)	-	-	(126)	(1)	(127)
Business operating income	**8,018**	**994**	**(55)**	**8,957**	**492**	**9,449**

(1) The net income/(loss) of the Animal Health business is presented in a separate income statement line item Net income/(loss) of the held-for-exchange Animal Health business for 2015 and prior years, in accordance with IFRS 5. Until final completion of the transaction, the Animal Health business remains an operating segment of the Group pursuant to IFRS 8 (see Notes D.2.1. and D.36. to our consolidated financial statements included at Item 18 of this annual report).

(2) Non-GAAP financial measure which includes the Animal Health business.

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The following table presents our segment results for the year ended December 31, 2013.

(*million*)	Pharmaceuticals	Vaccines	Other	Total Group	Animal Health[1]	Total: aggregated basis[2]
Net sales	**27,250**	**3,716**	**-**	**30,966**	**1,985**	**32,951**
Other revenues	295	30	-	325	30	355
Cost of sales	(8,518)	(1,776)	-	(10,294)	(689)	(10,983)
Research and development expenses	(4,087)	(518)	-	(4,605)	(165)	(4,770)
Selling and general expenses	(7,362)	(588)	-	(7,950)	(653)	(8,603)
Other operating income and expenses	422	3	26	451	(1)	450
Share of profit/(loss) of associates and joint ventures	48	41	-	89	(4)	85
Net income attributable to non-controlling interests	(162)	1	-	(161)	(1)	(162)
Business operating income	**7,886**	**909**	**26**	**8,821**	**502**	**9,323**

(1) The net income/(loss) of the Animal Health business is presented in a separate income statement line item Net income/(loss) of the held-for-exchange Animal Health business for 2015 and prior years, in accordance with IFRS 5. Until final completion of the transaction, the Animal Health business remains an operating segment of the Group pursuant to IFRS 8 (see Notes D.2.1. and D.36. to our consolidated financial statements included at Item 18 of this annual report).

(2) Non-GAAP financial measure which includes the Animal Health business.

Business Net Income

Business net income is a non-GAAP financial measure that we use to evaluate our Group s performance. See Business Net Income above for the definition of business net income and a reconciliation to Net income attributable to equity holders of Sanofi.

Business net income totaled 6,847 million in 2014, versus 6,686 million in 2013, an increase of 2.4%; it represented 21.6% of net sales in both 2014 and 2013 (20.3% of aggregate net sales both in both 2014 and 2013).

Business Earnings Per Share

We also report business earnings per share, a non-GAAP financial measure which we define as business net income divided by the weighted average number of shares outstanding (see Business Net Income above).

Business earnings per share was 5.20 in 2014, 3.0% higher than the 2013 figure of 5.05, based on an average number of shares outstanding of 1,315.8 million in 2014 and 1,323.1 million in 2013.

Liquidity and Capital Resources

Our operations generate significant positive cash flows. We fund our day-to-day investments (with the exception of significant acquisitions) primarily with operating cash flow, and pay regular dividends on our shares. Our net debt increased in 2015, following an increase during 2014 to finance our acquisitions of equity interests in Regeneron and Alnylam, and a reduction in our net debt in 2013.

We define debt, net of cash and cash equivalents as (i) the sum total of short-term debt, long-term debt and interest rate and currency derivatives used to hedge debt, minus (ii) the sum total of cash and cash equivalents and interest rate and currency derivatives used to hedge cash and cash equivalents. As of December 31, 2015, our debt, net of cash and cash equivalents stood at 7,254 million versus 7,171 million as of December 31, 2014 and 6,043 million as of December 31, 2013. See Note D.17. to our consolidated financial statements included at Item 18 of this annual report.

In order to assess the Company s financing risk, we also use the gearing ratio , a non-GAAP financial measure. The gearing ratio is defined as the ratio of debt, net of cash and cash equivalents, to total equity. As of December 31, 2015, our gearing ratio was 12.5% of our net equity versus 12.7% as of December 31, 2014 and 10.6% as of December 31, 2013.

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Consolidated Statement of Cash Flows

The table below shows our summarized cash flows for the years ended December 31, 2015, 2014 and 2013:

(million)	2015	2014	2013
Net cash provided by / (used in) operating activities excluding the held-for-exchange Animal Health business	8,290	7,165	6,558
Net cash provided by / (used in) investing activities excluding the held-for-exchange Animal Health business	(3,011)	(3,357)	(1,178)
Net cash provided by / (used in) financing activities excluding the held-for-exchange Animal Health business	(3,578)	(5,194)	(3,757)
Impact of exchange rates on cash and cash equivalents	(232)	34	(79)
Net change in cash and cash equivalents excluding the Animal Health business	**1,469**	**(1,352)**	**1,544**
Net cash provided by / (used in) operating activities of the held-for-exchange Animal Health business	630	525	396
Net cash provided by / (used in) investing activities of the held-for-exchange Animal Health business	(246)	(103)	(95)
Net cash provided by / (used in) financing activities of the held-for-exchange Animal Health business	(23)	14	31
Net change in cash and cash equivalents of the Animal Health business	**361**	**436**	**332**
Impact on cash and cash equivalents of the reclassification of the Animal Health business to Assets held for sale or exchange	**(23)**	**-**	**-**
Net change in cash and cash equivalents (decrease) / increase	**1,807**	**(916)**	**1,876**

Generally, factors that affect our earnings for example, pricing, volume, costs and exchange rates flow through to cash from operations. The most significant source of cash from operations is sales of our branded pharmaceutical products and human vaccines. Receipts of royalty payments also contribute to cash from operations.

Year Ended December 31, 2015 Compared with Year Ended December 31, 2014

Net cash provided by operating activities excluding the held-for-exchange Animal Health business amounted to 8,290 million in 2015, versus 7,165 million in 2014.

Operating cash flow before changes in working capital (excluding the net income or loss of the held-for-exchange Animal Health business) for 2015 was 7,235 million, versus 6,257 million in 2014. Working capital requirements fell by 1,055 million in 2015, compared with a reduction of 908 million in 2014, due mainly to an increase in non-current liabilities related to commercial terms of business.

Our operating cash flow before changes in working capital is generally affected by the same factors that affect Operating income , which is discussed in detail above under Results of Operations Year Ended December 31, 2015 Compared with Year Ended December 31, 2014 . The principal difference is that operating cash flow before changes in working capital includes our share of the profits and losses of associates and joint ventures, net of dividend and similar income received.

Net cash used in investing activities excluding the held-for-exchange Animal Health business amounted to 3,011 million in 2015, compared with 3,357 million in 2014.

Acquisitions of property, plant and equipment and intangible assets totaled 2,772 million, versus 1,453 million in 2014. The main items were investments in industrial and research facilities (1,163 million in 2015, versus 970 million in 2014) and contractual payments for intangible rights, mainly under license and collaboration agreements (1,465 million in 2015, versus 354 million in 2014).

Acquisitions of investments during 2015 amounted to 362 million, net of cash acquired and after including assumed liabilities and commitments, compared with 2,294 million in 2014. The main items were our acquisitions of shares in Regeneron (117 million in 2015 1,629 million in 2014) and Alnylam (79 million in 2015, 535 million in 2014).

After-tax proceeds from disposals (211 million) related mainly to the divestment of our equity interest in Merrimack Pharmaceuticals and the sale of rights in Sklice® to Arbor Pharmaceuticals LLC in the United States. In 2014, after-tax proceeds from disposals (262 million) related mainly to the divestment of Genzyme s equity interest in Ionis Pharmaceuticals (formerly Isis Pharmaceuticals) and to a payment received from Tolmar in exchange for the transfer of rights to Eligard™ and Aplenzin® in the United States.

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Net cash used in financing activities excluding the held-for-exchange Animal Health business amounted to 3,578 million in 2015, compared with 5,194 million in 2014. The 2015 figure includes net external debt finance raised of 1,346 million; this compares with net external debt finance repaid (i.e., net change in short-term and long-term debt) of 390 million in 2014. It also includes the effect of changes in share capital (repurchases of own shares, net of capital increases), amounting to 1,211 million (versus 1,121 million in 2014), and the dividend payout to our shareholders of 3,694 million (versus 3,676 million in 2014).

The net change in cash and cash equivalents excluding the held-for-exchange Animal Health business was an increase of 1,469 million in 2015, compared with a decrease of 1,352 million in 2014.

Net cash flows for the held-for-exchange Animal Health business represented net cash inflows of 361 million in 2015 and 436 million in 2014.

The net change in cash and cash equivalents during 2015 (after the 23 million impact on cash and cash equivalents of the reclassification of the Animal Health business to Assets held for sale or exchange), was an increase of 1,807 million; this compares with a reduction of 916 million in 2014.

Year Ended December 31, 2014 Compared with Year Ended December 31, 2013

Net cash provided by operating activities excluding the held-for-exchange Animal Health business amounted to 7,165 million in 2014, versus 6,558 million in 2013.

Operating cash flow before changes in working capital for 2014 was 6,257 million, versus 6,363 million in 2013. Working capital requirements fell by 908 million in 2014, compared with a reduction of 195 million in 2013, due mainly to an increase in trade accounts payable.

Our operating cash flow before changes in working capital is generally affected by the same factors that affect Operating income , which is discussed in detail above under Results of Operations Year Ended December 31, 2014 Compared with Year Ended December 31, 2013 . The principal difference is that operating cash flow before changes in working capital reflects our share of the profits and losses of associates and joint ventures, net of dividend and similar income received.

Net cash used in investing activities excluding the held-for-exchange Animal Health business totaled 3,357 million in 2014, compared with 1,178 million in 2013.

Acquisitions of property, plant and equipment and intangible assets totaled 1,453 million, versus 1,306 million in 2013. The main items were investments in industrial and research facilities (970 million, versus 1,026 million in 2013) and contractual payments for intangible rights under license and collaboration agreements (354 million, versus 188 million in 2013).

Acquisitions of investments during 2014 amounted to 2,294 million, net of cash acquired and after including assumed liabilities and commitments. The main items were our acquisitions of equity interests in Regeneron (1,629 million) and Alnylam (535 million). In 2013, acquisitions of investments totaled 253 million, net of cash acquired and after including assumed liabilities and commitments. The main items were our acquisitions of equity interests in Genfar, and payments of contingent consideration arising from the acquisition of Genzyme.

After-tax proceeds from disposals (262 million) related mainly to the divestment of Genzyme s equity interest in Ionis Pharmaceuticals (formerly Isis Pharmaceuticals) and to a payment received from Tolmar in exchange for the transfer of rights to Eligard and Aplenzin® in the United States. In 2013, after-tax proceeds from disposals (408 million) mainly comprised the sale to Covis Pharma of commercial rights to pharmaceutical products in the United States, the receipt of a $125 million payment associated with changes to the contractual terms of the

alliance on Actonel®, and disposals of property, plant and equipment in the United States and France.

Net cash used in financing activities excluding the held-for-exchange Animal Health business amounted to 5,194 million in 2014, compared with 3,757 million in 2013. The 2014 figure included net external debt finance repaid (i.e. net change in short-term and long-term debt) of 390 million; this compares with net external debt finance raised of 568 million in 2013. It also included the effect of changes in share capital (repurchases of own shares, net of capital increases), amounting to 1,121 million (versus 637 million in 2013), and the dividend payout to our shareholders of 3,676 million (versus 3,638 million in 2013).

The net change in cash and cash equivalents excluding the held-for-exchange Animal Health business was a decrease of 1,352 million in 2014, compared with an increase of 1,544 million in 2013.

Net cash flows for the held-for-exchange Animal Health business represented net cash inflows of 436 million in 2014 and 332 million in 2013.

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The net change in cash and cash equivalents during 2014 was a decrease of 916 million, compared with an increase of 1,876 million in 2013.

Consolidated Balance Sheet and Debt

Total assets were 102,321 million as of December 31, 2015, versus 97,392 million as of December 31, 2014, an increase of 4,929 million.

Debt, net of cash and cash equivalents (see definition above) was 7,254 million as of December 31, 2015, versus 7,171 million as of December 31, 2014. The table below shows our financial position for the years ended December 31, 2015, 2014 and 2013:

(million)	2015	2014	2013
Long-term debt	13,118	13,276	10,414
Short-term debt and current portion of long-term debt	3,436	1,538	4,176
Cash and cash equivalents	(9,148)	(7,341)	(8,257)
Related interest rate and currency derivatives	(152)	(302)	(290)
Debt, net of cash and cash equivalents	**7,254**	**7,171**	**6,043**

Our gearing ratio (debt, net of cash and cash equivalents as a proportion of total equity) fell from 12.7% in 2014 to 12.5% in 2015. Analyses of debt as of December 31, 2015 and December 31, 2014, by type, maturity, interest rate and currency, are provided in Note D.17. to our consolidated financial statements.

The financing arrangements in place as of December 31, 2015 at Sanofi parent company level are not subject to covenants regarding financial ratios and do not contain any clauses linking credit spreads or fees to our credit rating.

Other key movements in the balance sheet are described below.

Total equity amounted to 58,210 million as of December 31, 2015, versus 56,268 million as of December 31, 2014. The net year-on-year increase in equity was attributable primarily to:

- increases: our net income for the year ended December 31, 2015 (4,388 million), the change in currency translation differences (1,915 million, mainly on the U.S. dollar), and net movements in actuarial gains and losses during the period (465 million);
- decreases: the dividend payout to our shareholders in respect of the 2014 financial year (3,694 million) and repurchases of our own shares (1,781 million).

As of December 31, 2015, we held 4.0 million of our own shares, recorded as a deduction from equity and representing 0.3% of our share capital.

Goodwill and Other intangible assets (51,583 million in total) decreased by 2,157 million, mainly reflecting:

- decreases: amortization and impairment losses recognized during the period (3,532 million), and the reclassification to Assets held for sale or exchange of the goodwill (1,510 million) and other intangible assets (2,147 million) of the Animal Health business;

- increases: acquisitions of other intangible assets (2,245 million), and currency translation differences on the remeasurement of assets denominated in foreign currencies (2,895 million, mainly on the U.S. dollar).

Investments in associates and joint ventures increased by 292 million to 2,676 million, mainly as a result of currency translation differences on the remeasurement of assets denominated in foreign currencies.

Other non-current assets were 150 million higher at 2,725 million, mainly due to the acquisition of shares in Alnylam.

Provisions and other non-current liabilities (9,169 million) decreased by 409 million, mainly as a result of movements in actuarial gains and losses on defined-benefit pension plans (reduction of 650 million) and currency translation differences (increase of 190 million).

Deferred taxes represented a net asset of 1,819 million, a year-on-year increase of 1,064 million. This increase was mainly due to reversals of deferred tax liabilities on the remeasurement of acquired intangible assets (725 million) and tax losses available for carry-forward (424 million).

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Liabilities related to business combinations and to non-controlling interests decreased by 13 million to 1,251 million. The main movements in this item are fair value remeasurements of (i) the contingent consideration payable to Bayer as a result of an acquisition made by Genzyme prior to the latter s acquisition by Sanofi and (ii) the contingent value rights (CVRs) issued by Sanofi in connection with the Genzyme acquisition (see Note D.18. to our consolidated financial statements included at Item 18 of this annual report).

Assets held for sale or exchange (5,752 million) and liabilities related to assets held for sale or exchange (983 million) mainly comprise the assets and liabilities of the held-for-exchange Animal Health business (see Note D.8. to our consolidated financial statements included at Item 18 of this annual report).

Liquidity

We expect that our existing cash resources and cash from operations will be sufficient to finance our foreseeable working capital requirements. At year-end 2015, we held cash and cash equivalents amounting to 9,148 million, substantially all of which were held in euros (see Note D.13. to our consolidated financial statements included at Item 18 of this annual report). As at December 31, 2015, our subsidiaries based in Venezuela held cash and cash equivalents in bolivars representing 90 million, which are subject to foreign exchange controls (see Note A.4. to our consolidated financial statements included at Item 18 of this annual report). As at December 31, 2015, 385 million of our cash and cash equivalents were held by our captive insurance and reinsurance companies in accordance with insurance regulations.

Since 2010, some countries in Southern Europe have been facing severe financial difficulties (see Item 3.D Risk Factors Risks Relating to Our Business We are subject to the risk of non-payment by our customers). Deteriorating credit and economic conditions and other factors in these countries have resulted in, and may continue to result in an increase in the average length of time taken to collect our accounts receivable in these countries. Should these factors continue, it may require us to re-evaluate the collectability of these receivables in future periods. We carefully monitor sovereign debt issues and economic conditions and evaluate accounts receivable in these countries for potential collection risks. We have been conducting an active recovery policy, adapted to each country and including intense communication with customers, negotiations of payment plans, charging of interest for late payments, and legal action.

During 2015, the amount of our trade receivables in Europe continued to fall, primarily as a result of a reduction in the sums owed to us by public sector customers in Spain and Italy. Over the Group as a whole, the amount of trade receivables overdue by more than 12 months which consists mainly of amounts due from public sector bodies fell from 170 million as of December 31, 2014 to 159 million as of December 31, 2015 (see Note D.10. to our consolidated financial statements), mainly as a result of the reclassification of Animal Health receivables to Assets held for sale or exchange as of December 31, 2015.

In November 2011, Sanofi obtained the necessary corporate authorizations to purchase any or all of the outstanding Contingent Value Rights (CVR) and subsequently purchased CVRs in 2011. In 2012 following a tender offer initiated in September 2012 on the basis of the same corporate authorization, Sanofi purchased an additional 40,025,805 CVRs (for a total consideration of approximately $70 million), followed by a further 10,928,075 CVRs (for approximately $9 million) in 2013, 1,879,774 CVRs (for approximately $1 million) in 2014, and none in 2015. As of December 31, 2015, a total of 236,456,456 CVRs were outstanding out of the 291,313,510 issued at the time of the Genzyme acquisition.

At year-end 2015, we had no commitments for capital expenditures that we consider to be material to our consolidated financial position. Undrawn confirmed credit facilities amounted to a total of 8.0 billion at December 31, 2015. For a discussion of our treasury policies, see Item 11. Quantitative and Qualitative Disclosures about Market Risk.

We expect that cash from our operations will be sufficient to repay our debt. For a discussion of our liquidity risks, see Item 11. Quantitative and Qualitative Disclosures about Market Risk.

Off-Balance Sheet Arrangements / Contractual Obligations and Other Commercial Commitments

We have various contractual obligations and other commercial commitments arising from our operations. Our contractual obligations and our other commercial commitments as of December 31, 2015 are shown in Notes D.3., D.17., D.18., D.21. and D.36. to our consolidated financial statements included at Item 18 of this annual report. Note D.21. to our consolidated financial statements discloses details of commitments under our principal research and development collaboration agreements. For a description of the principal contingencies arising from certain business divestitures, refer to Note D.22.e) to our 2015 consolidated financial statements.

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The Group s contractual obligations and other commercial commitments are set forth in the table below:

December 31, 2015	Payments due by period[1]				
		Less than			
(million)	Total	1 year	1 to 3 years	3 to 5 years	More than 5 years
· Future contractual cash-flows relating to debt and debt hedging instruments[2]	17,818	3,594	3,799	3,440	6,985
· Operating lease obligations	1,604	274	436	263	631
· Finance lease obligations[3]	89	23	36	8	22
· Irrevocable purchase commitments[4]					
given	4,228	2,324	1,305	274	325
received	(269)	(158)	(55)	(33)	(23)
· Research & development license agreements					
Commitments related to R&D and other commitments	1,957	831	811	216	99
Potential milestone payments[5]	3,552	335	455	1,546	1,216
Obligations related to R&D license agreements reflected on the balance sheet	683	522	109	52	-
· Obligations relating to business combinations[6]	5,073	126	485	362	4,100
· Firm commitment related to the BMS agreement[7]	114	-	114	-	-
· Estimated benefit payments on unfunded pensions and post employment benefits[8]	1,399	64	133	155	1,047
Total contractual obligations and other commitments	**36,248**	**7,935**	**7,628**	**6,283**	**14,402**
Undrawn general-purpose credit facilities	**8,008**	**7**	**-**	**8,000**	**1**

(1) Including payments related to contractual obligations and other commercial commitments of the Animal Health business, reclassified to Assets and liabilities held for sale or exchange as of December 31, 2015 in accordance with IFRS 5 (see Notes D.2.1. and D.36. to our consolidated financial statements included at Item 18 of this annual report).

(2) Of which 17,795 million related to payments excluding the Animal Health business (see Note D.17. to our consolidated financial statements included at Item 18 of this annual report) and 23 million related to the Animal Health business.

(3) Of which 83 million related to payments excluding the Animal Health business (see Note D.3. to our consolidated financial statements included at Item 18 of this annual report) and 6 million related to the Animal Health business.

(4) These comprise irrevocable commitments to third parties for (i) property, plant and equipment, net of down payments (of which 436 million related to payments excluding the Animal Health business see Note D.3. to our consolidated financial statements included at Item 18 of this annual report and 27 million related to the Animal Health business) and (ii) goods and services.

(5) This line includes all potential milestone payments on projects regarded as reasonably possible, i.e., on projects in the development phase.

(6) See Note D.18. to our consolidated financial statements included at Item 18 of this annual report.

(7) See Note C.2. to our consolidated financial statements included at Item 18 of this annual report.

(8) Of which 1,352 million related to payments excluding the Animal Health business (see Note D.19.1. to our consolidated financial statements included at Item 18 of this annual report) and 47 million related to the Animal Health business. The table above does not include the ongoing annual employer s contributions to plan assets, estimated at 177 million in 2016 (of which 175 million excluding the Animal Health business and 2 million related to the Animal Health business).

We may have payments due to our current or former research and development partners under collaborative agreements. These agreements typically cover multiple products, and give us the option to participate in development on a product-by-product basis. When we exercise our option with respect to a product, we pay our collaboration partner a fee and receive intellectual property rights to the product in exchange. We are also generally required to fund some or all of the development costs for the products that we select, and to make payments to our partners when those products reach development milestones.

We have entered into collaboration agreements under which we have rights to acquire products or technology from third parties through the acquisition of shares, loans, license

agreements, joint development, co-marketing and other contractual arrangements. In addition to upfront payments on signature of the agreement, our contracts frequently require us to make payments contingent upon the completion of development milestones by our alliance partner or upon the granting of approvals or licenses.

Because of the uncertain nature of development work, it is impossible to predict (i) whether Sanofi will exercise further options for products, or (ii) whether the expected milestones will be achieved, or (iii) the number of compounds that will reach the relevant milestones. It is therefore impossible to estimate the maximum aggregate amount that Sanofi will actually pay in the future under existing collaboration agreements.

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Item 5. Operating and Financial Review and Prospects

Given the nature of its business, it is highly unlikely that Sanofi will exercise all options for all products or that all milestones will be achieved.

The main collaboration agreements relating to development projects are described in Note D.21.1. to our consolidated financial statements included at Item 18 of this annual report. Milestone payments relating to development projects under these agreements included in the table above exclude projects (4.7 billion in 2015, 4.2 billion in 2014) and payments contingent upon the attainment of sales targets once a product is on the market (8.0 billion in 2015, 4.7 billion in 2014).

Critical accounting and reporting policies

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

- **Revenue recognition.** Our policies with respect to revenue recognition are discussed in Note B.14. to our consolidated financial statements included at Item 18 of this annual report. Revenue arising from the sale of goods is presented in the income statement under Net sales . Net sales comprise revenue from sales of pharmaceutical products, vaccines, and active ingredients, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities. Revenue is recognized when all of the following conditions have been met: the risks and rewards of ownership have been transferred to the customer; the Group no longer has effective control over the goods sold; the amount of revenue and costs associated with the transaction can be measured reliably; and it is probable that the economic benefits associated with the transaction will flow to the Group.

We offer various types of price reductions on our products. In particular, products sold in the United States are covered by various programs (such as Medicare and Medicaid) under which products are sold at a discount. Rebates are granted to healthcare authorities, and under contractual arrangements with certain customers. Some wholesalers are entitled to chargeback incentives based on the selling price to the end customer, under specific contractual arrangements. Cash discounts may also be granted for prompt payment. The discounts, incentives and rebates described above are estimated on the basis of specific contractual arrangements with our customers

or of specific terms of the relevant regulations and/or agreements applicable for transactions with healthcare authorities, and of assumptions about the attainment of sales targets. They are recognized in the period in which the underlying sales are recognized, as a reduction of sales revenue. We also estimate the amount of product returns, on the basis of contractual sales terms and reliable historical data; the same recognition principles apply to sales returns. For additional details regarding the financial impact of discounts, rebates and sales returns, see Note D.23. to our consolidated financial statements included at Item 18 of this annual report.

Non-product revenues, mainly comprising royalty income from license arrangements that constitute ongoing operations of the Group, are presented in Other revenues .

- **Business combinations.** As discussed in Note B.3. Business combinations and transactions with non-controlling interests to our consolidated financial statements included at Item 18 of this annual report, business combinations are accounted for by the acquisition method. The acquiree s identifiable assets, liabilities and contingent liabilities that satisfy the recognition criteria of IFRS 3 Business Combinations are

measured initially at their fair values as at the acquisition date, except for non-current assets classified as held for sale, which are measured at fair value less costs to sell. Business combinations completed on or after January 1, 2010 are accounted for in accordance with the revised IFRS 3 and the revised IAS 27, Consolidated and Individual Financial Statements , now superseded by IFRS 10 Consolidated Financial Statements . In particular, contingent consideration to former owners agreed in a business combination, e.g. in the form of payments upon the achievement of certain R&D milestones, is recognized as a liability at fair value as of the acquisition date. Any subsequent changes in amounts recorded as a liability are recognized in the consolidated income statement (see Note D.18. Liabilities related to business combinations and non-controlling interests to our consolidated financial statements included at Item 18 of this annual report).

Goodwill impairment and intangible assets. As discussed in Note B.6. Impairment of property, plant and equipment, intangible assets, and investments in associates and joint ventures and in Note D.5. Impairment of intangible assets and property, plant and equipment to our consolidated financial statements included at Item 18 of this annual report, we test our intangible assets periodically for impairment. We test for impairment on the basis of the same objective criteria that were used for the initial valuation. Our initial valuation and ongoing tests are based on the relationship of the value of our projected future cash flows associated with the asset to either the purchase price of the asset (for its initial

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valuation) or the carrying amount of the asset (for ongoing tests). The determination of the underlying assumptions relating to the recoverability of intangible assets is subjective and requires the exercise of considerable judgment. Key assumptions relating to goodwill impairment and intangible assets are the perpetual growth rate and the post-tax discount rate. Any changes in key assumptions could result in an impairment charge. A sensitivity analysis to the key assumptions is disclosed in Note D.5. Impairment of intangible assets and property, plant and equipment to our consolidated financial statements included at Item 18 of this annual report.

- **Pensions and post-retirement benefits.** As described in Note B.23. Employee benefit obligations to our consolidated financial statements included at Item 18 of this annual report, we recognize our pension and retirement benefit commitments as liabilities on the basis of an actuarial estimate of the potential rights vested in employees and retirees as of the balance sheet date, net of the valuation of funds to meet these obligations. We prepare this estimate at least on an annual basis taking into account financial assumptions (such as discount rates) and demographic assumptions (such as life expectancy, retirement age, employee turnover, and the rate of salary increases).

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

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

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

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

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

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Item 6. Directors, Senior Management and Employees

Item 6. Directors, Senior Management and Employees

A. Directors and Senior Management

Since January 1, 2007, Sanofi has separated the offices of Chairman and Chief Executive Officer. The annual evaluations conducted since that date have indicated that this governance structure is appropriate to the Group s current configuration. This arrangement was maintained with the appointment of Serge Weinberg to the office of Chairman on May 17, 2010, on May 6, 2011 and again on May 4, 2015. The Board of Directors continues to consider that this governance structure is appropriate in the Group s current context.

As an exception, resulting from the removal of Christopher Viehbacher from office as Chief Executive Officer on October 29, 2014, the Board of Directors asked Serge Weinberg to temporarily occupy the functions of both Chairman and Chief Executive Officer. Upon the appointment of Olivier Brandicourt as Chief Executive Officer on April 2, 2015, the Group s governance returned to the separation of the offices of Chairman and Chief Executive Officer.

Due to the exceptional and temporary nature of the combination of the two offices, the Board of Directors, on recommendation of the Appointments and Governance Committee, did not consider it necessary or appropriate to appoint a lead independent director. However, the Board of Directors, at its meeting held on November 18, 2014, decided to assign the chairmanship of the Appointments and Governance Committee to an independent director to replace the Chairman of the Board of Directors. With the return to the separation of the two offices, Serge Weinberg resumed the chairmanship of the Appointments and Governance Committee on October 28, 2015.

The **Chairman** organizes and directs the work of the Board, and is responsible for ensuring the proper functioning of the corporate decision-making bodies in compliance with good governance practices. The Chairman coordinates the work of the Board of Directors with its Committees. The Chairman is accountable to the Shareholders General Meeting, which he chairs.

When the offices of Chairman and Chief Executive Officer are separated, the Chairman may remain in office until the Ordinary Shareholders General Meeting called to approve the financial statements held during the calendar year in which he reaches the age of 70.

The **Chief Executive Officer** is responsible for the management of the Company, and represents the Company

in dealings with third parties within the limit of the corporate purpose. The Chief Executive Officer has the broadest powers to act in all circumstances in the name of the Company, subject to the powers that are attributed by law to the Board of Directors and to the Shareholders General Meeting and within the limits set by the Board of Directors.

The Chief Executive Officer may not be more than 65 years old.

Limitations on the powers of the Chief Executive Officer set by the Board

The Board of Directors Meeting of July 28, 2009 set limits on the powers of the Chief Executive Officer in a decision that supplements the Board Charter. The prior authorization of the Board of Directors is required to commit Sanofi to investments, acquisitions and divestments in the following cases:

- a 500 million cap for each undertaking pertaining to a previously approved strategy; and

- a 150 million cap for each undertaking not pertaining to a previously approved strategy.

When the consideration payable to the contracting parties for such undertakings includes potential installment payments contingent upon the achievement of future results or objectives, such as the registration of one or more products, the caps are calculated by aggregating the various payments due from signature of the contract until (and including) filing of the first application for marketing authorization in the United States or in Europe.

Following the appointment of a new Chief Executive Officer and on the recommendation of the Appointments and Governance Committee, the Board of Directors reassessed these limitations and decided to maintain them.

Board of Directors

The Company is administered by a Board of Directors, comprising fourteen members as of December 31, 2015.

Subject to the powers expressly attributed to the Shareholders General Meeting and within the scope of the Company s corporate purpose, the Board of Directors powers cover all issues relating to the proper management of the Company, and through its decisions the Board determines all matters falling within its authority.

The terms of office of the directors are staggered, such that members of the Board seek reappointment on a regular basis in the most equal proportions possible. Exceptionally, the Shareholders Ordinary General Meeting may appoint a director to serve for a term of one, two or three years, in order to ensure adequate rotation of Board members.

Each year, the Board of Directors conducts a review to ensure that there is an appropriate balance in its

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composition and in the composition of its Committees. In particular, the Board seeks to ensure a more balanced representation of men and women and diversity of background and country of origin, since the business of the Group is both diversified and global. The Board investigates and evaluates potential candidates whenever individual directors are up for election. Above all, the Board seeks talented directors, who show independence of mind and who are competent, dedicated and committed.

Independence of Board Members

Under the terms of the AFEP-MEDEF corporate governance code (hereafter referred to as the AFEP-MEDEF Code), a director is deemed to be independent when he or she has no relationship of any nature whatsoever with the Company, the Group it belongs to or its senior management which could compromise the exercise of the director s freedom of decision. More specifically, in order to qualify as independent, directors may not:

- be an employee or corporate officer of the Company, or a corporate officer of a related company (criterion 1);
- be a customer, supplier, or investment banker or corporate banker of the Company (criterion 2);
- have close family ties with any corporate officer of the Company (criterion 3);
- have acted as auditor for the Company over the course of the last five years (criterion 4);
- be representative of a significant shareholder or of a controlling interest of the Company (criterion 5).

The influence of other factors such as length of service on the Board, the ability to understand challenges and risks, and the courage to express ideas and form a judgment, is also evaluated before a director qualifies as independent.

In compliance with our Board Charter and pursuant to the AFEP-MEDEF Code, the Board of Directors meeting of October 28, 2015 reviewed the independence of current directors. Of the fourteen directors, eleven were deemed to be independent directors with reference to the independence criteria used by the Board of Directors pursuant to the AFEP-MEDEF Code: Serge Weinberg, Bonnie Bassler, Uwe Bicker, Robert Castaigne, Jean-René Fourtou, Claudie Haigneré, Patrick Kron, Fabienne Lecorvaisier, Suet-Fern Lee, Carole Piwnica and Klaus Pohle.

	Criterion 1	Criterion 2	Criterion 3	Criterion 4	Criterion 5	Length of service under 12 years	Qualification
Serge Weinberg	No[1]	Yes	Yes	Yes	Yes	Yes	Independent
Bonnie Bassler	Yes	Yes	Yes	Yes	Yes	Yes	Independent
Uwe Bicker	Yes	Yes[2]	Yes	Yes	Yes	Yes	Independent
Robert Castaigne	Yes	Yes	Yes	Yes	Yes	No[3]	Independent
Jean-René Fourtou	Yes	Yes	Yes	Yes	Yes	Yes	Independent
Claudie Haigneré	Yes	Yes	Yes	Yes	Yes	Yes	Independent
Patrick Kron	Yes	Yes	Yes	Yes	Yes	Yes	Independent

Fabienne Lecorvaisier	Yes	Yes	Yes	Yes	Yes	Yes	Independent
Suet-Fern Lee	Yes	Yes	Yes	Yes	Yes	Yes	Independent
Carole Piwnica	Yes	Yes	Yes	Yes	Yes	Yes	Independent
Klaus Pohle	Yes	Yes[(2)]	Yes	Yes	Yes	Yes	Independent

The Board s conclusions on particular situations are set out below.

(1) Serge Weinberg
In 2013, the rules governing the office of the Chairman of the Board changed, allowing the Board to regard the Chairman as an independent director in accordance with the continuous assessment of the Board of Directors. Until 2013, Serge Weinberg had not been regarded as an independent director only because of the previous version of the AFEP-MEDEF Code which in its former article 8.4 did not

distinguish the case where the functions of Chairman and Chief Executive Officer are separated from the case where both functions are combined. Effective June 2013, the AFEP-MEDEF Code (in its new article 9.4) stipulates that if the offices of Chairman and Chief Executive Officer are separated, the Chairman is not automatically regarded as non-independent, but his (or her) independence has to be scrutinized in the light of the criteria generally used to assess directors independence. The Board of Directors took the view that no factor other than his role as Chairman is liable to undermine his independence, especially given that prior to

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joining the Board he had no relationship with Sanofi. The Board assessment concerning his situation was reflected in the previous annual reports on Form 20-F. On October 29, 2013 the Board of Directors determined that Serge Weinberg was an independent director.

When the offices of Chairman of the Board and Chief Executive Officer were temporarily combined on October 29, 2014, the Board of Directors determined that Serge Weinberg could no longer be regarded as independent. When the two offices were separated again, the Board of Directors determined that Serge Weinberg could be regarded as independent and could therefore resume the chairmanship of the Appointments and Governance Committee. Serge Weinberg does not receive any variable compensation, whether in cash or in shares, which complies with the recommendation the AMF published in its 2015 report on corporate governance and compensation of corporate officers of listed companies.

(2) Business Relationships Review
In its examination of the independence of each Director, the Board of Directors took into account the various relationships that could exist between Directors and the Group and concluded that no such relationships were of a nature that might undermine their independence. The Board of Directors noted that the Company and its subsidiaries had, in the normal course of business, over the last three years, sold products and provided services to, and/or purchased products and received services from, companies in which certain of the Company s directors who are classified as independent or members of their close family were senior managers or employees during 2015. On each occasion, the amounts paid to or received from such companies over the past three years were determined on an arm s length basis and did not represent amounts that the Board regarded as undermining the independence of the Directors in question. Similarly, the Board of Directors did not find the office of trustee held by Uwe Bicker and Klaus Pohle with the Aventis Foundation (Germany) was of such a nature as to undermine their independence as members of the Sanofi Board of Directors. Appointments to the Board of Trustees as well as the management of the Foundation are made completely independently of Sanofi.

(3) Robert Castaigne
The Board of Directors considers that the situation of Robert Castaigne has changed since his first appointment to the Board. Prior to 2012, Robert Castaigne had not been regarded as an independent director due to his past relationship with Total. Since April 2008, when the independence criteria of the AFEP-MEDEF Code were adopted, his situation has changed in two ways:

- Robert Castaigne retired from Total more than four years ago.
- Total passed below the threshold of 5% of our voting rights as per notification of February 16, 2012. In 2012, Total ceased to have any equity interest in our Company.

Consequently, the Board of Directors took the view that Robert Castaigne s relationship with Total no longer created a presumption of non-independence.

Moreover, the Board of Directors does not believe that belonging to the Board for more than 12 years of itself disqualifies a director from being independent. The length of service criterion is intended to address the concern that the passage of time may deprive a director of his ability to challenge senior management. This is a legitimate concern, which Sanofi takes very seriously.

This is why the Board of Directors applies this criterion pragmatically in light of the specific circumstances of each case. In the case of Robert Castaigne, the Board considers that this director has demonstrated a questioning approach, which is fundamentally what the AFEP-MEDEF

criteria are seeking to check. For more information see C. Board Practices , below.

Finally, there was no other factor calling into question Robert Castaigne s independence.

Consequently, the Board determined on this basis, at its meeting of May 4, 2012 and upon the recommendation of its Appointments and Governance Committee, that Robert Castaigne qualified as an independent director. This position was reconfirmed at its meeting of November 18, 2014.

It should be noted that this decision has no detrimental effect on compliance with the independence rules of the AFEP-MEDEF Code, which is the main objective of the Code. The fact that the proportion of independent directors on the Board is over 78% demonstrates that the Board in no way underestimates the importance of having a majority of independent directors in its governance.

No more than one-third of the serving members of our Board of Directors may be over 70 years of age.

Board evaluation

Under the terms of the Board Charter, a discussion of the Board s operating procedures must be included in the agenda of at least one Board meeting every year. The Charter also requires a formal evaluation to be performed every three years.

The terms of office of certain directors came up for renewal in 2015. As part of this process, their contribution to the work of the Board and its committees was assessed, and in each case was judged to have met the Group s needs and been in line with its expectations.

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In 2015, the Board decided for the first time to retain an independent consultant to perform a formal evaluation of the work of the Board and its committees. This decision was largely motivated by a commitment to ensure that lessons were learned from recent events.

Each Board member completed a questionnaire, and was then interviewed by consultants in late 2015 and early 2016. Issues addressed by these questions included:

- governance methods and structures;
- the effectiveness of the Board;
- how the committees are perceived by the Board;
- composition of the Board;
- Board competencies and working practices;
- relations between the Board and senior management, shareholders and other stakeholders.

A significant improvement in governance was observed following the change of Chief Executive Officer. The new Chief Executive Officer involves the Board in key decisions, and is showing greater commitment to transparency. The quality of interactions between the Executive Committee and the Board has also improved.

In addition, recent experiences have helped enhance the quality of teamwork within the Board, and encouraged convergence of viewpoints.

The Board identified the following areas for improvement:

- fuller information about the Company and its operations, about risks, and about human resources policy;
- more frequent analysis of disruption scenarios associated with trends in the market and the competitive environment, and the impact of digital technologies. The Board has scheduled a fact-finding mission in the western United States for March 2016 in order to deepen its understanding of digital technology issues. In addition, the expanded Strategy Committee meeting held in October will be extended to a full day in order to address additional issues;
- detailed consideration of succession planning for the Chairman of the Board, the Chief Executive Officer and the Executive Committee members. The Appointments and Governance Committee and the Chief Executive Officer started to work together on this project towards the end of 2015.

Acting on the recommendation of the Appointments and Governance Committee, the Board decided to raise the number of executive sessions (Board meetings held without the Chief Executive Officer present) to two per year.

The Board reiterated the objective expressed in its roadmap on the future composition of the Board of bringing more scientific and pharmaceutical expertise, and more non-French and female directors, onto the Board.

Two candidates whose profile fits these priorities will be submitted for approval by the shareholders at the Annual General Meeting on May 4, 2016.

Composition of the Board of Directors as of December 31, 2015

Positions held in listed companies are flagged by an asterisk. Each person s principal position is indicated in bold.

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Item 6. Directors, Senior Management and Employees

Serge Weinberg

1,636 shares

Date of birth:	February 10, 1951
Nationality:	French
First elected:	December 2009
Last reappointment:	May 2015
Term expires:	2019

Directorships and appointments of Serge Weinberg

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments		**In French companies**
	Chairman of the Board and Chief Executive Officer of Sanofi*	Chairman of Weinberg Capital Partners
	Chairman of the Strategy Committee of Sanofi	Chairman of Financière Piasa, Piasa Holding and Maremma Manager of Alret
	Chairman of the Appointments and Governance Committee of Sanofi	Chairman of the Supervisory Board of Financière Climater SAS Vice Chairman and Director of Financière Sasa Director of Madrigall
		In foreign companies
	None	None
Past directorships since 2011		**In French companies**
	None	Director of Team Partners Group (until 2011), Alliance Automotive Participations SAS (until 2014) and Schneider Electric* (until 2014) Member of the Supervisory Board of Amplitude Group (until 2011), Alfina (until 2011), Financière BFSA (until 2013), and Schneider Electric* (until 2013) Weinberg Capital Partners permanent representative on the Board of Alliance Industrie (until 2011) and Sasa Industrie (until 2013) Vice Chairman and Director of Financière Poinsétia (until 2011)
		In foreign companies
	None	Chairman of Corum (Switzerland, until 2013)

Education and business experience

Graduate in law, degree from the *Institut d Etudes Politiques*

Graduate of ENA (*Ecole Nationale d Administration*)

Since 2005	**Chairman of Weinberg Capital Partners**
1976-1982	*Sous-préfet* and then Chief of Staff of the French Budget Minister (1981)
1982-1987	Deputy General Manager of FR3 (French Television Channel) and then Chief Executive Officer of Havas Tourisme
1987-1990	Chief Executive Officer of Pallas Finance
1990-2005	Various positions at PPR* group including Chairman of the Management Board for 10 years
2006-2008	Director of Alliance Industrie
2007-2008	Director of Road Holding
2006-2009	Chairman of the Board of Accor*
2006-2010	Member of the Board of Pharma Omnium International (until 2010)
2005-2010	Vice Chairman of the Supervisory Board of Schneider Electric*

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Olivier Brandicourt

1,000 shares

Date of birth:	February 13, 1956
Nationality:	French
First elected:	April 2015
Term expires:	2018

Directorships and appointments of Olivier Brandicourt

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	**Director and Chief Executive Officer of Sanofi***	**In French companies** None
	Chairman of the Executive Committee of Sanofi	
	Member of the Strategy Committee of Sanofi	
		In foreign companies Member of the Board of Management of the Pharmaceutical Research and Manufacturers of America (PhRMA, United States) and the Board of Directors of the National Committee on U.S.-China Relations (United States) Member of the Council of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA, Switzerland) Member and Vice-Chair of the Board of Trustees of the Children s Aid Society of New York (United States) Honorary Member of the Royal College of Physicians (United Kingdom)
	None	
Past directorships since 2011	None	**In French companies** None
	None	**In foreign companies** Bayer Group (Germany): Chief Executive Officer and Chairman of the Executive Committee of Bayer HealthCare AG (until 2015) Member of the Executive Council of Bayer AG* (until 2015)

Education and business experience

Degree in Medical Mycology, Pasteur Institute, France

Master in Human Biology, Paris XII University, France
Medical Degree with subspecialty in Infectious Diseases and Tropical Medicine, Paris V University, France

1979-1981	National Service for Cooperation with the *Office de la recherche scientifique et technique outre-mer* (ORSTOM) (Republic of Congo)
1981-1987	Research Fellow and Hospital & University Assistant in the Department of Parasitology, Tropical Medicine and Public Health at the Pitié-Salpêtrière Hospital (France)
1987-2000	Various operational and commercial positions at Warner-Lambert/Parke-Davis, including Vice-President and General Manager (1998-2000)
2000-2013	Various operational and managerial positions at Pfizer Inc.*, including member of the Executive Leadership Team (2010-2013) and President & General Manager Emerging Markets & Established Business Unit (2012-2013)
2013-2015	Chief Executive Officer and Chairman of the Executive Committee of Bayer HealthCare AG and Member of the Executive Council of Bayer AG*

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Item 6. Directors, Senior Management and Employees

Laurent Attal

1,000 shares

Date of birth:	February 11, 1958
Nationality:	French
First elected:	May 2012
Term expires:	2016

Directorships and appointments of Laurent Attal

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	Director of Sanofi* Member of the Strategy Committee of Sanofi	**In French companies** Director of *Fondation d Entreprise L Oréal* **In foreign companies** None
Past directorships since 2011	None	**In French companies** None **In foreign companies** None

Education and business experience

Doctor in medicine, dermatologist
MBA from INSEAD (*Institut Européen d Administration des Affaires*)

Since 1986	Various positions within the L Oréal* Group notably within the active cosmetics division, and as President and Chief Executive Officer of L Oréal USA (United States)
Since 2002	Member of L Oréal* Executive Committee
Since 2010	**Vice President General Manager Research and Innovation at L Oréal***

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Bonnie Bassler

1,000 shares

Date of birth:	April 21, 1962
Nationality:	American
First elected:	November 2014
Last reappointment:	May 2015
Term expires:	2019

Directorships and appointments of Bonnie Bassler

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	Independent director of Sanofi*	**In French companies** None
	None	**In foreign companies** Member of the National Science Board (National Science Foundation) Board of Director of the American Association for the Advancement of Science
Past directorships since 2011	None	**In French companies** None
	None	**In foreign companies** None

Education and business experience

Graduated in biochemistry, University of California, Davis
Doctor in biochemistry, Johns Hopkins University

Since 2013	**Squibb Professor and Chair at the Department of Molecular Biology, Princeton University**
Since 2005	Investigator at the Howard Hughes Medical Institute
Since 2003	Professor at the Department of Molecular Biology, Princeton University
2002-2008	Director at the Molecular Biology Graduate Program
2010-2011	President of the American Society for Microbiology
2012	L Oréal-UNESCO women in Science Award Winner
2011-2014	Chair of the Board of Governors of the American Academy of microbiology

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Item 6. Directors, Senior Management and Employees

Uwe Bicker

1,000 shares

Date of birth:	June 14, 1945
Nationality:	German
First elected:	May 2008
Last reappointment:	May 2012
Term expires:	2016

Directorships and appointments of Uwe Bicker

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	Independent director of Sanofi* Member of the Strategy Committee of Sanofi	**In French companies** None
	None	**In foreign companies** Trustee of the Aventis Foundation[1] (not-for-profit, Germany) Chairman of the Board of Marburg University (Germany) Member of the Advisory Board of Morgan Stanley (Germany)
Past directorships since 2011	None	**In French companies** None
	None	**In foreign companies** Member of the Board of Trustees of Bertelsmann Stiftung (Bertelsmann Foundation, Germany, until 2011) Chairman of the Supervisory Board of Siemens Healthcare Diagnostics Holding GmbH (Germany, until 2012) Vice-Chairman of the Supervisory Board of Epigenomics AG (Germany) and of Definiens AG (Germany, until 2012) Member of the Supervisory Board of Future Capital AG (Germany, until 2013)

Education and business experience

Doctorate in chemistry and in medicine
Honorary Doctorate, Klausenburg University
Honorary Senator, Heidelberg University

Since 1983	Professor at the Medical Faculty of Heidelberg (Germany)
Since 2011	**Dean at the Medical Faculty, Heidelberg University** (Germany)
1975-1994	Various positions at Boehringer Mannheim GmbH (later Roche AG) (Germany)
1994-2004	Various positions at Hoechst group (Germany)
1997-2007	Chairman of the Supervisory Board of Dade Behring GmbH (Germany)
2011-2013	Managing Director at the University Clinic of Mannheim (Germany)

(1) No compensation is paid for this office. Appointments to the Board of Trustees of the Foundation are made independently of Sanofi.

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Robert Castaigne

1,000 shares

Date of birth:	April 27, 1946
Nationality:	French
First elected:	February 2000
Last reappointment:	May 2014
Term expires:	2018

Directorships and appointments of Robert Castaigne

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	Independent director of Sanofi*	**In French companies** Société Générale*: Director Member of the Audit and Internal Control Committee Member of the Risk Committee
	Chairman of the Audit Committee of Sanofi	Vinci*: Director Member of the Audit Committee Chairman of the Remuneration Committee
		In foreign companies Novatek* (Russia): Director Member of the Audit Committee Member of the Remuneration and Nomination Committee
	None	
Past directorships since 2011	None	**In French companies** None
	None	**In foreign companies** Director and member of the Audit Committee of *Compagnie Nationale à Portefeuille* (Belgium, until 2011)

Education and business experience

Degree from *Ecole Centrale de Lille* and *Ecole Nationale Supérieure du Pétrole et des Moteurs*
Doctorate in economics

1972-2008	Various positions at the Total* group, including Chief Financial Officer and member of the Executive Committee (1994-2008)

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Jean-René Fourtou

4,457 shares

Date of birth:	June 20, 1939
Nationality:	French
First elected:	August 2004
Last reappointment:	May 2012
Term expires:	2016

Directorships and appointments of Jean-René Fourtou

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments		**In French companies**
	Independent director of Sanofi* Chairman of the Compensation Committee of Sanofi Member of the Appointments and Governance Committee of Sanofi Member of the Strategy Committee of Sanofi	Honorary Chairman of Vivendi*
		In foreign companies
	None	Director of Generali* (Italy)
Past directorships since 2011		**In French companies**
	None	Chairman of the Supervisory Board of Vivendi* (until 2014) Chairman of the Supervisory Board of Canal Plus* Group (until 2011) Director of AXA Millésimes SAS (until 2011)
		In foreign companies
	None	Member of the Supervisory Board of Maroc Telecom* (Vivendi Group, Morocco, until 2014) Director and member of the Compensation Committee of Nestlé* (Switzerland, until 2012)

Education and business experience

Degree from *École Polytechnique*

1963-1986	Various positions at the Bossard group, including Chairman and Chief Executive Officer (1977-1986)
1986-1999	Chairman and Chief Executive Officer of Rhône-Poulenc*
1999-2004	Vice Chairman of the Management Board, then Vice Chairman of the Supervisory Board and member of the Strategy Committee of Aventis*
2002-2008	Vice Chairman, Chairman then Honorary Chairman of the International Chamber of Commerce

2003-2009	Vice Chairman then member of the Supervisory Board, and member of the Ethics and Governance Committee of Axa*
2004-2010	Director of NBC Universal Inc. (United States)
2002-2010	Director of Cap Gemini SA*
2002-2014	Chairman and Chief Executive Officer of Vivendi* (2002-2005) then Chairman of the Supervisory Board of Vivendi* (2005-2014); currently Honorary Chairman of Vivendi*

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Claudie Haigneré

1,000 shares

Date of birth:	May 13, 1957
Nationality:	French
First elected:	May 2008
Last reappointment:	May 2012
Term expires:	2016

Directorships and appointments of Claudie Haigneré

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	Independent director of Sanofi* Member of the Appointments and Governance Committee of Sanofi Member of the Compensation Committee of Sanofi	**In French companies** Orange* (previously France Telecom): Director Member of the Innovation and Technologies committee Director of *Fondation de l Université de Lyon, Fondation C-Génial, Fondation d Entreprise L Oréal,* and *Fondation Lacoste* Member of *Académie des Technologies*, of *Académie des Sports*, of *Académie Nationale de l Air et de l Espace*, of *Académie des Sciences de l Outre-Mer* **In foreign companies** None
Past directorships since 2011	None	**In French companies** Chairman of Universcience *(Cité des Sciences et de l Industrie and Palais de la Découverte)* (until 2015) Director of the *Aéro Club de France* (until 2011), *Fondation de France (until 2015), of Ecole Normale Supérieure* (ENS, until 2015), *Campus Condorcet (until 2015)*, and PRES HESAM *(Pôle de Recherche et d Enseignement Supérieur Hautes Etudes Sorbonne Arts et Métiers*, until 2015) Chairman of the Board of Directors of *La Géode* (until 2015) Vice President of the IAA (International Academy of Astronautics, until 2011) **In foreign companies** None

Education and business experience

Rheumatologist, doctorate in sciences majoring in neurosciences
Selected in 1985 by the CNES (French National Space Center) as an astronaut candidate

1984-1992	Rheumatologist, Cochin Hospital (Paris)
1996	Scientific space mission to the MIR space station (Cassiopée, Franco-Russian mission)
2001	Scientific and technical space mission to the International Space Station (Andromède mission)
2002-2004	Deputy Minister for Research and New Technologies in the French government
2004-2005	Deputy Minister for European Affairs in the French government
2005-2009	Counselor at the European Space Agency (ESA)
2010-2015	President CEO of Universcience
2015	Senior advisor to the European Space Agency CEO

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Patrick Kron

1,000 shares

Date of birth:	September 26, 1953
Nationality:	French
First elected:	May 2014
Term expires:	2018

Directorships and appointments of Patrick Kron

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	Independent director of Sanofi*: Member of the Appointments and Governance Committee of Sanofi Member of the Compensation Committee of Sanofi Member of the Strategy Committee of Sanofi	**In French companies** **Chairman and Chief Executive Officer of Alstom*** Director of Bouygues*: Vice President of the Vocal Group of the Association *Les Arts Florissants* **In Foreign Companies** None
Past directorships since 2011	None	**In French Companies** Chairman of Alstom Resources Management SAS (until 2015) Director of *Association Française des Entreprises Privées* (AFEP, until 2015) **In Foreign Companies** Alstom*: Director of Alstom UK Holdings Ltd. (United Kingdom, until 2012) Director and Managing Director of Alstom Asia Pte. Ltd. (Singapore, until 2014)

Education and business experience

	Degree from *Ecole Polytechnique* and *Ecole Nationale Supérieure des Mines de Paris*
1979-1984	Various positions at the French Ministry of Industry, including as project officer at the *Direction régionale de l Industrie, de la Recherche et de l Environnement* (DRIRE) and in the Ministry s general directorate

1984-1988	Operational responsibilities in one of the Pechiney Group s most important factories in Greece then manager of the Greek subsidiary
1988-1993	Various senior operational and financial positions within the Pechiney Group
1993	Member of the Executive Committee of the Pechiney Group
1993-1997	Chairman of the Board of the Carbone Lorraine Company
1995-1997	Manager of the Food and Health Care Packaging Sector of Pechiney and Chief Operating Officer of the American National Can Company in Chicago (United States)
1998-2002	Chief Executive Officer of Imerys
Since 2003	**Chief Executive Officer then Chairman and Chief Executive Officer of Alstom***

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Fabienne Lecorvaisier

1,000 shares

Date of birth:	August 27, 1962
Nationality:	French
First elected:	May 2013
Term expires:	2017

Directorships and appointments of Fabienne Lecorvaisier

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	Independent director of Sanofi* Member of the Audit Committee of Sanofi	**In French companies** Air Liquide* Group: Director of Air Liquide International Chairman and Chief Executive Officer of Air Liquide Finance Director of Air Liquide France Industries, Air Liquide Eastern Europe and Aqualung International
	None	**In foreign companies** Air Liquide* Group: Executive Vice-President of Air Liquide International Corporation Director of American Air Liquide Holdings, Inc. and SOAEO Manager of Air Liquide US LLC
Past directorships since 2011	None	**In French companies** None
	None	**In foreign companies** Air Liquide* Group: Director of Air Liquide Japon (Japan, until 2013)

Education and business experience

Civil Engineer, graduate from *Ecole Nationale des Ponts et Chaussées*

Since 2008	**Chief Financial Officer and Executive Committee Member of Air Liquide***
Since 2013	In charge of the diving activities of Air Liquide* (Aqualung)
1985-1989	Member of the Corporate Finance Department, then Mergers and Acquisitions Department of Société Générale*

1989-1990	Senior Banking Executive in charge of the LBO Department (Paris)/Corporate Finance Department (Paris and London) at Barclays
1990-1993	Assistant General Manager of Banque du Louvre, Taittinger Group
1993-2007	Various positions within Essilor* including Group Chief Financial Officer (2001-2007) and Chief Strategy and Acquisitions Officer (2007-2008)

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Suet-Fern Lee

1,000 shares

Date of birth:	May 16, 1958
Nationality:	Singaporean
First elected:	May 2011
Last reappointment:	May 2015
Term expires:	2019

Directorships and appointments of Suet-Fern Lee

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	Independent director of Sanofi*	**In French companies** Axa*: Director Member of the Finance Committee
	None	**In foreign companies** Director of Rickmers Trust Management Pte Ltd* (Singapore), Stamford Corporate Services Pte Ltd (Singapore), and the World Justice Project (USA)
Past directorships since 2011	None	**In French companies** None
	None	**In foreign companies** Director of Sembcorp Industries Ltd* (Singapore, until 2011), Macquarie International Infrastructure Fund Ltd* (Bermuda, until 2015), and National Heritage Board (Singapore, until 2015) Chairman of the Board of directors of the Asian Civilizations Museum (Singapore, until 2015)

Education and business experience

Law degree from Cambridge University (1980)
Admitted to London (1981) and Singapore (1982) Bars
Managing Director of Morgan Lewis Stamford LLC (Singapore)

Since 2006	Member of the Board of Trustees of Nanyang Technological University (Singapore) Member of the Accounting Advisory Board of National University of Singapore Business School (Singapore)
Since 2007	Member of the Advisory Committee of the Singapore Management University School of Law (Singapore)
Since 2014	Member of the Senate of the Singapore Academy of Law where she also chairs the Committee on Legal Education and Studies (Singapore) Chairman of the Expert Panel of Centre of Cross-Border Commercial Law in Asia of the Singapore Management University School of Law (Singapore)

2000-2007	Director of ECS Holdings Limited* (Singapore)
2004-2007	Director of International Capital Investment Limited (Singapore)
	Director of Media Asia Entertainment Group Limited (Hong Kong)
	Director of Transpac Industrial Holdings Limited* (Singapore)
2005-2008	Director of China Aviation Oil* (Singapore)
2006-2008	Director of Sincere Watch* (Hong Kong)
2005-2009	Director of Richina Pacific Limited* (Bermuda)
2008-2010	Director of Transcu Group Limited* (Singapore)
2010-2011	President of the Inter-Pacific Bar Association

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Christian Mulliez

1,494 shares

Date of birth:	November 10, 1960
Nationality:	French
First elected:	June 2004
Last reappointment:	May 2014
Term expires:	2018

Directorships and appointments of Christian Mulliez

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	Director of Sanofi*	**In French companies** Chairman of the Board of Directors of Regefi Director of DG 17 Invest
	Member of the Audit Committee of Sanofi	
	Member of the Compensation Committee of Sanofi	
		In foreign companies
	None	Director of L Oréal USA Inc. (United States) and The Body Shop International (United Kingdom)
Past directorships since 2011	None	**In French companies** None
		In foreign companies
	None	Director of Galderma Pharma (Switzerland, until 2014)

Education and business experience

Degree from ESSEC (*Ecole Supérieure des Sciences Economiques et Commerciales*)

Since 2003	**Executive Vice-President, Chief Financial Officer of L Oréal***
1984-2002	Various positions at Synthélabo and then at Sanofi-Synthélabo, including Vice President Finance

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Carole Piwnica

1,000 shares

Date of birth:	February 12, 1958
Nationality:	Belgian
First elected:	December 2010
Last reappointment:	May 2012
Term expires:	2016

Directorships and appointments of Carole Piwnica

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	Independent director of Sanofi* Member of the Audit Committee of Sanofi	**In French companies** Eutelsat Communications*: Independent Director Chairman of the Committee of Governance, Compensation and Appointment Rothschild & Co* (previously Paris Orléans): Independent member of the Supervisory Board Member of the Audit Committee and the Strategy Committee **In foreign companies** **Director of Naxos UK Ltd** (United Kingdom) Director of Big Red (United States), Elevance (United States) and i2O (United States) Director of Amyris Inc.* (United States)
Past directorships since 2011	None	**In French companies** None **In foreign companies** Aviva Plc.* (United Kingdom, until 2011): Director Chairman of the Corporate Responsibility Committee Member of the Compensation Committee Director of Louis Delhaize* (Belgium, until 2013) and of RecyCoal Ltd. (United Kingdom, until 2015)

Education and business experience

Degree in law, *Université Libre de Bruxelles*
Masters in law, New York University
Admitted to Paris and New York Bars

Since 2006 **Founder Director of Naxos UK Ltd** (United Kingdom)

1985-1991	Attorney at Proskauer, Rose (New York) and Shearman & Sterling (Paris) with practice in mergers and acquisitions
1991-1994	General Counsel of Gardini & Associés
1994-2000	Chief Executive Officer of Amylum France, then Chairman of Amylum Group
1998-2004	Director of Spadel (Belgium)
1996-2006	Director of Tate & Lyle Plc. (United Kingdom)
2000-2006	Director and Vice-Chairman of Tate & Lyle Plc. for Governmental Affairs (United Kingdom)
1996-2006	Chairman of the Liaison Committee and director of the *Confédération Européenne des Industries Agro-Alimentaires* (CIAA)
2000-2006	Chairman of the Export Commission and director of the *Association Nationale des Industries Alimentaires* (ANIA)
2006-2009	Member of the Ethical Committee of Monsanto* (United States)
1996-2010	Director of Toepfer GmbH (Germany)
2007-2010	Director of Dairy Crest Plc.* (United Kingdom)

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Klaus Pohle

2,500 shares

Date of Birth:	November 3, 1937
Nationality:	German
First appointment:	August 2004
Last reappointment:	May 2012
Term expires:	2016

Directorships and appointments of Klaus Pohle

	Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	Independent director of Sanofi*	**In French companies** None
	None	**In foreign companies** Trustee of Aventis Foundation[1] (not-for-profit, Germany)
Past directorships since 2011	None	**In French companies** None
	None	**In foreign companies** Director of Labelux Group GmbH* (Switzerland, until 2011) Coty Inc.* New York (United States, until 2011): Director Chairman of the Audit Committee

Education and business experience

Doctorate in economics from Berlin University (Germany)
Doctorate in law from Frankfurt University (Germany)
LLM from Harvard University (United States)

Professor of Business Administration at the Berlin Institute of Technology (Germany)

1966-1980	Various positions at the BASF group (Germany)
1981-2003	Deputy Chief Executive Officer and Chief Financial Officer of Schering AG (Germany)
2003-2005	Chairman of the German Accounting Standards Board (Germany)
2004-2008	Various positions at Hypo Real Estate Holding AG*, Munich, including Chairman of the Supervisory Board (Germany)
2005-2009	Member of the Supervisory Board and Chairman of the Audit Committee at DWS Investment GmbH, Frankfurt (Germany)

Changes in the Composition of the Board

The composition of the Board of Directors changed in 2015.

The co-opting of Bonnie Bassler and Olivier Brandicourt as Directors of our Company was ratified by the Shareholders General Meeting held on May 4, 2015. The appointment of Bonnie Bassler reinforces the scientific and pharmaceutical expertise within our Board and is in line with our policy of onboarding more women, and more international and younger directors.

Two other terms of office were renewed in 2015: those of Serge Weinberg and Suet Fern Lee.

Igor Landau and Gérard Van Kemmel, whose terms of office were up for renewal, did not express any wish to be reappointed.

Consequently, and in line with the medium-term objective set by our Board, the size of the Board of Directors was reduced by one.

Following the enactment of the June 14, 2013 French Employment Protection Act, the Appointments and Governance Committee assessed its impact on Sanofi. The Board of Directors concluded that Sanofi did not fall within the scope of this Act because it has no obligation to set up a works council and indeed has not set one up, the workforce of the parent company being less than 50.

Under current French legislation, given that employees own less than 3% of our share capital, the Board does not include a director representing employee shareholders.

1 No compensation is paid for this office. Appointments to the Board of Trustees of the Foundation are made independently of Sanofi.

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Nevertheless, five Group employee representatives attend Board meetings without voting rights pursuant to the agreement implemented with the European Works Council signed on February 24, 2005.

One subsidiary falling within the scope of the French Employment Protection Act appointed an employee representative to its Board in 2015.

Following the enactment of the August 17, 2015 French Social Dialogue and Employment Act, a study will be conducted to determine the most appropriate level of employee representation within our Group as well as the most appropriate way to effect such representation.

Executive Committee

The Executive Committee is chaired by the Chief Executive Officer.

The Committee meets at least twice a month, and as of the date of this annual report on Form 20-F, has the following permanent members:

- **Olivier Brandicourt**, Chief Executive Officer;
- **Olivier Charmeil,** Executive Vice President, Vaccines;
- **Jérôme Contamine,** Executive Vice President, Chief Financial Officer;
- **Peter Guenter**, Executive Vice President, General Medicines and Emerging Markets;
- **Carsten Hellmann**, Executive Vice President, Merial;
- **Suresh Kumar,** Executive Vice President, External Affairs;
- **Karen Linehan,** Executive Vice President, Legal Affairs and General Counsel;
- **Philippe Luscan,** Executive Vice President, Global Industrial Affairs;
- **Muzzammil Mansuri**, Executive Vice President, Strategy and Business Development;

- **David P. Meeker**, Executive Vice President, Head of Sanofi Genzyme;

- **Roberto Pucci,** Executive Vice President, Human Resources;

- **Pascale Witz**, Executive Vice President, Diabetes and Cardiovascular; and

- **Elias Zerhouni,** President, Global Research and Development.

The name, business address, present principal occupation or employment and material occupations, positions, offices or employment for the past five years of each of the executive officers of Sanofi are set forth below. The business

address and phone number of each such executive officer is c/o Sanofi, 54 rue La Boétie, 75008 Paris, France, +33 1 53 77 40 00.

Olivier Brandicourt

Chief Executive Officer

Chairman of the Executive Committee

Date of birth: February 13, 1956

Olivier Brandicourt was appointed Chief Executive Officer on April 2, 2015, and is also a member of the Strategy Committee of Sanofi.

For additional information regarding his professional education and business experience see Composition of the Board of Directors as of December 31, 2015 in A. Directors and Senior Management of this Item 6.

Olivier Brandicourt is a citizen of France.

Olivier Charmeil

Executive Vice President, Vaccines

Date of birth: February 19, 1963

Olivier Charmeil is a graduate of HEC (*Ecole des Hautes Etudes Commerciales*) and of the *Institut d Etudes Politiques* in Paris. From 1989 to 1994, he worked in the Mergers & Acquisitions department of Banque de l Union Européenne. He joined Sanofi Pharma in 1994 as head of Business Development. Subsequently, he held various positions within the Group, including Chief Financial Officer (Asia) for Sanofi-Synthélabo in 1999 and *Attaché* to the Chairman, Jean-François Dehecq, in 2000, before being appointed as Vice President, Development within the Sanofi-Synthélabo International Operations Directorate, where he was responsible for China and support functions. In 2003, Olivier Charmeil was appointed Chairman and Chief Executive Officer of Sanofi-Synthélabo France, before taking the position of Senior Vice President, Business Management and Support within the Pharmaceutical Operations Directorate. In this role, he piloted the operational integration of Sanofi-Synthélabo and Aventis. He was appointed Senior Vice President Asia/Pacific, Pharmaceutical Operations in February 2006 and since January 1, 2008, Operations Japan have reported to him, as have Asia/Pacific and Japan Vaccines since February 2009. Since January 1, 2011, Olivier Charmeil has served as Executive Vice President Vaccines and as a member of the Executive Committee. He became the International Federation Pharmaceutical Manufacturers & Associations (IFPMA) representative on the GAVI Board on August 1, 2014 and as a result is also chairman of the CEO Steering Committee of IFPMA uniting the CEOs of the member companies (GSK, Merck, Johnson & Johnson, Pfizer, Takeda, Novartis and Daiichi Sankyo).

In May, 2015, Olivier Charmeil and André Syrota were appointed as Co-Leaders of Medicine of the Future , an initiative developed by the French Minister for Economy,

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Finance, Industry and Digital Affairs, the French Minister for Social Affairs, Health and Women s Rights and the French Minister for National and Higher Education and Research. They have been tasked with assembling a group of industrialists and academics, with the objective of imagining how French industry can accelerate the development, launch and export of new products and innovation, with an emphasis on medical devices and biotechnology.

Olivier Charmeil is a citizen of France.

Jérôme Contamine

Executive Vice President, Chief Financial Officer

Date of birth: November 23, 1957

Jérôme Contamine is a Graduate of *École Polytechnique* (X), *ENSAE*, and *ENA* (*Ecole Nationale d Administration*). After four years at the *Cour des Comptes*, as a Senior State General Auditor, he joined Elf Aquitaine in 1988, as advisor to the Chief Financial Officer, and became Group Finance and Treasury Director in 1991. He became the General Manager of Elf Petroleum Norway in 1995, after being named Deputy Vice President of Elf Upstream Division for Europe and the U.S. In 1999, he was appointed as a member of the taskforce for integration with Total, in charge of the reorganization of the merged entity, TotalFinaElf, and in 2000 became Vice President Europe and Central Asia, Upstream Division of Total. The same year, he joined Veolia Environnement as CFO and Deputy General Manager. In 2003, he was appointed Vice-President Senior Executive, Deputy Chief Executive Officer, Financial Director of Veolia Environnement. Since 2006 he has been a Director of Valeo. Jérôme Contamine joined Sanofi as Executive Vice President, Chief Financial Officer (CFO) in March 2009.

Jérôme Contamine is a citizen of France.

Peter Guenter

Executive Vice President, General Medicines and Emerging Markets

Date of birth: September 2, 1962

Peter Guenter holds a Master s Degree in Physical Education from the Faculty of Medicine and Health Sciences, University of Ghent, Belgium. Peter started his career in Sales at SmithKline in 1986. He joined the Group in 1995 and held various positions in France, Europe and Global Marketing. In 2000, he was appointed General Manager Belgium and then Vice President for Eastern Europe and subsequently Northern Europe. In 2008, he took up the position of General Manager, Commercial Operations for Germany and in 2011, Peter became General Manager for the Multi-Country-Organisation for Germany, Switzerland and Austria. He was appointed Senior Vice President, Europe Global Operations in July 2011. He became a member of the Executive Committee and was appointed as Executive Vice President, Global Commercial operations in July 2013.

In January 2016, he was appointed as head of the General Medicines & Emerging Markets Global Business Unit.

Peter Guenter is a citizen of Belgium.

Carsten Hellmann

Executive Vice President, Merial

Date of birth: April 24, 1964

Carsten Hellmann undertook his first degree in Business Administration in Copenhagen in 1989 before completing an MSc in the UK in Information Management & Technology in 1990.

Carsten Hellmann began his career in 1990 at Radiometer Medical A/S as a product specialist before moving into a product manager role. He joined Novo Nordisk in 1993 and held different roles in marketing, business development, strategic alliances and business intelligence with increasing responsibilities. In 1996 he joined Synthelabo Scandinavia as Sales & Marketing Director and in 1997 Pronosco A/S, a diagnostics start up specialized in osteoporosis as Chief Operating Officer. In 2000 he was named Chief Executive Officer at Nunc Group where he oversaw the P&L and entire value chain of the company, from R&D to sales. Carsten Hellmann oversaw the integration processes during the acquisition of the Apogent Group (Nunc s owner) by Fisher Scientific and subsequently also became Group Vice President of Fisher. He joined Chr. Hansen Holding A/S in 2006 as Executive Vice President, Global Sales, and member of the executive management and board. He was appointed member of the Executive Committee of Sanofi and CEO of Merial in September 2013. In 2014, he joined the Board of Directors of the International Federation for Animal Health.

Carsten Hellmann is a citizen of Denmark.

Suresh Kumar

Executive Vice President, External Affairs

Date of birth: February 18, 1955

Suresh Kumar has an Economics degree from Delhi University and a Masters in Management from Bombay University. Suresh Kumar has more than 30 years of experience in the healthcare industry beginning in 1978 in India with Johnson and Johnson. At Warner Lambert from 1989 to 1999, he held increasingly senior roles in consumer healthcare in Canada, North America, Latin America and Asia. He again joined Johnson & Johnson in 1999 as a Member of the Group Operating Committee and International Vice President of the Worldwide Consumer Pharmaceuticals business. In 2006, he joined the Clinton Foundation as Special Advisor focused on Sub-Saharan Africa, where he created programs focused on improving lives and livelihoods through improved agricultural performance and food security. In 2010, the United States Senate unanimously confirmed Suresh Kumar as Assistant Secretary of Commerce and Director General of the U.S.

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and Foreign Commercial Service where he spearheaded global trade for the Obama Administration. From 2013, he served as a Partner with Oliver Wyman leading the firm s Public Sector Practice and as part of the Health and Life Sciences Team. He was appointed to his present position in June 2015.

Suresh Kumar is a citizen of Canada and of the United States of America.

Karen Linehan

Executive Vice President, Legal Affairs and General Counsel

Date of birth: January 21, 1959

Karen Linehan graduated from Georgetown University with Bachelor of Arts and Juris Doctorate degrees. Prior to practicing law, Ms. Linehan served on the congressional staff of the Speaker of the U.S. House of Representatives from September 1977 to August 1986. Until December 1990, she was an Associate in a mid-size law firm in New York. In January 1991, she joined Sanofi as Assistant General Counsel of its U.S. subsidiary. In July 1996, Ms. Linehan moved to Paris to work on international matters within the Group and she has held a number of positions within the Legal Department, most recently as Vice President Deputy Head of Legal Operations. She was appointed to her current position in March 2007.

Karen Linehan is a citizen of the United States of America and Ireland.

Philippe Luscan

Executive Vice President, Global Industrial Affairs

Date of birth: April 3, 1962

Philippe Luscan is a graduate of the *École Polytechnique* and the *École des Mines* in Biotechnology in Paris. He began his career in 1987 as a Production Manager at Danone. In 1990, he joined the Group as Director of the Sanofi Chimie plant at Sisteron, France, and subsequently served as Industrial Director of Sanofi in the United States, as Vice President Supply Chain and as Vice President Chemistry in September 2006. He was appointed to his present position in September 2008. Since January 1, 2015, Philippe Luscan is also President of Sanofi in France.

Philippe Luscan is a citizen of France.

Muzammil Mansuri

Executive Vice President, Strategy and Business Development

Date of birth: January 20, 1954

Muzammil Mansuri holds a Bachelor of Science degree in Chemistry and a Ph.D. in Organic Chemistry from University College London. He held post-doctoral positions at the University of California, Los Angeles (UCLA) and Columbia

University. He started his career in 1981 with Shell Research Limited where he began as a research scientist. After Shell, he spent several years with Bristol-Myers Company in various R&D roles with increasing responsibility. From 2007 to 2010, he was Chairman and CEO at CGI Pharmaceuticals. Before joining Sanofi, Muzammil s most recent position was Senior Vice President, Research & Development Strategy and Corporate Development at Gilead Sciences. He was appointed to his current position in February 2016.

Muzammil Mansuri is a citizen of the Unites States of America and United Kingdom.

David P. Meeker

Executive Vice President, Head of Sanofi Genzyme

Date of birth: October 4, 1954

Dr. Meeker received his M.D. from the University of Vermont Medical School. He completed an Internal Medicine residency at Beth Israel Hospital in Boston and a Pulmonary/Critical Care fellowship at Boston University. He completed the Advanced Management Program at Harvard Business School in 2000.

Prior to joining Genzyme, Dr. Meeker was the Director of the Pulmonary Critical Care Fellowship at the Cleveland Clinic and an assistant professor of medicine at Ohio State University. He is the author of more than 40 articles and multiple book chapters.

Dr. Meeker joined Genzyme in 1994 as Medical Director to work on the Gene Therapy and Cystic Fibrosis program. Subsequently, as Vice President, Medical Affairs, he was responsible for the development of therapeutic products, including treatments in the current rare genetic diseases portfolio.

He was promoted to Senior Vice President in 1998, and in 2000 became the Business Unit Leader for Genzyme s Lysosomal Storage Disease and Thyrogen programs in Europe. Dr. Meeker was promoted to President of the Global LSD business unit in 2003. In this role, he oversaw the global launches of Aldurazyme®, Fabrazyme® and Myozyme®. In 2008, he was promoted to Executive Vice President of Therapeutics, Biosurgery and Transplant. In 2009, he became Chief Operating Officer. In this role, he was responsible for Genzyme s commercial organization, overseeing the business units, country management organization and global market access functions. He became Chief Executive Officer of Genzyme in November 2011 and a member of the Executive committee in September 2013.

In January 2016, he was appointed as head of the Specialty Care Global Business Unit.

David P. Meeker is a citizen of the United States of America.

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Roberto Pucci

Executive Vice President, Human Resources

Date of birth: December 19, 1963

Roberto Pucci has a law degree from the University of Lausanne, Switzerland. He started his career in 1985 at Coopers & Lybrand in Geneva, Switzerland as an external auditor. He then joined Hewlett-Packard (HP) in 1987, where he held various positions in Human Resources in Switzerland and Italy including HR Manager for the European Headquarters and Human Resources Director in Italy. In 1999, he became Director, Compensation & Benefits for Agilent Technologies, a spin off from HP, and was appointed Vice President Human Resources Europe in 2003. In 2005 he moved to the United States to join Case New Holland, a subsidiary of the Fiat Group, as Senior Vice President, Human Resources, and was appointed, in 2007, Executive Vice President, Human Resources for the Fiat Group in Torino, Italy. Roberto Pucci joined Sanofi as Executive Vice President Human Resources in October 2009.

Roberto Pucci is a citizen of Italy and Switzerland.

Pascale Witz

Executive Vice President, Diabetes and Cardiovascular

Date of birth: January 27, 1967

Pascale holds a Master s degree in life sciences /molecular biology from *Institut National des Sciences Appliquées Lyon* and an MBA from INSEAD. Pascale started her career in a research lab before moving to marketing at Becton Dickinson France in 1991. She joined GE Healthcare in 1996, where she had a successful career during 17 years. Pascale Witz headed up a number of businesses, first in Europe, Middle East and Africa (EMEA): she was Vice President Six Sigma and Quality (2000-2001), Vice President Information Technology (2001-2002), General Manager, Nuclear Medicine & PET (2002-2004), Vice President Sales & Marketing Services (2005-2006), and General Manager, Computed Tomography (2006-2007). She then became Vice President & General Manager of the Global Interventional Radiology and Interventional Cardiology Business (2008-2009). In 2009 she was appointed President & CEO of the medical diagnostics business, a pharmaceutical business acquired by GE Healthcare (previously Amersham Health). She became a member of Sanofi s Executive Committee and was appointed Executive Vice President, Global Divisions & Strategic Commercial Development in July 2013.

In January 2016, she was appointed as head of the Diabetes and Cardiovascular Global Business Unit.

Pascale Witz is a citizen of France.

Elias Zerhouni

President, Global Research and Development

Date of birth: April 12, 1951

Born in Algeria where he completed his initial medical training, Dr. Zerhouni continued his academic career at the Johns Hopkins University and Hospital (United States) in 1975 where he rose to the rank of professor of Radiology and Biomedical engineering. He served as Chair of the

Russell H. Morgan Department of Radiology and Radiological Sciences, Vice Dean for Research and Executive Vice Dean of the School of Medicine from 1996 to 2002 before his appointment as Director of the National Institutes of Health of the United States of America from 2002 to 2008. Dr. Zerhouni was received as member of the U.S. National Academy of Sciences Institute of Medicine in 2000. He was appointed as Chair of Innovation at the College de France, elected member of the French Academy of Medicine in 2010 and received the Transatlantic Innovation Leadership award in December 2011. He is the author of over 200 scientific publications and has invented 8 patents. In February 2009, Sanofi named Dr. Zerhouni Scientific Advisor to the Chief Executive Officer and to the Senior Vice-President Research & Development. He was appointed President Global Research & Development and has served on the Executive Committee of Sanofi since January 2011. He was appointed as member of the U.S. National Academy of Engineering in 2013.

Dr. Zerhouni is a citizen of the United States of America.

As of December 31, 2015, none of the members of the Executive Committee had their principal business activities outside of Sanofi.

B. Compensation

Compensation and arrangements for corporate officers

The compensation policy for corporate officers is established by the Board of Directors upon the recommendation of the Compensation Committee.

The Board of Directors follows the AFEP-MEDEF Code when setting the compensation of our corporate officers.

The AFEP-MEDEF Code and the recommendations of the *Autorité des marchés financiers* (the French market regulator, hereafter referred to as AMF), require specific disclosures about the implementation of the recommendations and, if applicable, explanations of the reasons why any of them may not have been implemented. Currently, there is one divergence from the AFEP-MEDEF Code related to compensation. As an exception to our usual practice (applied since 2009) of awarding stock options and performance shares in March, in 2015 those awards were made in June. For more information see C. Board Practices below.

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Item 6. Directors, Senior Management and Employees

Serge Weinberg

Serge Weinberg has held the office of Chairman of the Board of Directors since May 17, 2010. From October 29, 2014 until April 2, 2015, he was also Chief Executive Officer. He was an outside appointment and has never had an employment contract with Sanofi distinct from his current office.

The Chairman of the Board also chairs the Appointments and Governance Committee and the Strategy Committee.

In accordance with our Board Charter and in close collaboration with the Senior Management, the Chairman represents the Company in high-level dealings with governmental bodies and with the Group s key partners, both nationally and internationally, and participates in defining the major strategic choices of the Group especially

as regards mergers, acquisitions and alliances. The Chairman and the Chief Executive Officer, when the two offices are separated, keep each other fully informed of one another s actions.

The compensation of the Chairman of the Board of Directors consists solely of fixed compensation and benefits in kind and excludes any variable compensation, any awards of stock options and performance shares and any directors attendance fees.

The corporate officers do not receive directors attendance fees in their capacity as directors. Consequently, Serge Weinberg does not receive directors attendance fees in his capacity as Chairman of the Board, Chairman of the Appointments and Governance Committee or Chairman of the Strategy Committee.

Compensation awarded to Serge Weinberg (table no. 1 of the AFEP-MEDEF Code)

(in euros)	2015	2014	2013
Compensation payable for the year (details provided in the table below)	708,218	708,174	708,040
Value of stock options awarded during the year	N/A	N/A	N/A
Value of performance shares awarded during the year	N/A	N/A	N/A
Total	**708,218**	**708,174**	**708,040**

Compensation payable and paid to Serge Weinberg (table no. 2 of the AFEP-MEDEF Code)

	2015		2014		2013	
(in euros)	Payable	Paid	Payable	Paid	Payable	Paid
Fixed compensation[(1)]	700,000	700,000	700,000	700,000	700,000	700,000
Annual variable compensation	N/A	N/A	N/A	N/A	N/A	N/A
Exceptional compensation	N/A	N/A	N/A	N/A	N/A	N/A

Attendance fees	N/A	N/A	N/A	N/A	N/A	N/A
Benefits in kind	8,218	8,218	8,174	8,174	8,040	8,040
Total	**708,218**	**708,218**	**708,174**	**708,174**	**708,040**	**708,040**

The amounts reported are gross amounts before taxes.

(1) Fixed compensation payable in respect of a given year is paid during that year.

On March 3, 2015, upon the recommendation of the Compensation Committee, the Board of Directors set the terms of Serge Weinberg s compensation.

For 2015, his fixed compensation was maintained at an annual amount of 700,000, with no adjustment in consideration of his acting as Chief Executive Officer on a temporary basis. When the Board of Directors asked him to assume the office of Chief Executive Officer, it was decided at his request not to modify his compensation.

He did not receive any variable compensation, stock options, or performance shares during 2015, and nor did he receive

director s attendance fees as a member of the Board of Directors.

The amount reported for benefits in kind relates mainly to a company car with a chauffeur.

Serge Weinberg does not benefit from the Sanofi top-up pension plan.

On March 3, 2016, upon the recommendation of the Compensation Committee, the Board of Directors set the terms of Serge Weinberg s compensation. For 2016, his fixed compensation is maintained at an annual rate of 700,000. Consequently, Serge Weinberg s compensation

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has remained unchanged since his arrival in 2010. In line with AMF recommendations, he will not receive any variable compensation, stock options, or performance shares. Nor will he receive any attendance fees.

Compensation policy

The compensation policy of the Chief Executive Officer follows the same structures and principles as the Group compensation policy described later in this section of the report.

The Sanofi compensation policy seeks to be consistent with market and industry practice in order to provide competitive levels of compensation, to create a strong link between company and individual performance, and to maintain a balance between short-term performance and mid-long-term performance.

The compensation of the Chief Executive Officer is set by the Board of Directors upon the recommendation of the Compensation Committee with reference to compensation paid to the chief executive officers of major global pharmaceutical companies and of major companies in the CAC 40 stock market index. Consistency with market practice is fundamental in order to attract and retain the talents necessary to the Group s success.

Sanofi compensation policy for the Chief Executive Officer aims at achieving a balance in the compensation structure between fixed compensation, short-term variable cash compensation, and medium-term variable equity compensation. The proportions of annual fixed and variable compensation are stable over time. Compensation adjustments based on performance and market practice are carried out through equity compensation, which is medium-term and aims at aligning the interests of the Chief Executive Officer with those of our shareholders and stakeholders.

Our overall compensation policy is designed to motivate and reward performance by ensuring that a significant portion of executive and employee compensation is contingent on the attainment of financial, operational and social criteria aligned with the corporate interest and creation of shareholder value. Variable cash compensation and equity compensation are the two principal levers for action. As an exception and at his request, Serge Weinberg did not receive any such compensation for the period during which he acted as Chief Executive Officer.

Equity compensation is a critical tool for the worldwide attractiveness of Sanofi as an employer, and aims to align employee and shareholder interests and reinforce employees ties to the Group.

Upon the recommendation of the Compensation Committee, the Board of Directors determines the performance conditions attached to equity compensation for all beneficiaries at Sanofi and its subsidiaries worldwide,

favoring the attainment of objectives based on the Group s consolidated results and balance sheet.

Since 2011 our equity compensation plan rules have been made available to our shareholders on the governance page of our website (*www.sanofi.com*) in the same form as that distributed to our employees.

Since 2011 the Board of Directors has substantially reworked our equity compensation policy to reinforce the link with long-term performance for all beneficiaries and to reduce potential dilution. As a result of very positive shareholder feedback collected through corporate governance roadshows, contacts with governance professionals and the results of votes at Annual General Meetings, the Board decided to maintain and reinforce this policy in 2013.

The current policy can generally be characterized by reduced dilution; diversified, multi-year performance conditions; increased transparency; and specific additional requirements for the Chief Executive Officer.

The policy requires that grants be primarily based on performance shares with only a limited number of high-level executives continuing to receive stock options. In 2015, the Board of Directors decided upon the recommendation of the Compensation Committee that future equity grants would be based on a target value for the award that is linked to the Sanofi share price and to the beneficiary s base salary, rather than being based on the number of equity instruments awarded. That target value may be subject to change in the period between determination of the list of beneficiaries and the actual award by the Board, as a result of volatility in the price of our shares.

Greater reliance on performance shares allows the Board of Directors to maintain a comparable level of employee incentivization while reducing the dilutive effect for existing shareholders. However, the Board of Directors continues to believe that options remain an appropriate component of the compensation of high level executives, due to their ratchet effect.

The Board of Directors makes any grant of stock options or performance shares contingent on several distinct performance criteria in order to ensure that Sanofi equity compensation incentivizes overall performance and does not encourage excessive risk taking. Failure to achieve these conditions over the entire performance period results in a reduction or loss of the initial grant.

Grants are also contingent on the beneficiary s continued employment in the Sanofi Group (4 years for options, 3 to 4 years for performance shares).

The exercise price of stock options set by the Board never incorporates a discount, and must be at least equal to the average of the quoted market prices on the 20 trading sessions preceding the date of grant by the Board.

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Item 6. Directors, Senior Management and Employees

The Board is not allowed to reset prior grants, for instance with easier performance conditions or a lower exercise price.

Each grant to the Chief Executive Officer takes into account previous grants and his global compensation.

Compensation of the Chief Executive Officer, Olivier Brandicourt

The Board of Directors meeting held on February 19, 2015 appointed Olivier Brandicourt as Chief Executive Officer and co-opted him as a Director of Sanofi with effect from April 2, 2015.

He was an outside appointment and has never had an employment contract with Sanofi distinct from his appointment as Chief Executive Officer.

The compensation of Olivier Brandicourt is made up of the following elements:

- fixed compensation;
- benefits in kind;
- annual variable compensation subject to annual individual objectives;
- equity compensation consisting of stock options and performance shares, contingent on both internal and external performance conditions measured over three years and subject to stringent lock-up obligations.

In addition, Olivier Brandicourt benefits from:

- a top-up defined benefit pension plan;
- a termination benefit contingent upon performance conditions, only payable if departure is non-voluntary and linked to a change in control or strategy; and
- a non-compete indemnity.

Compensation, options and shares awarded to Olivier Brandicourt (table no. 1 of the AFEP-MEDEF Code)

(in euros)	2015
Compensation payable for the year (details provided in the table below)	4,386,888
Value of stock options awarded during the year[1]	3,546,400
Value of performance shares awarded during the year[2]	8,826,720
Total	**16,760,008**

(1) *Valued at date of grant using the Black & Scholes method assuming fulfillment of the performance conditions.*

(2) *Valued at date of grant assuming fulfillment of the performance conditions. The value is the difference between the quoted market price of the share on the date of grant and the dividends to be paid over the next three years.*

Compensation payable and paid to Olivier Brandicourt (table no. 2 of the AFEP-MEDEF Code)

	2015	
(in euros)	Payable	Paid
Fixed compensation[1]	895,455	895,455
Annual variable compensation[2]	1,491,300	0
Exceptional compensation[3]	2,000,000	2,000,000
Attendance fees	0	0
Benefits in kind	133	133
Total	**4,386,888**	**2,895,588**

The amounts reported are gross amounts before taxes.

(1) *Fixed compensation payable in respect of a given year is paid during that year and (in 2015) prorated to reflect the period during which he held office.*

(2) *Variable compensation in respect of a given year is determined and paid at the start of the following year. The variable compensation is calculated on the basis of the annual fixed compensation to which a monthly pro rata is applied.*

(3) *Amounts payable in connection on taking up office, as described below.*

Acting on the recommendation of the Compensation Committee, the Board authorized the financial terms of Olivier Brandicourt s appointment, as summarized below:

- His annual compensation is made up of the following elements:

  fixed annual compensation of 1,200,000 (gross);
  variable annual compensation with a target of 150% of his fixed annual compensation, subject to quantitative and qualitative performance conditions and capped at 250% of his fixed annual compensation.

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- As compensation for benefits forfeited upon his departure from his previous employer, Olivier Brandicourt received or will receive:

  a lump-sum payment of 2 million (gross), paid upon his taking up office;

  a lump-sum payment of 2 million (gross), payable in January 2016 and subject to a condition of continued employment;

  a grant of 66,000 performance shares, subject to 3-year performance conditions. The vesting of these shares is contingent upon the average of the ratios of business net income to net sales for each financial year being at least 18% over the 3 years of the plan.

Olivier Brandicourt was also awarded a deemed ten years of service.

These elements were intended to compensate him for the significant benefits he lost because of his departure from Bayer (variable compensation, equity-based compensation).

For obvious confidentiality reasons, Sanofi cannot disclose the amount of the benefits forfeited by Olivier Brandicourt, Bayer not being required to disclose his compensation. Nevertheless, statements made to the newspapers by Dr Marijn Dekker, CEO of Bayer, unequivocally confirm the compensatory nature of certain benefits.

All the short-listed candidates required to be compensated for benefits that would have been forfeited when leaving their previous employer; the terms on which Olivier Brandicourt was hired aim to replicate the diversity of what he forfeited, with a comparable level of risk.

For 2015, the variable compensation of Olivier Brandicourt was in a potential range between 0% and 250% of his fixed compensation, with a target of 150%.

His variable compensation for 2015 was established on the basis of quantitative and qualitative criteria. These criteria were as follows:

- attainment of financial targets (40%). This objective included sales growth (one-third) and growth in Business Net Income (two-thirds);
- improvement of the Diabetes franchise and the successful launch of Toujeo® in the United States (10%);
- new product registrations and submissions compared to our budget (15%);
- review of our strategic plan (15%) including the definition of a strategy with a particular emphasis on Diabetes and Oncology;
- success in assuming his duties (20%). This objective covered inter alia:

establishing an efficient Executive Committee;
simplifying the organizational structure and clarifying accountabilities;

transparent communication with the Chairman of the Board and the Board of Directors;

positive feedback on internal and external corporate communication;

inception of succession planning.

The objectives based on financial targets, the Diabetes franchise and product registrations and submissions are all quantitative criteria, and accounted for 65% of the variable compensation criteria. The strategic plan review and success in assuming office are qualitative criteria, and accounted for 35% of the variable compensation criteria.

Upon the recommendation of the Compensation Committee and in light of experience, the Board of Directors decided that the percentage of variable compensation linked to quantitative criteria could be reduced regardless of actual performance, in order to give greater weight to the criterion relating to Olivier Brandicourt s success in assuming his duties. If used, this flexibility would operate solely to reduce the amount of variable compensation, rather than to compensate for underperformance on the quantitative criteria.

In general, the performance criteria apply not only to variable compensation but also to the vesting of stock options and performance shares in compliance with our targets, which are ambitious.

For reasons of confidentiality, the specific targets set for the quantitative and qualitative criteria, even though they have been properly and precisely established, cannot be disclosed. In evaluating these criteria, the performance of major global pharmaceutical companies was taken into account.

Acting on the recommendation of the Compensation Committee, the Board of Directors meeting of March 3, 2016 reviewed the attainment of each criterion and sub-criterion, and determined that:

- the financial objectives (sales and Business Net Income), which represented 40% of the overall objectives, had been 142% fulfilled relative to the potential range of 0% to 250% and the target of 150%;

- the individual objectives (Diabetes franchise, launch of Toujeo®, registrations and submissions, strategic review, and assumption of duties), which represented 60% of the overall objectives, had been 181.5% fulfilled, relative to the potential range of 0% to 250% and the target of 150%.

The Board was fully satisfied with the way in which Olivier Brandicourt had assumed office and come up to speed during the first nine months of 2015, and also with the major corporate actions initiated and the operational actions already taken.

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Item 6. Directors, Senior Management and Employees

Acting on the recommendation of the Compensation Committee, the Board of Directors meeting of March 3, 2016 set Olivier Brandicourt s variable compensation for 2015 at 1,988,400, equivalent to 165.7% of his fixed compensation and representing an amount of 1,491,300 on a pro rata time basis for the amount of time spent in office during the year.

Olivier Brandicourt s 2015 variable compensation is to be paid in 2016.

Olivier Brandicourt is subject to, benefits from and contributes to the same health coverage and death & disability plans as are applicable to other employees of the Group based in France.

Olivier Brandicourt received a benefit in kind in 2015 representing social contribution payments of 133 made by Sanofi on his behalf. Sanofi policy is to make these payments (which arise on employer s pension contributions and are normally payable by the employee) on behalf of all of its employees in France, including Olivier Brandicourt.

Acting on the recommendation of the Compensation Committee, the Board of Directors meeting of March 3, 2016 decided to maintain Olivier Brandicourt s fixed annual

compensation at the same level as for 2015 (1,200,000), and also to retain the same variable annual compensation structure whereby 40% is based on financial indicators (sales and Business Net Income) and 60% on specific individual objectives.

Those individual objectives comprise:

- new product launches (10%);
- ongoing transformation of the Group (25%);
- research and development (15%); and,
- organization and staff relations (10%).

For 2016, Olivier Brandicourt s variable compensation is in a potential range between 0% and 250% of his fixed compensation.

Acting on the recommendation of the Compensation Committee, the Board of Directors meeting of March 3, 2016 decided that for 2016, Olivier Brandicourt will be awarded 220,000 stock subscription options and 50,000 performance shares subject to the authorizations submitted to the Shareholders General Meeting to be held on May 4, 2016.

Stock options awarded to Olivier Brandicourt in 2015 (table no. 4 of the AFEP-MEDEF Code)

Origin	Date of Board grant	Nature of options	Value (in)	Number of options awarded in 2015	Exercise price (in)	Exercise period
Sanofi	06/24/2015	Subscription options	3,546,400	220,000	89.38	06/25/2019 06/24/2025

On June 24, 2015, 220,000 stock subscription options were awarded to Olivier Brandicourt. In compliance with the AFEP-MEDEF Code, the entire award is contingent upon both internal criteria based upon Business Net Income and Return on Assets (ROA), and an external criterion based on Total Shareholder Return (TSR) in comparison to a reference set of pharmaceutical companies. These criteria were selected because they align medium-term equity-based compensation on the strategy adopted by the Company.

This award is broken down as follows:

- The performance criterion based on Business Net Income covers 50% of the award and refers to the ratio, at constant exchange rates, between actual Business Net Income and the Business Net Income specified in the budget. This criterion corresponds to average actual achievement of business net income versus budgeted business net income over the entire period. Budgeted business net income is approved by the Board of Directors at the beginning of each year. If the ratio is less than 95%, the corresponding options will lapse. The Business Net Income target may not be lower that the lower range of the guidance published by the Company at the beginning of each year.
- The ROA-based criterion covers 30% of the award and includes a target ROA, below which some or all of the options will lapse.
- The TSR-based criterion covers 20% of the award. The overall return to shareholders is evaluated both on the value of Sanofi shares (the increase in the share price) and the value distributed to shareholders (dividends), i.e. the two sources of a return on investment in Sanofi shares. Our TSR is compared with a benchmark panel of 10 companies: Astra Zeneca, Bayer, BMS, Eli Lilly, GSK, Johnson & Johnson, Merck, Novartis, Pfizer, and Roche. The number of options exercisable depends upon our position in comparison to the TSR for the other companies of this panel. Below the median, the corresponding options will lapse.
- In addition to the three conditions set forth above, an implicit condition exists in the form of the exercise price, as well as the condition of continuing employment.
- In order to bring equity-based compensation into line with medium-term performance, performance will be measured over three financial years.
- Vesting is now subject to a non-compete clause.

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- In the event that Olivier Brandicourt leaves the Company for reasons other than (i) resignation or (ii) dismissal for serious cause or gross misconduct, the overall allocation percentage will be prorated to reflect the amount of time he remained in office during the vesting period.

The Board regards these performance conditions as good indicators of the development of shareholder value in terms of: the quality of investment decisions in a period where external growth plays a greater role than in the past (ROA condition); a commitment to delivering challenging bottom-line results in a tough business environment (Business Net Income condition); and matching or exceeding our peer group in terms of shareholder returns (TSR condition).

Although for reasons of confidentiality the quantitative measures for the internal criteria cannot be disclosed, even though they have been properly and precisely established, the targets and the level of attainment for the internal criteria will be disclosed at the end of the performance measurement period.

Using the Black & Scholes method, each option awarded on June 24, 2015 was valued at 16.12, valuing the total benefit at 3,546,400.

The Board of Directors had previously decided to limit the number of options that could be awarded to Olivier Brandicourt to 15% of the total limit approved by the Shareholders General Meeting held on May 3, 2013 (0.7% of our share capital). The number of options awarded to Olivier Brandicourt in 2015 represents 2.41% of the total limit approved by that Meeting and 50.6% of the total award to all beneficiaries on June 24, 2015.

It is important to note that since 2015, stock options have been restricted to members of the Executive Committee residing outside of France and to beneficiaries in countries where performance shares cannot be granted; they are no longer awarded to all beneficiaries of equity compensation plans. This explains why the proportion of the option plans granted to the Chief Executive Officer is higher than in the past.

Stock options exercised by Olivier Brandicourt in 2015 (table no. 5 of the AFEP-MEDEF Code)

No stock options are currently exercisable.

Stock options held by Olivier Brandicourt

Origin	Date of Board grant	Nature of options	Value (in)	Number of options awarded	Exercise price (in)	Exercise period
Sanofi		Subscription				06/25/2019
	06/24/2015	options	3,546,400	220,000	89.38	06/24/2025

In 2011, as part of its commitment to transparency, Sanofi undertook to publish in its annual report the level of attainment determined by the Board of Directors for performance conditions applicable to future equity-based compensation plans awarded to the Chief Executive Officer and other members of the Executive Committee. The Board believes that disclosing the level of attainment allows our shareholders to better understand the demanding nature of the performance conditions. The levels of attainment of the 2009, 2011 and 2012 plans were published in

our

previous annual reports. The levels of attainment of the 2011 and 2012 plans were below 100%, demonstrating the stringency of the performance conditions imposed on executive officers and employees. Sanofi intends to continue this policy.

The total number of unexercised options held by Olivier Brandicourt represented 0.02% of the share capital as at December 31, 2015.

Performance shares awarded to Olivier Brandicourt in 2015 (table no. 6 of the AFEP-MEDEF Code)

Origin	Date of Board award	Value (in)	Number of performance shares awarded in 2015	Vesting date	Availability date
Sanofi	06/24/2015	5,248,320	66,000	06/25/2019	06/26/2019
Sanofi	06/24/2015	3,578,400	45,000	06/25/2019	06/26/2019

On June 24, 2015, 111,000 performance shares were awarded to Olivier Brandicourt. In compliance with the AFEP-MEDEF Code, the entire award is contingent upon performance criteria.

66,000 of those performance shares were awarded as partial compensation for benefits forfeited by Olivier Brandicourt when leaving his previous employer. The vesting of these shares is contingent upon a performance condition

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measured over three years whereby the average of the ratios of business net income (see Item 5 Business Net Income) to net sales for each financial year must be at least 18% over the 3 years of the plan.

The remaining 45,000 performance shares represent his annual award for 2015. Vesting of the shares is contingent upon both internal criteria based on Business Net Income and Return on Assets (ROA), and an external criterion based upon Total Shareholder Return (TSR) in comparison to a benchmark panel set of pharmaceutical companies. These criteria were selected because they align medium-term equity-based compensation with the strategy adopted by the Company.

This award is broken down as follows:

- The performance criterion based on Business Net Income covers 50% of the award and refers to the ratio, at constant exchange rates, between actual Business Net Income and the Business Net Income specified in the budget. This criterion corresponds to average actual business net income versus budgeted business net income over the entire period. Budgeted business net income is approved by the Board of Directors at the beginning of each year. If the ratio is less than 95%, the corresponding performance shares will lapse. The Business Net Income target may not be lower that the lower range of the guidance published by the Company at the beginning of each year.

- The ROA-based criterion covers 30% of the award and includes a target ROA below which some or all of the performance shares will lapse.

- The TSR-based criterion covers 20% of the award. The overall return to shareholders is evaluated both on the value of Sanofi shares (the increase in the share price) and the value distributed to shareholders (dividends), i.e. the two sources of return on investment in Sanofi shares. Our TSR is compared with a benchmark panel comprised of 10 companies: Astra Zeneca, Bayer, BMS, Eli Lilly, GSK, Johnson & Johnson, Merck, Novartis, Pfizer, and Roche. The number of shares vesting depends upon our position in comparison to the TSR for the other companies of this panel. Below the median, the corresponding performance shares will lapse.
- In order to bring equity-based compensation into line with medium-term performance, performance will be measured over three financial years.

- Vesting is now also subject to a non-compete clause.

- In the event that Olivier Brandicourt leaves the Company for reasons other than (i) resignation or (ii) dismissal for serious cause or gross misconduct, the overall allocation percentage will be prorated to reflect the amount of time he remained in office during the vesting period.

The Board regards these performance conditions as good indicators of the development of shareholder value in terms of: the quality of investment decisions in a period where external growth plays a greater role than in the past (ROA condition); a commitment to delivering challenging bottom-line results in a tough business environment (Business Net Income condition); and matching or exceeding our peer group in terms of shareholder returns (TSR condition).

Although for reasons of confidentiality the quantitative measures for the internal criteria cannot be disclosed, even though they have been properly and precisely established, the targets and the level of attainment for the internal criteria will be disclosed at the end of the performance measurement period.

Each performance share awarded on June 24, 2015, was valued at 79.52, valuing the total benefit at 8,826,720.

The Board of Directors had previously decided to limit the number of performance shares that could be awarded to corporate officers to 5% of the total limit approved by Shareholders General Meeting held on May 4, 2015 (1.2% of our share capital). The number of shares awarded to Olivier Brandicourt in 2015 represents 0.71% of this total limit approved by that Meeting and 2.9% of the total award to all beneficiaries on June 24, 2015.

Performance shares awarded to Olivier Brandicourt which became available in 2015 (table no. 7 of the AFEP-MEDEF Code)

No performance shares became available.

Performance shares awarded to Olivier Brandicourt

Origin	Date of Board award	Value (in)	Number of performance shares awarded	Vesting date	Availability date
Sanofi	06/24/2015	5,248,320	66,000	06/25/2019	06/26/2019
Sanofi	06/24/2015	3,578,400	45,000	06/25/2019	06/26/2019

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In 2011, as part of its commitment to transparency, Sanofi undertook to publish in its annual report the level of attainment determined by the Board of Directors for performance conditions applicable to future equity-based compensation plans awarded to the Chief Executive Officer and other members of the Executive Committee. The Board believes that disclosing the level of attainment allows our shareholders to better understand the demanding nature of the performance conditions. The levels of attainment of the 2009, 2011 and 2012 plans were published in our previous annual reports. The levels of attainment of the 2011 and 2012 plans were below 100%, demonstrating the stringency of the performance conditions imposed on executive officers and employees. Sanofi intends to continue this policy.

The total number of performance shares awarded to Olivier Brandicourt represented 0.008% of our share capital as of December 31, 2015.

Christopher Viehbacher

On October 29, 2014, Christopher Viehbacher was removed from office as Chief Executive Officer with immediate effect. Serge Weinberg took over as of this date the office of Chief Executive Officer.

The Board considered that the removal of Christopher Viehbacher was the result neither of a change in strategy nor of a change in control. Consequently the Board concluded that the conditions to activate the payment of the severance indemnity were not met and thus that there was no need to assess the attainment of the performance conditions which would determine its amount. This assessment of the terms and conditions of the termination benefit, although strictly complying with the AFEP-MEDEF Code, led to an unusual situation whereby his termination benefit did not apply and instead a settlement agreement, which fell outside the scope of the Code, was put in place.

Christopher Viehbacher interpreted the situation differently and claimed full payment of the termination benefit, alleging that there had in fact been a change in strategy. The Board of Directors then sought to bring an end to this controversy, which was detrimental to Sanofi. Following negotiations between the respective legal advisers of the two parties, a settlement agreement was signed on January 22, 2015, three months after Christopher Viehbacher s departure from Sanofi.

The terms agreed when Christopher Viehbacher was originally hired by Sanofi did not include a non-compete clause because at that time, such clauses were not customary. However, at the time of the settlement agreement there was a high risk of competition with Sanofi, given Christopher Viehbacher s age and the circumstances of his departure. The Board therefore decided that it would be in Sanofi s interests to include a non-compete clause in the settlement agreement, to apply from January 22, 2015 (the date of signature of the agreement) through June 30, 2015.

The settlement agreement, which was intended to achieve full and final resolution on the controversy, could not contain performance conditions since signature and execution of the agreement occurred concomitantly. In addition, the timing of events was such that it would have been pointless to waive application of the non-compete clause given that (i) this rule applies to termination benefits subject to the AFEP-MEDEF Code but not to negotiated settlement agreements and (ii) the non-compete clause was intended to remedy an immediate risk given that Christopher Viehbacher had already left the company.

The termination benefit agreed in 2008 (which was a related party agreement requiring shareholder approval) complied fully with the recommendations of the AFEP-MEDEF Code, but in the event turned out not to be applicable under those same recommendations. Conversely, neither the settlement agreement nor the non-compete clause contained in that agreement fell within the scope of the AFEP-MEDEF Code.

As regards Christopher Viehbacher s ability to exercise stock options already awarded to him, and the vesting of performance shares already awarded to him, Sanofi has for many years (in line with its fully transparent approach) published the employee plan rules on its corporate governance webpage, along with a separate document describing the TSR and continuing employment criteria that apply specifically to the Chief Executive Officer.

According to that document, *if Mr. Viehbacher s responsibilities as Chief Executive Officer should terminate, he will retain his right to the performance shares or to exercise his options, except as follows (subject to determination by the Board of Directors): (i) in case of resignation, the loss of his right to exercise the options or of his right to the performance shares will take effect on the date his responsibilities as Chief Executive Officer terminate; and (ii) in case of removal for serious cause or gross misconduct (faute grave), the loss of his right to exercise the options or of his right to the performance shares will take effect on the date on which removal is notified .*

Because he was not removed from office for serious cause or gross misconduct, there was no waiver of the continuing employment condition, but rather a strict application of the plan rules. Sanofi complies with the letter and the spirit of the AMF recommendation no. 2012-02: our 2014 annual report clearly indicates the list of options and performance shares granted to Christopher Viehbacher at the time of his removal from office (page 166 for the options, and page 168 for the performance shares).

In 2011, as part of its commitment to transparency, Sanofi undertook to publish in its annual report the level of attainment determined by the Board of Directors for performance conditions applicable to future equity-based compensation plans awarded to Christopher Viehbacher and other members of the Executive Committee. The Board believes that disclosing the level of attainment allows our

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shareholders to better understand the demanding nature of the performance conditions. The 2009 and 2011 share-based plans were the first plans for which the Board of Directors determined the level of fulfillment of the performance conditions.

On March 9, 2011, 300,000 subscription options were awarded to Christopher Viehbacher. The entire award was contingent upon performance conditions.

For the first period (2011 and 2012) which related to 50% of the March 9, 2011 grant, the performance was as follows:

- the performance criterion based on Business Net Income (which covered 40% of the award) was fulfilled, being 106% of the target;
- the ROA-based criterion (which covered 40% of the award) was fulfilled, being 1.7% above the target;
- the TSR-based criterion (which covered 20% of the award) was fulfilled, Sanofi ranking 5th among the panel of 12 peers.

The Board of Directors, in its meeting of February 6, 2013, determined that the global performance rate for the first period was greater than 100% and therefore, since the performance condition had been fulfilled, 50% of the stock subscription options granted would be exercisable at the end of the four-year vesting period subject to meeting the condition of continuing employment.

For the second period (2013 and 2014), the performance was as follows:

- the performance criterion based on Business Net Income (which covered 40% of the award) was 97.7% fulfilled;
- the ROA-based criterion (which covered 40% of the award) was fulfilled, being 0.2% above the target;
- the TSR-based criterion (which covered 20% of the award) was 78.6% fulfilled, Sanofi ranking 8th among the panel of 11 peers.

The Board of Directors, in its meeting of March 3, 2015, determined that the global performance rate for the second period was 94.8% and therefore, since the performance condition had been partially fulfilled, 94.8% of the stock subscription options granted would be exercisable at the end of the four-year vesting period. The Board of Directors determined that the global performance rate for the March 9, 2011 option plan was 97.4% and therefore 292,200 options would be exercisable at the end of the 4-year vesting period.

On March 5, 2012, 240,000 subscription options and 42,000 performance shares were awarded to Christopher Viehbacher. The entire award was contingent upon performance conditions for the period 2012-2014.

The Board of Directors, in its meeting of February 4, 2015, determined that:

- the performance criterion based on Business Net Income (which covered 40% of the award) was 84.4% fulfilled;
- the ROA-based criterion (which covered 40% of the award) was fulfilled, being 0.5% above the target;
- the TSR-based criterion (which covered 20% of the award) was 57.6% fulfilled, Sanofi ranking 9th among the panel of 11 peers.

The Board of Directors, in its meeting of February 4, 2015, determined that the global performance rate was 85.3% and therefore, since the performance condition had been partially fulfilled, 204,720 options would be exercisable at the end of the 4-year vesting period and that 35,826 shares would vest.

On March 5, 2013, 240,000 subscription options and 45,000 performance shares were awarded to Christopher Viehbacher. The entire award was contingent upon performance conditions for the period 2013-2015.

The Board of Directors, in its meeting of February 8, 2016, determined that:

- the performance criterion based on Business Net Income (which covered 40% of the award) was 83.2% fulfilled;
- the ROA-based criterion (which covered 40% of the award) was fulfilled, being 0.2 percentage point above the target;
- the TSR-based criterion (which covered 20% of the award) was not fulfilled, Sanofi ranking 9th among the panel of 11 peers.

The Board of Directors, in its meeting of February 8, 2016, determined that the global performance rate was 73.3% and therefore, since the performance condition had been partially fulfilled, 175,920 options would be exercisable at the end of the 4-year vesting period and that 32,985 shares would vest.

To qualify for his pension under the Sanofi top-up defined-benefit pension plan, Christopher Viehbacher would have had to be able to claim his pension rights under the compulsory schemes. Because he was removed from office and consequently left Sanofi before the age at which he had legally acquired full pension rights, he also lost his entire entitlement under the top-up plan.

Arrangements for corporate officers

Pension arrangements

Olivier Brandicourt is covered by a top-up defined-benefit pension plan falling within the scope of Article L. 137-11 of the French Social Security Code, (which has been called the Sanofi plan since the Company changed its name). The plan is offered to all employees of Sanofi and its French subsidiaries who meet the eligibility criteria specified in the plan rules. This plan, which remains open, was set up on October 1, 2008 as the final stage in the process of harmonizing the status of personnel across the French subsidiaries.

This top-up defined-benefit pension plan is offered to executives (as defined by AGIRC, a confederation of executive pension funds) of Sanofi and its French subsidiaries who meet the eligibility criteria specified in the

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plan rules; the benefit is contingent upon the plan member ending his or her career within the Group. The plan is reserved for executives with at least ten years of service whose annual base compensation has for ten years (not necessarily consecutive) exceeded four times the French social security ceiling, and is wholly funded by the Company and outsourced to an insurance company.

Based on the assumptions used in the actuarial valuation of this plan, 575 executives were potentially eligible for this plan (15 retirees, 87 early retirees and 472 active employees) as of December 31, 2015.

The top-up pension, which may not exceed 37.50% (1.5% per year of service capped at 25 years) of the reference compensation, is in the form of a life annuity, and is transferable as a survivor s pension. The annuity is based on the arithmetical average of the three highest years annual gross compensation (fixed plus variable) paid during any three of the five years preceding final cessation of employment. This reference compensation is capped at 60 times the French social security ceiling (PASS) applicable in the year in which the rights vest.

Because Olivier Brandicourt has pursued his career in different countries and in different groups, he has not continuously paid his contribution to the French compulsory industry schemes. Taking into account the award of a deemed ten years of service on taking up office, he had accumulated 10.75 years of service as of December 31, 2015. The reference compensation being limited to 60 PASS (i.e. 2,282,400 in 2015) the amount of the annuity is 16.125% of this amount, i.e. 368,037.

This retirement plan is subject to various charges and contributions such as CSG, CRDS, CSAM, CASA and a 7% and a 14% contribution on the annuity, 24% on the external financing.

In order to benefit from benefit the Sanofi retirement plan when leaving the Group, Olivier Brandicourt has to be entitled to benefit fully from compulsory industry schemes, which requires that he reach the legal retirement age (taking into account his age, not before 2018) and to have the mandatory number of three-month periods of qualifying employment. Sanofi does not have sufficient information to determine whether retirement in 2018 is a realistic scenario in terms of qualifying employment, since most of his career has been spent outside France.

If Olivier Brandicourt were to retire in 2018, he would have accumulated 13 years of service, entitling him to an annuity equal to 19.5% of his reference compensation. That annuity would supplement the schemes for which he may be eligible in France or abroad, subject to a cap on the total pension from all sources set at 52% of the reference compensation. If the total amount of the annuities paid under all such schemes were to exceed the 52% cap, the amount of the Sanofi top-up defined-benefit pension would be reduced accordingly in order to respect this cap.

The award of a deemed ten years of service to Olivier Brandicourt on his taking up office was intended solely to compensate him for benefits forfeited elsewhere. Given the lack of any internal candidates following the dismissal of the previous Chief Executive Officer, Sanofi had to make an outside appointment; consequently, whichever outside candidate was appointed would have had to be compensated for benefits forfeited elsewhere.

This benefit has been taken into account by the Board of Directors when fixing his global compensation.

The eligibility of Olivier Brandicourt for this plan was approved by the Shareholders General Meeting of May 4, 2015.

Termination arrangement

Any activation of this termination benefit can only be carried out if the departure of the Chief Executive Officer is forced, i.e. in the event of removal from office or resignation linked to a change in strategy or control of the Company. In practice, non-renewal of the term of office of the Chief Executive Officer at its expiration date is not applicable as this office is held for an indefinite term.

Any activation of this termination benefit is excluded:

- in the event of removal from office for gross or serious cause or misconduct (*faute grave ou faute lourde*);

- if he elects to leave the Company in order to hold another position;

- if he is assigned to another position within the Group;

- if he is able to benefit from pension rights in the near future.

The amount of this termination benefit is limited to 24 months of total compensation on the basis of the fixed compensation effective on the date he ceases to hold office and the last variable compensation received prior to that date, subject to the performance criteria described below.

In accordance with article L. 225-42-1 of the French Commercial Code and with the AFEP-MEDEF Code, payment of the termination benefit is contingent upon fulfillment of two performance criteria listed below, assessed over the three financial years preceding his ceasing to hold office.

The two criteria are:

- the average of the ratios of business net income to net sales for each financial year must be at least 15% (see Item 5 Business Net Income);

- the average of the ratios of operating cash flow before changes in working capital to net sales for each financial year must be at least 18%.

The amount of this benefit will be reduced by any benefit received as consideration for the non-compete undertaking,

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so that the cumulative amount of these two benefits may never exceed two years of total fixed and variable compensation.

The Shareholders General Meeting of May 4, 2015 approved the section on the termination benefit contained in the auditors special report on related party transactions.

Non-compete undertaking

In the event of his departure from the Company, Olivier Brandicourt undertakes not to join a competitor of the Company as an employee or executive officer, or to provide services to or cooperate with such a competitor, during a 12-month period following his departure.

In return for his undertaking, he will receive an indemnity corresponding to one year s total compensation on the basis of his fixed compensation effective on the day he ceases to hold office and the last individual variable compensation received prior to that date. This indemnity will be payable in 12 monthly installments.

However, the Board of Directors reserves the unilateral right to release him from this undertaking for some or all of that 12-month period. In such a case, the non-compete indemnity would not be due for the period of time waived by the company.

The Shareholders General Meeting of May 4, 2015 approved the section on the non-compete undertaking contained in the auditors special report on related party transactions.

Commitments in favour of the Chairman and Chief Executive Officer in office as of December 31, 2015 (table n°10 of the AFEP-MEDEF Code)

	Contract of employment	Top-up pension plan	Compensation or benefits payable or potentially payable on termination of office	Compensation payable under non-competition clause
Serge Weinberg	None	None	None	None
Olivier Brandicourt	None	Yes	Yes	Yes

Lock-up obligation for shares obtained on exercise of stock options or on disposition of performance shares by the Chief Executive Officer

Until he ceases to hold office, the Chief Executive Officer will be required to retain, in the form of Sanofi shares, 50% of any capital gains (net of taxes and social contributions) obtained by the exercise of stock options or upon disposition of performance shares awarded by Sanofi. He must hold these shares in registered form until he ceases to hold office.

In compliance with the AFEP-MEDEF Code and our Board Charter, Olivier Brandicourt has undertaken to refrain from entering into speculative or hedging transactions, and, so far as Sanofi is aware, no such instruments have been contracted.

Compensation and pension payments for Directors other than the Chairman and the Chief Executive Officer

Attendance fees (table no. 3 of the AFEP-MEDEF Code)

The table below shows amounts paid to each member of the Sanofi Board of Directors in respect of 2014 and 2015, including those whose term of office ended during those years.

Attendance fees in respect of 2014, the amount of which was approved at the Board meeting of March 3, 2015 were partially paid in July 2014. The balance was paid in 2015.

Attendance fees in respect of 2015, the amount of which was approved at the Board meeting of March 3, 2016, were partially paid in July 2015. The balance will be paid in 2016.

For 2015, the basic annual attendance fee was set at 15,000, apportioned on a time basis for Directors who assumed or left office during the year.

For 2016, the basic annual attendance fee was set at 30,000, to be apportioned on a time basis for Directors who assume or leave office during the year.

For 2015, the variable portion of the fee is linked to actual attendance by Directors in accordance with the principles described below:

- Directors resident in France receive 5,000 per Board or Committee meeting attended, except for Audit Committee meetings for which the fee is 7,500 per meeting attended;
- Directors resident outside France but within Europe receive 7,000 per Board meeting attended, and 7,500 per Committee meeting attended;
- Directors resident outside Europe receive 10,000 per Board meeting attended and per Strategy Committee meeting attended;
- the chairman of the Compensation Committee receives 7,500 per Committee meeting;
- the chairman of the Audit Committee receives 10,000 per Committee meeting.

The attendance fee payable to a Director who participates by conference call or by videoconference is equivalent to half of the attendance fee received by a Director resident in France who attends in person.

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As an exception, multiple meetings held on the same day give entitlement to a single attendance fee:

- if on the day of a Shareholders General Meeting, the Board of Directors meets both before and after the Meeting, only one attendance fee is paid for both;

- if a Director participates in a meeting of the Compensation Committee and in a meeting of the Appointments and Governance Committee on the same day, only one attendance fee is paid for both.

Hence, in accordance with the AFEP-MEDEF Code, attendance fees are allocated predominantly on a variable basis.

The introduction of a separate attendance fee scale depending on whether or not the director is a European resident is intended to take into account the constraints associated with a significantly longer travel time to attend meetings in person.

The Shareholders Annual General Meeting of May 6, 2011 approved a proposal to increase the maximum amount of annual attendance fees to 1,500,000. For 2014, as for 2009 and 2010, this amount was scaled down in order to keep attendance fees within the total attendance fee entitlement.

	2015				2014				
	Attendance fees in respect of 2015		Pensions paid in	Total	Attendance fees in respect of 2014		Pensions paid in	Total Theoretical	Total Actual
Names *(in euros)*	Fixed	Variable	2015	Compensation	Fixed	Variable	2014	Compensation[7]	Compensation[8]
Laurent Attal	15,000	60,000		75,000	15,000	75,000		90,000	79,662
Bonnie Bassler[1]	15,000	72,500		87,500	1,250	0		1,250	1,106
Uwe Bicker	15,000	82,000		97,000	15,000	104,500		119,500	105,773
Robert Castaigne	15,000	110,000		125,000	15,000	95,000		110,000	97,365
Thierry Desmarest[2]	-	-		-	12,500	75,000		87,500	77,449
Lord Douro[3]	-	-		-	6,250	60,500		66,750	66,750
Jean-René Fourtou	15,000	105,000	1,720,829	1,840,829	15,000	120,000	1,720,829	1,855,829	1,840,322
Claudie Haigneré	15,000	80,000		95,000	15,000	110,000		125,000	110,641
Patrick Kron[4]	15,000	77,500		92,500	10,000	32,500		42,500	37,618
Igor Landau[5][6]	6,250	22,500	2,355,970	2,384,720	15,000	55,000	2,355,970	2,425,970	2,417,929
Fabienne Lecorvaisier	15,000	90,000		105,000	15,000	95,000		110,000	97,365
Suet-Fern Lee	15,000	70,000		85,000	15,000	92,500		107,500	95,152
Christian Mulliez	15,000	125,000		140,000	15 000	142,500		157,500	139,408
Carole Piwnica[6]	15,000	73,750		88,750	15,0000	92,500		107,500	95,152
Klaus Pohle	15,000	87,000		102,000	15,000	136,000		151,500	133,655
Gérard Van Kemmel[5]	6,250	70,000		76,250	15,000	190,000		205,000	181,452
Total	**192,500**	**1,125,250**	**4,076,799**	**5,394,549**	**210,000**	**1,476,000**	**4,076,799**	**5,762,799**	**5,576,799**
Total attendance fees (theoretical)	**1,317,750**				**1,686,500**				

Total attendance fees (actual)	**1,317,750**	**1,500 ,000**

Amountsreported are gross amounts before taxes.

(1) Assumed office November 18, 2014.

(2) Left office October 23, 2014.

(3) Left office May 5, 2014.

(4) Assumed office May 5, 2014.

(5) Left office May 4, 2015.

(6) Board member resident outside France, but treated as a French resident for tax purposes.

(7) Before reducing attendance fees pro rata by approximately 0.89%.

(8) After reducing attendance fees pro rata by approximately 0.89%.

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Pensions

The amount recognized in 2015 in respect of corporate pension plans for directors with current or past executive responsibilities at Sanofi (or companies whose obligations have been assumed by Sanofi) was 12.3 million.

As retirees, Jean-René Fourtou and Igor Landau are covered by the GRCD top-up pension plan instituted in 1977 for senior executives of Rhône-Poulenc. This plan was amended in 1994, 1996, 1999 and 2003, and as of December 31, 2015 applied to 31 beneficiaries (one active executive, two early retirees and 28 retired executives, including three survivor s pensions). At its meeting of February 11, 2008, the Board of Directors decided to close this plan to new entrants. Christopher Viehbacher did not benefit from this top-up pension plan.

Compensation of Senior Management

The compensation of Executive Committee members other than the Chief Executive Officer is established upon the recommendation of the Compensation Committee taking into consideration the practices of major global pharmaceutical companies.

In addition to fixed compensation, they receive variable compensation. Variable compensation generally represents 70% to 100% of their fixed compensation. The amount of the individual variable compensation is set pursuant to market practice. It rewards the individual contribution of each Executive Committee member to the Group s performance as well as the performance of his/her organization.

For 2015, the variable compensation was composed of two elements:

- meeting quantitative objectives (accounting for 50%), which are measured at Group level (sales growth one-third, business net income two-thirds, and for this year a booster that can increase the quantitative portion by up to 10% depending on new product launches) and at the level of the Executive Committee member s organization or function; and

- meeting quantitative and qualitative objectives, both individually (30%) and collectively (20%) within the Executive Committee (together accounting for 50%).

The objectives are intended to reflect growth (growth in net sales, business net income, registration and submission of new products in the U.S. and in Europe, growth in net sales of new products); cash flow optimization; talent management and critical skills (including selected key recruitments in critical areas for the Group); talent retention; increase in the

number of women in senior management positions; and promotion of high potential individuals.

In addition to cash compensation, Executive Committee members may be awarded share subscription or purchase options and/or performance shares (see E. Share Ownership below for details of the related plans).

With respect to 2015, the total gross compensation paid and accrued in respect of members of the Executive Committee (including Olivier Brandicourt amounted to 20.5 million, including 8.1 million in fixed compensation.

In addition Christopher Viehbacher s variable compensation for 2014 (1.3 million), settlement indemnity (3 million) and non-compete indemnity (1.3 million) were paid in 2015.

In 2011, the Board of Directors made significant changes to its equity compensation policy. In order to limit the dilutive effect on shareholders, the Board of Directors determined to primarily award performance shares, except for a limited group of high level executives who may continue to receive options. The members of the Executive Committee are included in this limited group. Furthermore, whoever the beneficiary is, any award of options or performance shares is now fully contingent upon the performance targets being achieved over several financial years, and upon the beneficiary still being an employee when the option is exercised or the performance share is delivered.

On June 24, 2015, 422,500 stock subscription options were awarded to members of the Executive Committee (including 220,000 options awarded to Olivier Brandicourt). In compliance with the AFEP-MEDEF Code, the entire award is contingent upon internal criteria based upon Business Net Income and Return on Assets (ROA). These criteria were selected because they align medium-term equity-based compensation on the strategy adopted by the Company.

This award is broken down as follows:

- The performance criterion based on Business Net Income covers 60% of the award and refers to the ratio, at constant exchange rates, between actual Business Net Income and the Business Net Income specified in the budget. This criterion corresponds to average actual business net income versus budgeted business net income over the entire period. Budgeted business net income is approved by the Board of Directors at the beginning of each year. If the ratio is less than 95%, the corresponding options will lapse. The Business Net Income target may not be lower that the lower range of the guidance published by the Company at the beginning of each year.

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- The ROA-based criterion covers 40% of the award and includes a target ROA, below which some or all of the options will lapse.

- In addition to the two conditions set forth above, an implicit condition exists in the form of the exercise price, as well as the condition of continuing employment.

- In order to bring equity-based compensation into line with medium-term performance, performance will be measured over three financial years.

- Vesting is now also subject to a non-compete clause.

- In case of departure for reasons other than resignation and dismissal for gross or serious cause or misconduct, the global allocation rate will be prorated to take into account the effective presence in the Group during the vesting period.

The Board regards these performance conditions as good indicators of the development of shareholder value in terms of: the quality of investment decisions in a period where external growth plays a greater role than in the past (ROA condition), and a commitment to delivering challenging bottom-line results in a tough business environment (Business Net Income condition).

Although for reasons of confidentiality the quantitative measures for the internal criteria cannot be disclosed, even though they have been properly and precisely established, the targets and the extent to which the internal criteria are met will be disclosed at the end of the performance measurement period.

During 2015, 263,104 stock subscription options were exercised by individuals who were members of the Executive Committee when they exercised.

These exercises related to two option plans that pre-date the creation of the Executive Committee (sanofi-aventis subscription option plan of May 31, 2005 with an exercise price of 70.38 and sanofi-aventis subscription option plan of December 14, 2006 with an exercise price of 66.91), and two others that post-date the creation of the Executive Committee (sanofi-aventis subscription option plan of March 1, 2010 with an exercise price of 54.12 and sanofi-aventis subscription option plan of March 9, 2011 with an exercise price of 50.48).

On March 9, 2011, 277,500 stock subscription options were awarded to members of the Executive Committee (on top of the 300,000 subscription options awarded to Christopher Viehbacher). In compliance with the AFEP-MEDEF Code, the entire award was contingent upon two internal criteria based on Business Net Income and Return on Assets (ROA).

For the first period (2011 and 2012) which related to 50% of the March 9, 2011 grant, the performance was as follows:

- The performance criterion based on Business Net Income (which covered 50% of the award) was fulfilled, being 106% of the target;

- The ROA-based criterion (which covered 50% of the award) was fulfilled, being 1.7% above the target;

The Board of Directors, in its meeting of February 6, 2013, determined that the global performance rate for the first period was greater than 100% and therefore, since the performance condition had been fulfilled, 50% of the stock subscription options granted would be exercisable at the end of the four-year vesting period subject to meeting the condition of continuing employment.

For the second period (2013 and 2014), the performance was as follows:

- The performance criterion based on Business Net Income (which covered 50% of the award) was 97.7% fulfilled;

- The ROA-based criterion (which covered 50% of the award) was fulfilled, being 0.2% above the target;

The Board of Directors, in its meeting of March 3, 2015, determined that the global performance rate for the second period was equal to 98.9% and therefore, since the performance condition had been partially fulfilled, 98.9% of the stock subscription options granted would be exercisable at the end of the four-year vesting period. The Board of Directors determined that the global performance rate for the March 9, 2011 option plan was 99.5% and therefore 276,133 options would be exercisable at the end of the 4-year vesting period.

On March 5, 2012, 205,500 subscription options were awarded to members of the Executive Committee (on top of the 240,000 subscription options awarded to Christopher Viehbacher). In compliance with the AFEP-MEDEF Code, the entire award was contingent upon performance conditions for the period 2012-2014.

The Board of Directors, in its meeting of February 4, 2015, determined that:

- The performance criterion based on Business Net Income (which covered 50% of the award) was 84.4% fulfilled;

- The ROA-based criterion (which covered 50% of the award) was fulfilled, being 0.5% above the target.

The Board of Directors, in its meeting of February 4, 2015, determined that the global performance rate was 92.2% and therefore, since the performance condition had been partially fulfilled, 189,471 options would be exercisable at the end of the 4-year vesting period.

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On March 5, 2013, 180,000 stock subscription options were awarded to members of the Executive Committee (on top of the 240,000 subscription options awarded to Christopher Viehbacher). In compliance with the AFEP-MEDEF Code, the entire award was contingent upon performance conditions for the period 2013-2015.

The Board of Directors, in its meeting of February 8, 2016, determined that:

- the performance criterion based on Business Net Income (which covered 50% of the award) was 83.2% fulfilled;
- the ROA-based criterion (which covered 50% of the award) was fulfilled, being 0.2 percentage point above the target.

The Board of Directors, in its meeting of February 8, 2016, determined that the global performance rate was 91.6% and therefore, since the performance condition had been partially fulfilled, 164,880 options would be exercisable at the end of the 4-year vesting period.

On June 24, 2015, 364,500 performance shares (including 111,000 performance shares awarded to Olivier Brandicourt) were awarded to members of the Executive Committee. In compliance with the AFEP-MEDEF Code, the entire award is contingent upon both internal criteria based upon Business Net Income and Return on Assets (ROA). These criteria were selected because they align medium-term equity-based compensation on the strategy adopted by the Company.

This award is broken down as follows:

- The performance criterion based on Business Net Income covers 60% of the award and refers to the ratio, at constant exchange rates, between actual Business Net Income and the Business Net Income specified in the budget. This criterion corresponds to average actual business net income versus budgeted business net income over the entire period. Budgeted business net income is approved by the Board of Directors at the beginning of each year. If the ratio is less than 95%, the corresponding performance shares will lapse. The Business Net Income target may not be lower that the lower range of the guidance published by the Company at the beginning of each year.
- The ROA-based criterion covers 40% of the award and includes a target ROA, below which some or all of the performance shares will lapse.
- In order to bring equity-based compensation into line with medium-term performance, performance will be measured over three financial years.
- Vesting is now subject to a non-compete clause.
- In the event that a beneficiary leaves the Company for reasons other than (i) resignation or (ii) dismissal for

serious cause or gross misconduct, the overall allocation percentage will be prorated to reflect the amount of time he or she remained with the Group during the vesting period.

The Board regards these performance conditions as good indicators of the development of shareholder value in terms of: the quality of investment decisions in a period where external growth plays a greater role than in the past (ROA condition), and a commitment to delivering challenging bottom-line results in a tough business environment (Business Net Income condition).

Although for reasons of confidentiality the quantitative measures for the internal criteria cannot be disclosed, even though they have been properly and precisely established, the targets and the level of attainment for the internal criteria will be disclosed at the end of the performance measurement period.

On March 5, 2012, 95,900 performance shares were awarded to members of the Executive Committee (in addition to the 42,000 performance shares awarded to Christopher Viehbacher). In compliance with the AFEP-MEDEF Code, the entire award was contingent upon performance conditions for the period 2012-2014.

The Board of Directors, in its meeting of February 4, 2015, determined that:

- the performance criterion based on Business Net Income (which covered 50% of the award) was 84.4% fulfilled;

- the ROA-based criterion (which covered 50% of the award) was fulfilled, being 0.5% above the target.

The Board of Directors, in its meeting of February 4, 2015, determined that the global performance rate was 92.2% and therefore, since the performance condition had been partially fulfilled, 88,420 shares would vest.

On March 5, 2013, 84,000 performance shares were awarded to members of the Executive Committee (on top of the 45,000 performance shares awarded to Christopher Viehbacher). In compliance with the AFEP-MEDEF Code, the entire award was contingent upon performance conditions for the period 2013-2015.

The Board of Directors, in its meeting of February 8, 2016, determined that:

- the performance criterion based on Business Net Income (which covered 50% of the award) was fulfilled, reaching 83.2% of the target;

- the ROA-based criterion (which covered 50% of the award) was fulfilled, being 0.2 percentage point above the target.

The Board of Directors, in its meeting of February 8, 2016, determined that the global performance rate was 91.6% and

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therefore, since the performance condition had been partially fulfilled, 76,944 shares would vest.

Under French law, Directors may not receive options solely as compensation for service on our Board, and consequently our Company may grant options only to those Directors who are also our officers.

Because some of our non-executive Directors were formerly officers or executive officers of our Company or its predecessor companies, some of our non-executive Directors hold Sanofi stock options.

We do not have separate profit-sharing plans for key executives. As employees, they are able to participate in our voluntary and statutory profit-sharing schemes on the same terms as our other employees. These plans are described below under Employee profit-sharing schemes.

The total amount accrued as of December 31, 2015 in respect of corporate pension plans for (i) directors with current or past executive responsibilities at Sanofi or at companies whose obligations have been assumed by Sanofi and (ii) members of the Executive Committee was 127.8 million, including 18.6 million recognized in the income statement for the year ended December 31, 2015.

This total amount accrued as of December 31, 2015 included 52.6 million for members of the Executive Committee collectively, including 17.2 million recognized in the income statement for the year ended December 31, 2015.

C. Board Practices

Neither we nor our subsidiaries have entered into service contracts with members of our Board of Directors providing for benefits upon termination of employment. With respect to Olivier Brandicourt see also B. Compensation Compensation and arrangements for corporate officers above.

Application of the AFEP-MEDEF Code

The AFEP-MEDEF Code requires us to specifically report on the application of its recommendations and, if applicable, explain why any of them have not been applied. Sanofi follows the guidelines contained in the AFEP-MEDEF Code as amended. Currently our departures from this Code are as follows:

Paragraph of the AFEP-MEDEF Code	Recommendation of the AFEP-MEDEF Code	Sanofi Implementation
4. The Board of Directors and Strategy	The internal rules of the Board should specify the principle that any material transaction outside the scope of the firm s stated strategy is subject to prior approval by the Board of Directors.	The limitations on the powers of the Chief Executive Officer are not contained in our Board Charter but in a decision of our Board dated July 28, 2009 (see A. Directors and Senior Management Limitations on the powers of the Chief Executive Officer set by the Board). These limitations, like our Board Charter, are published every year in our annual report. Because the publication and decision making processes are the same, this departure is technical and has no practical repercussions.
9.4. Independent Directors	The criteria to be reviewed by the committee and the Board in order to qualify as independent and to prevent risks	Our Board of Directors does not strictly follow the recommendation according to which being a Board member for more than 12 consecutive years is of itself sufficient to

of conflicts of interest between the director and the management, the corporation, or its group, are the following:

- not to have been a director of the corporation for more than twelve years.

automatically disqualify a director from being regarded as independent. This is only one criterion that must be evaluated on a case by case basis, and not mechanically. It is only after reviewing all the factors that a director can be determined as being independent or non-independent. While length of service may in certain circumstances be associated with a loss of independence, in other circumstances it may enhance the capacity of a director to question senior management and give greater independence of mind.

In response to a question asked by the *Haut Comité de Gouvernement d Entreprise* (the body in charge of overseeing the implementation of the

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Paragraph of the AFEP-MEDEF Code	Recommendation of the AFEP-MEDEF Code	Sanofi Implementation
		AFEP-MEDEF Code), our Board explained that it considers that its Appointments and Governance Committee is best placed to assess the behavior and hence the true independence of a director.
		The Board of Directors takes the view that it is not favoring competence over independence but rather checking a director s willingness and ability to form an independent opinion, to ask for further details and question the decisions of Senior Management. Consequently, our Board of Directors provides explanations for the specific cases it reviews (see above, A. Directors and Senior Management Board Members Independence)
10.2. Evaluation of the Board of Directors	The evaluation should have three objectives:	The independence qualification is assessed on a yearly basis.
	· assess the way in which the Board operates;	The issue of competence and individual contribution to the activities of the Board and its committees is addressed on a continuous basis with a specific review when a director is up for reappointment as a board or committee member and not through the annual assessment.
	· check that the important issues are suitably prepared and discussed;	The Chairman of the Board continually assesses the involvement of each Board member; annual assessments include one on one interviews with the Secretary to the Board.
	· measure the actual contribution of each director to the Board s work through his or her competence and involvement in discussions.	
23.2.4. Stock options and performance shares	Awards are made at the same time of year; e.g. after publication of the financial statements for the previous financial year, and on an annual basis, in order to limit any windfall effects.	Since 2009, our Board of Directors has awarded stock options and performance shares in its early March meetings and hence after publication of annual results for the previous year.
		Exceptionally, the awards for 2015 were made in June, for two main reasons.

Firstly, the new Chief Executive Officer had not yet joined the Group in March, and it was considered preferable to make the awards to all beneficiaries on the same date.

Secondly, the August 6, 2015 Act on economic growth, business and equal opportunity (the Macron Act) had not yet been enacted. In light of the date on which this Act passed into law, a new authorization will be submitted for shareholder approval at the Annual General Meeting on May 4, 2016 in order to implement the provisions of the new Act. Consequently, the awards for 2016 will also be made after the Annual General Meeting.

Subsequently, the Board intends to resume the practice of making the awards annually in March.

During 2015, the Board of Directors met eleven times, with an overall attendance rate among Board members of over 91%. This attendance rate includes participation by

conference call, though only a limited number of Directors participated in this way. The individual attendance rates varied between 80% and 100%.

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The following persons attended meetings of the Board of Directors in 2015:

- the Directors;
- the Secretary to the Board;
- five employee representatives who attend Board meetings without voting rights, pursuant to the agreement implemented with the European Works Council signed on February 24, 2005;
- and frequent attendance of: the Executive Vice President Chief Financial Officer, the Executive Vice President Global Commercial Operations, the Executive Vice President Global Divisions & Strategic Commercial Development and the President, Global Research & Development.

The agenda for each meeting of the Board is prepared by the Secretary after consultation with the Chairman, taking account of the agendas for the meetings of the specialist Committees and the suggestions of the directors.

Approximately one week prior to each meeting of the Board of Directors, the Directors each receive a file containing the agenda, the minutes for the prior meeting, and documentation relating to the agenda.

The minutes for each meeting are expressly approved at the next meeting of the Board of Directors.

In compliance with our Board Charter, certain issues are examined in advance by the various Committees according to their areas of competence in order for them to make a recommendation; these issues are then submitted for a decision by the Board of Directors.

The Board of Directors meets once a year without the Chairman of the Board and the Chief Executive Officer, in order to carry out the assessment of their performance. Upon the recommendation of the Appointments and Governance Committee and even before the assessment of the Board and of its Committees for 2015 was performed, the Board decided to raise the number of these executive sessions to two per year. These sessions take place at the beginning of Board meetings.

In 2015, the main activities of the Board of Directors related to the following issues:

- financial statements and financial matters:

  review of the individual company and consolidated financial statements for the 2014 financial year, review of the individual company and consolidated financial statements for the first half of 2015 and the consolidated financial statements for the first three quarters of 2015, review of the draft press releases and presentations to analysts with respect to the publication of such financial statements, examination of documents relating to management forecasts;
  financial arrangements adopted with respect to Group subsidiaries over the 2014 financial year;

delegation of authority to the Chief Executive Officer to issue bonds and to issue guarantees, and renewal of the share repurchase program;

reviews of the Board of Directors Management Report, the Chairman s Report and the reports of the statutory auditors;

recording the amount of share capital, the reduction in share capital through cancellation of treasury shares and the corresponding amendments to the Articles of Association;

- compensation matters:

  determination of the financial terms for the appointment of a new Chief Executive Officer and the determination of the variable compensation of the previous Chief Executive Officer for 2014;

  determination of the 2015 fixed compensation of the Chairman of the Board and an update of the 2014 and 2015 fixed and variable compensation of the members of the Executive Committee. During the presentation of the report of the Compensation Committee on the compensation of corporate officers, the Board of Directors deliberated in their absence: the Board of Directors first discussed the compensation of the Chairman in his absence, and then the compensation of the Chief Executive Officer with the Chairman present but with the Chief Executive Officer still absent;

  allocation of Directors attendance fees for 2014, principles of allocation for 2015 and allocation of attendance fees for the first half of 2015, and expenses of Directors and executive officers;

  adoption of equity-based compensation plans, consisting of stock subscription option plans and performance share awards in respect of 2015 and the determining fulfillment of the performance conditions of previous share-based plans;

- appointments and governance matters:

  resignation by the Chairman of the Board from the office of Chief Executive Officer, appointment of a new Chief Executive Officer and his co-opting as a Director, review of limitations on the powers of the Chief Executive Officer;

  the co-opting of a new director, composition of the Board, proposed reappointment of Directors at the 2015 Annual General Meeting, independence of Directors, reappointment of the Chairman of the Board

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appointment of a new Audit Committee chairman, review of the composition of the Committees in view of the new composition of the Board;

reviews of the Board of Directors Management Report, the Chairman s Report and the reports of the statutory auditors;

the notice of meeting for the General Meeting of Shareholders and of Holders of Participating Shares (Series issued in 1983, 1984 and 1987 and Series A participating shares issued in 1989), adoption of the draft resolutions, report of the Board of Directors on the resolutions, and special reports on the awards of stock subscription options and performance shares;

evaluation of the functioning of the Board and its Committees.

- a presentation on Toujeo®;
- review of significant proposed alliances and acquisitions, and strategic opportunities;
- Company policy on equal pay and opportunities; and
- approval in principle of a share issue reserved for employees.

Board Committees

Since 1999, our Board of Directors has been assisted in its deliberations and decisions by specialist committees. Chairmen and members of these committees are chosen by the Board from among its members, based on their experience.

The Committees are responsible for the preparation of certain items on the agenda of the Board of Directors. The decisions of the Committees are adopted by a simple majority with the chairman of the Committee having a casting vote. Minutes are established and approved by the Committee members.

The chairman of each specialist Committee reports to the Board on the work of the Committee in question, so that the Board is fully informed whenever it adopts a decision.

Audit Committee

At December 31, 2015, this Committee was composed of:

- **Robert Castaigne**; Chairman, since March 3, 2015;
- **Fabienne Lecorvaisier**;
- **Christian Mulliez**; and
- **Carole Piwnica**.

Three members of the Audit Committee are classified as independent pursuant to the criteria adopted by the Board of Directors. Robert Castaigne, Fabienne Lecorvaisier, and Carole Piwnica. In addition, all of the members, including Christian Mulliez, fulfill the conditions required to be classified as independent under the Sarbanes-Oxley Act.

All four members of the Committee have financial or accounting expertise as a consequence of their education and professional experience as reflected in their biographies. Furthermore, Robert Castaigne, Fabienne Lecorvaisier, and Christian Mulliez are deemed to be financial experts pursuant to the definition in the Sarbanes-Oxley Act and the definition in Article L. 823-19 of the French Commercial Code. See Item 16A. Audit Committee Financial Expert .

The Audit Committee met six times in 2015, including prior to the meetings of the Board of Directors during which the financial statements were approved. In addition to the statutory auditors, the principal financial officers, the Senior Vice President Group Internal Audit and other members of senior management of the Group attended meetings of the Audit Committee, in particular concerning risk exposure and off-balance-sheet commitments.

Audit Committee meetings take place at least two days prior to any meetings of the Board of Directors during which the annual or interim financial statements are to be examined.

The members of the Audit Committee have a good attendance record for meetings, with an overall attendance rate among members of more than 96%. Individual attendance rates varied between over 80% and 100%.

The statutory auditors attended all of the meetings of the Audit Committee; they presented their opinions on the annual and half yearly financial statements at the Committee meetings of February 2 and July 27, 2015, respectively.

In 2015, the main activities of the Audit Committee related to:

- preliminary review of the individual company and consolidated financial statements for the 2014 financial year, review of the individual company and consolidated financial statements for the first half of 2015 and of the consolidated financial statements for the first three quarters of 2015, a review of press releases and analysts presentations relating to the publication of such financial statements;
- the financial position of the Group, its indebtedness and liquidity;
- investigation and evaluation of internal control for 2014, as certified by the statutory auditors pursuant to Section 404 of the Sarbanes-Oxley Act, and an examination of the 2014 Annual Report on Form 20-F;
- reporting on guarantees;

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- review of the draft financial resolutions for the May 4, 2015 Shareholders General Meeting;
- the principal risks facing the Company, including an update on pharmacovigilance, report of the Risk Committee, impairment testing of goodwill, review of whistleblowing and compliance investigations, review of tax risks and deferred tax assets, review of litigation risks, review of the financial risks, update on pension funds and actuarial assumptions (meetings of March 2, April 27, October 26, and December 15, 2015);
- conclusions of Group management as internal control procedures, the 2014 Board of Directors Management Report, the 2014 Report under the French Financial Security Act, and the 2014 Chairman s Report, including the description of risk factors contained in the French *Document de Référence*;
- reporting on the implementation of the internal control and process department, reporting on internal audit activities and computer services;
- post-acquisitions review (BMP Sunstone, Genzyme), organization and monitoring of undertakings related to R&D agreements, partnerships (excluding Regeneron and Mannkind), and site divestitures, and progress reports on acquisitions; and
- the audit plan, statutory auditors allocation and fees, the budget for audit-related services and non-audit services and the 2015 statutory auditors report and fees.

The Committee did not have recourse to external consultants in 2015.

Compensation Committee

At December 31, 2015, this Committee was composed of:

- **Jean-René Fourtou** Chairman since May 4, 2015;
- **Claudie Haigneré**;
- **Patrick Kron**, since May 4, 2015; and
- **Christian Mulliez**.

Of the four members of the Compensation Committee, three are deemed to be independent.

The Compensation Committee met six times in 2015.

The members of the Compensation Committee have a very good attendance record for meetings, with an overall attendance rate among members of 100%.

When the Committee discusses the compensation policy for members of senior management who are not corporate officers, i.e. the members of the Executive Committee, the Committee invites the members of senior management who are corporate officers to attend.

In 2015, the main activities of the Compensation Committee related to:

- a compensation structure for the new Chief Executive Officer;
- fixed and variable compensation of corporate officers and senior management;
- the terms of the previous Chief Executive Officer s removal from office, determination of his 2014 variable compensation, determination of fulfillment of the performance conditions of his previous share-based plans;
- update on the 2014 and 2015 fixed and variable compensation of the members of the Executive Committee;
- establishment of the amount of Directors attendance fees for 2014, review of the expenses of Directors and corporate officers for 2014, principles of allocation of Directors attendance fees for 2015;
- review of the governance chapter of the 2014 *Document de Référence*, which contains disclosures about compensation;
- determination of fulfillment of the performance conditions of previous share-based plans;
- implementation of the equity-based compensation policy, including both stock options and performance shares, which was discussed at several meetings largely because of the need to review clauses relating to departure from the Group;
- review of draft compensation-related resolutions to be presented to the shareholders in 2015, in particular Say on Pay, renewal of the delegation of authority to the Board to allocate performance shares and the delegation related to share issues reserved for employees; and
- an update on the August 6, 2015 Act on economic growth, business and equal opportunity (the Macron Act).

The Committee did not have recourse to external consultants in 2015.

Appointments and Governance Committee

At December 31, 2015, this Committee was composed of:

- **Serge Weinberg** Chairman since October 28, 2015;
- **Jean-René Fourtou**;

- **Claudie Haigneré**; and

- **Patrick Kron**, since May 4, 2015.

All four members of the Appointments and Governance Committee are deemed to be independent.

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The Appointments and Governance Committee met six times in 2015.

The members of the Appointments and Governance Committee have a very good attendance record for meetings, with an overall attendance rate among members of 100%.

In 2015, the main activities of the Appointments and Governance Committee related to:

- the appointment of a new Chief Executive Officer;
- review of limitations on the powers of the Chief Executive Officer;
- results of the evaluation of the Board and its Committees;
- review of the Board of Directors Management Report, Chairman s Report, and the chapter of the 2014 *Document de Référence* containing disclosures about governance;
- update on the composition of the Board, appointment of a new Audit Committee Chairman, independence of Directors, proposals about the reappointment of Directors, update on the composition of the Committees after the May 4, 2015 Shareholders General Meeting, appointment of the Chairman of the Board as the Chairman of the Appointments and Governance Committee;
- establishing the format for the review of succession planning; and
- an update on the August 17, 2015 Act on social dialogue and employment, (the Rebsamen Act).

The Committee had recourse to external consultants in 2015, principally for the evaluation of the Board and its Committees.

Strategy Committee

At December 31, 2015, this Committee was composed of:

- **Serge Weinberg,** Chairman;

- **Olivier Brandicourt** (since April 2, 2015);
- **Laurent Attal;**
- **Uwe Bicker;**
- **Jean-René Fourtou;** and
- **Patrick Kron** (since May 4, 2015).

Of the six members of the Strategy Committee, four are deemed to be independent.

In 2015, the Strategy Committee met five times, including twice in expanded sessions that included other directors.

The members of the Strategy Committee have a very good attendance record for meetings, with an overall attendance rate among members of over 92%. Individual attendance rates varied between 60% and 100%.

The work of the Committee covered in particular the launch of Praluent®, overview of strategy, and several proposed external R&D collaborations, acquisitions and partnership opportunities.

The Committee did not have recourse to external consultants in 2015.

D. Employees

Number of Employees

In 2015, Sanofi employed 115,631 people worldwide, 2,135 more than in 2014. The tables below give a breakdown of employees by geographic area and function for the years ended December 31, 2015, 2014 and 2013.

Employees by geographic area

	As of December 31,							
	2015	**%**	**2014**	**%**	**2013**	**%**	**2012**	**%**
Europe	54,375	47.0%	53,341	47.0%	53,880	48.0%	56,265	50.2%
North America	19,263	16.7%	18,627	16.4%	18,795	16.8%	18,994	17.0%
Other countries	41,993	36.3%	41,528	36.6%	39,453	35.2%	36,715	32.8%
Total	**115,631**	**100%**	**113,496**	**100%**	**112,128**	**100%**	**111,974**	**100%**

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Employees by function

	As of December 31,							
	2015	%	2014	%	2013	%	2012	%
Sales	34,172	29.5%	34,118	30.1%	33,509	29.9%	32,270	28.8%
Research and Development	16,260	14.1%	16,257	14.3%	16,688	14.9%	17,066	15.2%
Production	45,744	39.6%	44,366	39.1%	44,031	39.3%	45,035	40.2%
Marketing and Support Functions	19,455	16.8%	18,755	16.5%	17,900	16.0%	17,603	15.7%
Total	**115,631**	**100%**	**113,496**	**100%**	**112,128**	**100%**	**111,974**	**100%**

Industrial Relations

In all countries where we operate, we strive to combine economic and social performance which we believe are inseparable.

Our responsibility towards our employees is based on the basic principles of the Group s Social Charter, which outlines the rights and duties of all Group employees. The Social Charter addresses Sanofi s key commitments towards its workforce: equal opportunity for all people without discrimination, the right to health and safety, respect for privacy, the right to information and professional training, social protection for employees and their families, freedom of association and the right to collective bargaining, and respect for the principles contained in the Global Compact on labor relations and ILO treaties governing the physical and emotional well-being and safety of children.

The Group s labor relations are based on respect and dialogue. In this spirit, the Company s management and employee representatives meet regularly to exchange views, negotiate, sign agreements and ensure that agreements are being implemented.

Employee dialogue takes place in different ways from one country to the next, as dictated by specific local circumstances. Depending on the circumstances, employee dialogue relating to information, consultation and negotiation processes may take place at national, regional or company level. It may be organized on an interprofessional or sectoral basis, or both. Employee dialogue may be informal or implemented through a specific formal body, or a combination of both methods. Whatever the situation, Sanofi encourages employees to voice their opinions, help create a stimulating work environment and take part in decisions aiming to improve the way we work. These efforts reflect one of the principles of the Social Charter whereby the improvement of working conditions and the Group s necessary adaptation to its environment go hand-in-hand.

Profit-sharing Schemes, Employee Savings Schemes and Employee Share Ownership

Profit-sharing Schemes

All employees of our French companies belong to voluntary and statutory profit-sharing schemes.

Voluntary Scheme (*Intéressement des salariés*)

These are collective schemes that are optional for the employer and contingent upon performance. The aim is to give employees an interest in the growth of the business and improvements in its performance.

The amount distributed by our French companies during 2015 in respect of voluntary profit-sharing for the year ended December 31, 2014 represented 4.60% of total payroll.

In June 2015, Sanofi entered into a two-year Group-wide agreement, effective from the 2015 financial year, and applicable to all French companies more than 50% owned by Sanofi. Under the agreement, Sanofi will pay collective variable compensation determined on the basis of either (i) growth in the Group s net sales (at constant exchange rates and on a constant structure basis) or (ii) the level of business net income, whichever is more favorable. For each of these criteria, a matrix will determine what percentage of total payroll is to be allocated to the scheme. This overall allocation is then reduced by the amount required by law to be transferred to a special profit-sharing reserve. The balance is then distributed between the employees, unless the transfer to the reserve exceeds the maximum amount determined under the specified criteria, in which case no profit share is paid to the employees.

Statutory Scheme (*Participation des salariés aux résultats de l entreprise*)

The scheme is a French legal obligation for companies with more than 50 employees that made a profit in the previous financial year.

The amount distributed by our French companies during 2015 in respect of the statutory scheme for the year ended December 31, 2014 represented 3.28% of total payroll.

In November 2007, Sanofi entered into a new Group-wide agreement for an indefinite period, covering all the employees of our French companies.

An amendment to this agreement was signed in April 2009, primarily to align the agreement on a change in French legislation (Law 2008-1258 of December 3, 2008) in order to protect against erosion in purchasing power, under which

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each qualifying employee can elect to receive some or all of his or her profit-sharing bonus without regard to the normally applicable mandatory lock-up period.

Distribution Formula

In order to favor lower-paid employees, the voluntary and statutory profit-sharing agreements entered into since 2005 split the benefit between those entitled as follows:

- 60% prorated on the basis of time spent in the Company s employment in the year; and
- 40% prorated on the basis of gross annual salary during the year, subject to a lower limit equal to the social security ceiling and an upper limit of three times the social security ceiling.

Employee Savings Schemes and Collective Retirement Savings Plan

The employee savings arrangements operated by Sanofi are based on a Group savings scheme (*Plan Epargne Groupe*) and a collective retirement savings plan (*Plan Epargne pour la Retraite Collectif*). These schemes reinvest the sums derived from the statutory and voluntary profit-sharing schemes (compulsory investments), and voluntary contributions by employees.

In June 2015, more than 94% of the employees who benefited from the profit-sharing schemes had opted to invest in the collective savings scheme and more than 86% of the employees who benefited from the profit-sharing schemes had opted to invest in the collective retirement savings plan.

In 2015, 111 million and 57.3 million were invested in the Group savings scheme and the collective retirement savings plan respectively through the voluntary and statutory schemes for 2014, and through top-up contributions.

Employee Share Ownership

At December 31, 2015, shares held by employees of Sanofi and of related companies and by former employees under Group employee savings schemes amounted to 1.28% of the share capital.

E. Share Ownership

Senior Management

Members of the Executive Committee hold shares of our Company amounting in the aggregate to less than 1% of our share capital.

During 2015, 263,104 stock subscription options were exercised by individuals who were members of the Executive Committee when they exercised.

These exercises related to two option plans that pre-date the creation of the Executive Committee (sanofi-aventis subscription option plan of May 31, 2005 with an exercise

price of 70.38 and sanofi-aventis subscription option plan of December 14, 2006 with an exercise price of 66.91), and two others that post-date the creation of the Executive Committee (sanofi-aventis subscription option plan of March 1, 2010 with an exercise price of 54.12 and sanofi-aventis subscription option plan of March 9, 2011 with an exercise price of 50.48).

Existing Option Plans as of December 31, 2015

As of December 31, 2015, a total of 15,867,615 options were outstanding, including 159,851 options to purchase Sanofi shares and 15,707,764 options to subscribe for Sanofi shares. Out of this total, 13,028,045 were immediately exercisable, including 159,851 options to purchase shares and 12,868,194 options to subscribe for shares.

Equity-based compensation, consisting of share subscription option plans and performance share plans, aims to align the employees objectives on those of the shareholders and to reinforce the link between employees and the Group. Under French law, this falls within the powers of the Board of Directors. Stock options (which may be options to subscribe for shares or options to purchase shares) are granted to employees and the Chief Executive Officer by the Board of Directors on the basis of recommendations from the Compensation Committee.

Granting options is a way of recognizing the beneficiary s contribution to the Group s development, and also of securing his or her future commitment to the Group.

For each plan, the Compensation Committee and the Board of Directors assess whether it should take the form of options to subscribe for shares or options to purchase shares, based on criteria that are primarily financial.

A list of beneficiaries is proposed by the Senior Management to the Compensation Committee, which reviews the list and then submits it to the Board of Directors, which decides to grant the options. The Board of Directors also sets the terms for the exercise of the options (including the exercise price) and the lock-up period. The exercise price never incorporates a discount, and must be at least equal to the average of the quoted market prices on the 20 trading days preceding the date of grant by the Board. Stock option plans generally specify a vesting period of four years and a total duration of ten years.

In 2011, the Board of Directors made significant changes to its equity-based compensation policy. In order to limit the dilutive effect on shareholders, the Board of Directors determined to primarily award performance shares, except for a limited group of senior managers who may continue to receive options. Furthermore, whoever the beneficiary is, any award of options or performance shares is now fully contingent upon the performance targets being met over three financial years.

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On June 24, 2015, 215,000 stock subscription options were awarded to 12 beneficiaries (excluding 220,000 options awarded to Olivier Brandicourt). Each option entitles the grantee to subscribe for one share, in the aggregate representing 0.03% of our share capital before dilution.

The entire award was contingent upon the same criteria based on Business Net Income and Return on Assets as the award to members of the Executive Committee. The quantitative measures of performance are the same as for the award to members of the Executive Committee. Vesting is now subject to a non-compete clause.

The percentage of options awarded to Olivier Brandicourt in 2015 represents 2.41% of the total limit approved by the

Shareholders General Meeting held on May 3, 2013 (0.7% of our share capital) and 50.6% of the total award to all beneficiaries on June 24, 2015.

Not all employees are able to benefit from awards of performance shares, but a new agreement on the voluntary scheme (*intéressement des salariés*) was concluded in June 2015 to ensure that all employees have an interest in the performance of the business (for more details see Profit-sharing Schemes, Employee Savings Schemes and Employee Share Ownership above).

In addition, all employees in France of the French subsidiaries of the Group benefited from a profit-sharing bonus amounting to 600 gross in October 2015.

Share Purchase Option Plans

Origin	Date of shareholder authorization	Date of Board grant	Number of options initially granted	- to corporate officers[1]	- to the 10 employees granted the most options[2]	Start date of exercise period	Expiry date	Purchase price (in)	Number exercised as of 12/31/2015	Number canceled as of 12/31/2015	Number outstanding
Synthélabo	6/28/1990	1/12/1996	208,000	0	52,000	1/12/2001	1/12/2016	8.56	204,330	0	3,670
Synthélabo	6/28/1990	4/05/1996	228,800	0	67,600	4/05/2001	4/05/2016	10.85	220,700	0	8,100
Synthélabo	6/28/1990	10/14/1997	262,080	0	165,360	10/14/2002	10/14/2017	19.73	256,880	5,200	0
Synthélabo	6/23/1998	3/30/1999	716,040	0	176,800	3/31/2004	3/30/2019	38.08	562,239	5,720	148,081

(1) Includes the Chairman and Chief Executive Officer, the Chief Executive Officer or equivalent officers as of the date of grant.

(2) Employed as of the date of grant.

Share Subscription Option Plans

Origin	Date of shareholder authorization	Date of grant	Number of options initially granted	- to corporate officers[1]	- to the 10 employees granted the most options[2]	Start date of exercise period	Expiry date	Subscription price (in)	Number exercised as of 12/31/2015	Number canceled as of 12/31/2015[3]	Number outstanding
sanofi-aventis	5/31/2005	5/31/2005	15,228,505	400,000	550,000	6/01/2009	5/31/2015	70.38	12,104,530	3,125,075	0
sanofi-aventis	5/31/2005	12/14/2006	11,772,050	450,000	585,000	12/15/2010	12/14/2016	66.91	7,353,145	1,183,050	3,239,355
sanofi-aventis	5/31/2007	12/13/2007	11,988,975	325,000	625,000	12/14/2011	12/13/2017	62.33	7,458,670	1,076,070	3,454,235
sanofi-aventis	5/31/2007	3/02/2009	7,736,480	250,000	655,000	03/04/2013	3/01/2019	45.09	4,903,429	623,415	2,209,636
sanofi-aventis	4/17/2009	3/01/2010	7,316,355	0	665,000	3/03/2014	02/28/2020	54.12	3,433,277	647,795	3,237,788
sanofi-aventis	4/17/2009	3/01/2010	805,000	275,000	805,000	3/03/2014	02/28/2020	54.12	606,150	50,000	148,850
sanofi-aventis	4/17/2009	3/09/2011	574,500	0	395,000	3/10/2015	3/09/2021	50.48	102,916	35,454	436,130
sanofi-aventis	4/17/2009	3/09/2011	300,000	300,000	0	3/10/2015	3/09/2021	50.48	150,000	7,800	142,200
Sanofi	5/06/2011	3/05/2012	574,050	0	274,500	3/06/2016	3/05/2022	56,44	0	78,425	495,625
Sanofi	5/06/2011	3/05/2012	240,000	240,000	0	3/06/2016	3/05/2022	56,44	0	35,280	204,720
Sanofi	5/06/2011	3/05/2013	548,725	0	261,000	3/06/2017	3/05/2023	72.19	0	43,500	505,225
Sanofi	5/06/2011	3/05/2013	240,000	240,000	0	3/06/2017	3/05/2023	72.19	0	0	240,000
Sanofi	5/03/2013	3/05/2014	769,250	0	364,500	3/06/2018	3/05/2024	73.48	0	49,750	719,500
Sanofi	5/03/2013	3/05/2014	240,000	240,000	0	3/06/2018	3/05/2024	73.48	0	0	240,000
Sanofi	5/03/2013	6/24/2015	12,500	0	12,500	6/25/2019	6/24/2025	89.38	0	500	12,000
Sanofi	5/03/2013	6/24/2015	202,500	0	202,500	6/25/2019	6/24/2025	89.38	0	0	202,500
Sanofi	5/03/2013	6/24/2015	220,000	220,000	0	6/25/2019	6/24/2025	89.38	0	0	220,000

(1) Includes the Chairman and Chief Executive Officer, the Chief Executive Officer, or equivalent officers as of the date of grant.

(2) Employed as of the date of grant.

(3) Including 183,640 options canceled due to the partial non-fulfillment of the performance conditions.

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The main characteristics of our stock options are also described in Note D.15.8. to our consolidated financial statements, included in Item 18 of this annual report.

Existing Restricted Share Plans as of December 31, 2015

Since 2009, the Board of Directors has awarded restricted shares to certain employees in order to give them a direct stake in the Company s future and performances via trends in the share price, as a partial substitute for the granting of stock options.

Restricted shares are awarded to employees on the basis of a list submitted to the Compensation Committee. This Committee then submits this list to the Board of Directors, which decides to award the shares. The Board of Directors sets the vesting conditions for the award, and any lock-up conditions for the shares.

In 2011, the Board of Directors made significant changes to its equity-based compensation policy. In order to limit the dilutive effect on shareholders, the Board of Directors determined to primarily award performance shares, except for a limited group of senior managers who may continue to receive options. Furthermore, whoever the beneficiary is, any award of options or performance shares is now fully contingent upon the performance targets being attained over three financial years.

On June 24, 2015, the Board of Directors set up two plans in addition to the award made to the Chief Executive Officer:

- a French plan awarding 1,286,420 performance shares to 2,441 beneficiaries, subject to a vesting period of three years followed by a lock-up period of two years; and
- an international plan awarding 2,435,420 restricted shares to 4,951 beneficiaries, subject to a vesting period of four years.

The entire award was contingent upon the same criteria based on Business Net Income and Return on Assets as the award of members of the Executive Committee. The quantitative measures of performance are the same as for the award of members of the Executive Committee. Vesting is now subject to a non-compete clause.

The 2015 awards represent a dilution of 0.29% of our share capital before dilution as of December 31, 2015.

Not all employees are able to benefit from awards of performance shares, but a new agreement on the voluntary scheme (*intéressement des salariés*) was concluded in June 2015 to ensure that all employees have an interest in the performance of the business (for more details see Profit-Sharing Schemes, Employee Savings Schemes and Employee Share Ownership above).

In addition, all employees in France of the French subsidiaries of the Group benefited from a profit-sharing bonus amounting to 600 gross in October 2015.

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Restricted Share Plans

Origin	Date of shareholder authorization	Date of award	Number of shares initially awarded	- to corporate officers[1]	- to the 10 employees awarded the most shares[2]	Date of award[3]	Vesting date	Availability date	Number transferred as of 12/31/2015	Number of rights canceled as of 12/31/2015[4]	Number outstanding
sanofi-aventis	4/17/2009	3/09/2011	1,366,040	0	71,000	3/09/2011	3/10/2013	3/10/2015	1,346,090	19,950	0
sanofi-aventis	4/17/2009	3/09/2011	1,934,610	0	103,300	3/09/2011	3/10/2015	3/10/2015	1,673,120	261,490	0
sanofi-aventis	4/17/2009	3/09/2011	30,000	30,000	0	3/09/2011	3/10/2013	3/10/2015	30,000	0	0
Sanofi	4/17/2009	3/05/2012	1,519,430	0	126,700	3/05/2012	3/06/2015	3/06/2017	1,377,886	141,744	0
Sanofi	4/17/2009	3/05/2012	5,670	0	5,670	3/05/2012	3/06/2016	3/06/2016	0	438	5,232
Sanofi	4/17/2009	3/05/2012	3,127,160	0	96,300	3/05/2012	3/06/2016	3/06/2016	6,191	631,575	2,496,032
Sanofi	4/17/2009	3/05/2012	42,000	42,000	0	3/05/2012	3/06/2015	3/06/2017	35,826	6,174	0
Sanofi	5/04/2012	3/05/2013	1,410,360	0	97,300	3/05/2013	3/06/2016	3/06/2018	1,600	27,850	1,380,910
Sanofi	5/04/2012	3/05/2013	1,550	0	1,550	3/05/2013	3/06/2017	3/06/2017	0	0	1,550
Sanofi	5/04/2012	3/05/2013	2,838,795	0	85,100	3/05/2013	3/06/2017	3/06/2017	3,550	253,935	2,585,510
Sanofi	5/04/2012	3/05/2013	45,000	45,000	0	3/05/2013	3/06/2016	3/06/2018	0	0	45,000
Sanofi	5/04/2012	3/05/2014	1,257,620	0	28,060	3/05/2014	3/06/2017	3/06/2019	0	16,050	1,241,570
Sanofi	5/04/2012	3/05/2014	2,605,515	0	35,400	3/05/2014	3/06/2017	3/06/2019	1,100	130,400	2,476,015
Sanofi	5/04/2012	3/05/2014	45,000	45,000	0	3/05/2014	3/06/2017	3/06/2019	0	0	45,000
Sanofi	5/04/2015	6/24/2015	1,157,420	0	63,000	6/24/2015	6/25/2018	6/25/2020	0	4,650	1,152,770
Sanofi	5/04/2015	6/24/2015	129,000	0	129,000	6/24/2015	6/25/2018	6/25/2020	0	0	129,000
Sanofi	5/04/2015	6/24/2015	2,310,920	0	84,500	6/24/2015	6/25/2019	6/26/2019	200	31,250	2,282,170
Sanofi	5/04/2015	6/24/2015	124,500	0	124,500	6/24/2015	6/25/2019	6/26/2019	0	0	124,500
Sanofi	5/04/2015	6/24/2015	66,000	66,000	0	6/24/2015	6/25/2019	6/26/2019	0	0	66,000
Sanofi	5/04/2015	6/24/2015	45,000	45,000	0	6/24/2015	6/25/2019	6/26/2019	0	0	45,000

(1) Includes the Chief Executive Officer as of the date of grant.

(2) Employed as of the date of grant.

(3) Subject to vesting conditions.

(4) Including 684,672 rights canceled due to the partial non-fulfillment of the performance conditions.

As of December 31, 2015, a total of 14,076,259 restricted shares were outstanding and contingent upon performance conditions.

Shares Owned by Members of the Board of Directors

As of December 31, 2015, members of our Board of Directors held in the aggregate 20,087 shares, or under 1% of the share capital and of the voting rights, excluding the beneficial ownership of 118,227,307 shares held by L Oréal as of such date which may be attributed to Laurent Attal or Christian Mulliez (who disclaim beneficial ownership of such shares).

Transactions in Shares by Members of the Board of Directors and equivalent persons in 2015

- On March 10, 2015, Elias Zerhouni, President Global Research and Development, sold 4,196 shares at a price of 83.18 per share.

- On March 26, 2015, Karen Linehan, Executive Vice President Legal Affairs and General Counsel, exercised 50,000 options to subscribe for shares at a price of 54.12 per share (sanofi-aventis subscription option plan of March 1, 2010) and 14,000 options to subscribe for shares at a price of 66.91 per share (sanofi-aventis subscription option plan of December 14, 2006), and sold the resulting 64,000 shares at a price of 88 per share.

- On May 20, 2015, Peter Guenter, Executive Vice President Global Commercial Operations, sold 6,190 shares at a price of 90.93 per share.

- On May 20, 2015, Jérôme Contamine, Executive Vice President Chief Financial Officer, exercised 22,854 options to subscribe for shares at a price of 54.12 per share (sanofi-aventis subscription option plan of March 1, 2010), and sold the resulting 22,854 shares at a price of 90.92 per share.

- On June 15, 2015, Bonnie Bassler, Director, purchased 1,000 shares at a price of 88.52 per share.

- On June 29, 2015, Patrick Kron, Director, purchased 1,000 shares at a price of 89.41 per share.

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Item 7. Major Shareholders and Related Party Transactions

Item 7. Major Shareholders and Related Party Transactions

A. Major Shareholders

The table below shows the ownership of our shares as of January 31, 2016, indicating the beneficial owners of our shares. To the best of our knowledge and on the basis of the

notifications received as disclosed below, except for L Oréal and BlackRock, Inc., no other shareholder currently holds more than 5% of our share capital or voting rights.

	Total number of issued shares		Number of actual voting rights (excluding treasury shares)[4]		Theoretical number of voting rights (including treasury shares)[5]	
	Number	%	Number	%	Number	%
L Oréal	118,227,307	9.05	236,454,614	16.51	236,454,614	16.31
BlackRock[1]	69,772,145	5.34	69,772,145	4.87	69,772,145	4.81
Treasury shares[2]	17,232,244	1.32			17,232,244	1.19
Employees[3]	16,661,761	1.28	32,159,761	2.25	32,159,761	2.22
Public	1,083,814,518	83.01	1,093,682,598	76.37	1,093,682,598	75.47
Total	**1,305,707,975**	**100**	**1,432,069,118**	**100**	**1,449,301,362**	**100**

(1) Based on BlackRock s declaration as of December 17, 2015.

(2) Includes net position of share repurchases under the Group s liquidity contract which amounted to 15,500 shares as of January 31, 2016. Amounts held under this contract vary over time.

(3) Shares held via the Sanofi Group Employee Savings Plan.

(4) Based on the total number of voting rights as of January 31, 2016.

(5) Based on the total number of voting rights as of January 31, 2016 as published in accordance with article 223-11 and seq. of the General Regulations of the Autorité des Marchés Financiers (i.e., calculated including suspension of the voting rights of treasury shares).

Our *statuts* (Articles of Association) provide for double voting rights for shares held in registered form for at least two years. All of our shareholders may benefit from double voting rights if these conditions are met, and no shareholder benefits from specific voting rights. For more information relating to our shares, see Item 10. Additional Information B. Memorandum and Articles of Association.

L Oréal and BlackRock Inc. are the only entities known to hold more than 5% of the outstanding Sanofi ordinary shares.

For the year ended December 31, 2015, we received a share ownership declaration informing us that a legal threshold had been passed. BlackRock Inc, acting on behalf of several funds and portfolios managed by its group, declared that it had passed above the legal threshold of 5% of our share capital and that it held 5.34% of our share capital and 4.82% of our voting rights (declaration of December 23, 2015).

In accordance with our Articles of Association, shareholders must notify us once they have passed the threshold of 1% of our share capital or our voting rights and each time they cross an incremental 1% threshold (see Item 10. Additional Information B. Memorandum and Articles of Association Requirements for Holdings Exceeding Certain Percentages).

For the year ended December 31, 2015, in accordance with our Articles of Association, we were informed that the

following share ownership declaration thresholds had been passed:

Dodge & Cox declared that it had passed above (declaration of March 19, 2015) and then below the threshold of 3% of our voting rights (declaration of March 31, 2015), then again above the threshold of 3% of our voting rights and as of its last declaration held 3.30% of our share capital and 3.01% of our voting rights (declaration of April 8, 2015);

Franklin Resources Inc. declared that it had passed above (declaration of March 16, 2015) and then below the threshold of 2% of our voting rights and as of its last declaration held 1.99% of our share capital and 1.79% of our voting rights (declaration of July 31, 2015);

L Oréal declared that it had passively passed above the threshold of 9% of our share capital and as of its last declaration held 9.03% of our share capital and 16.28% of our voting rights (declaration of May 27, 2015);

Natixis Asset Management declared that it had passed above (declaration of April 20, 2015) and then below the threshold of 1% of our voting rights and as of its last declaration held 0.98% of our voting rights (declaration of June 10, 2015).

As of December 31, 2015, individual shareholders (including employees of Sanofi and its subsidiaries, as well as retired employees holding shares via the Sanofi Group Employee Savings Plan) held approximately 7.2% of our share capital. Institutional shareholders (excluding L Oréal) held

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approximately 75.7% of our share capital. Such shareholders are primarily American (29.4%), French (13.6%) and British (12.6%). German institutions held 3.5% of our share capital, Swiss institutions held 2.5%, institutions from other European countries held 7.1% and Canadian institutions held 1.4% of our share capital. Other international institutional investors (excluding those from Europe and North America) held approximately 5.5% of our share capital. In France, our home country, we have 23,785 identified shareholders of record. In the United States, our host country, we have 53 identified shareholders of record and 18,460 identified ADS holders of record.

(Source: a survey conducted by Euroclear France as of December 31, 2015, and internal information).

Shareholders Agreement

We are unaware of any shareholders agreement currently in force.

B. Related Party Transactions

See Note D.33. to our consolidated financial statements included at Item 18 of this annual report.

C. Interests of Experts and Counsel

N/A

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Item 8. Financial Information

Item 8. Financial Information

A. Consolidated Financial Statements and Other Financial Information

Our consolidated financial statements as of and for the years ended December 31, 2015, 2014, and 2013 are included in this annual report at Item 18. Financial Statements.

Dividends on Ordinary Shares

We paid annual dividends for the years ended December 31, 2011, 2012, 2013 and 2014 and our shareholders will be asked to approve the payment of an annual dividend of 2.93 per share for the 2015 fiscal year at our next annual shareholders meeting. If approved, this dividend will be paid on May 12, 2016.

We expect that we will continue to pay regular dividends based on our financial condition and results of operations. The proposed 2015 dividend equates to a distribution of 52% of our business earnings per share. For information on the non-GAAP financial measure, business earnings per share , see Item 5. Operating and Financial Review and Prospects Business Net Income. The proposed dividend distribution will subject Sanofi to a 3% additional corporate tax charge on the amount distributed.

The following table sets forth information with respect to the dividends paid by our Company in respect of the 2011, 2012, 2013 and 2014 fiscal years and the dividend that will be proposed for approval by our shareholders in respect of the 2015 fiscal year at our May 4, 2016 shareholders meeting.

	2015[1]	2014	2013	2012	2011
Dividend per Share (in)	2.93	2.85	2.80	2.77	2.65
Dividend per Share (in $)[2]	3.19	3.46	3.86	3.65	3.43

(1) *Proposal, subject to shareholder approval.*

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

The declaration, amount and payment of any future dividends will be determined by majority vote of the holders of our shares at an ordinary general meeting, following the recommendation of our Board of Directors. Any declaration will depend on our results of operations, financial condition, cash requirements, future prospects and other factors deemed relevant by our shareholders. Accordingly, we cannot assure you that we will pay dividends in the future on a continuous and regular basis. Under French law, we are required to pay dividends approved by an ordinary general meeting of shareholders within nine months following the meeting at which they are approved.

Disclosure pursuant to Section 13(r) of the United States Exchange Act of 1934

Sanofi conducts limited business relating to human and animal health products with Iran contributing well under 1% of the Group s consolidated net sales in 2015. These activities, which are not financially material to the Group, are being disclosed pursuant to Section 13(r) of the United States Exchange Act of 1934, as amended. Sales consisted of bulk and branded pharmaceuticals, vaccines, and animal health supplies. U.S. affiliates of Sanofi, or foreign affiliates controlled by U.S. affiliates of Sanofi, are either not involved in these activities or operate under humanitarian licenses issued by the U.S. Treasury Department s Office of Foreign Assets Control. Limited business amounting to approximately 11.9 million in gross revenues has been conducted by non-U.S. subsidiaries of Sanofi not requiring an OFAC license with entities such as public hospitals or distributors tied to the Ministry of Health or Ministry of Agriculture. It is estimated that this activity contributed no

more than 4.8 million to net profits. A representative office in Tehran incurs incidental expenses from state-owned utilities.

In January 2016, Sanofi and the Iran Food and Drug Administration, affiliated with the Ministry of Health and Medical Education of the Islamic Republic of Iran, signed a Memorandum of Cooperation (MoC) regarding (i) potential future projects to reinforce current partnerships with reputable Iranian manufacturers (in particular to enhance industrial quality standards), (ii) collaborating with the Ministry of Health on programs for the prevention and control of certain chronic and non-communicable diseases (in particular diabetes) and (iii) potential future collaboration on epidemiological studies. The MOC did not generate any revenue, nor any net profit.

The Group believes its activities are compliant with applicable law. In light of the nature of the activities concerned, Sanofi and its affiliates intend to continue their activities in Iran.

Information on Legal or Arbitration Proceedings

This Item 8 incorporates by reference the disclosures found at Note D.22. to the consolidated financial statements found at Item 18 of this annual report; material updates thereto as of the date of this annual report are found below under the heading Updates to Note D.22 .

Sanofi and its subsidiaries are involved in litigation, arbitration and other legal proceedings. These proceedings typically are related to product liability claims, intellectual property rights (particularly claims against generic companies seeking to

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limit the patent protection of Sanofi products), competition law and trade practices, commercial claims, employment and wrongful discharge claims, tax assessment claims, waste disposal and pollution claims, and claims under warranties or indemnification arrangements relating to business divestitures. As a result, the Group may become subject to substantial liabilities that may not be covered by insurance and could affect our business and reputation. While we do not currently believe that any of these legal proceedings will have a material adverse effect on our financial position, litigation is inherently unpredictable. As a consequence, we may in the future incur judgments or enter into settlements of claims that could have a material adverse effect on results of operations, cash flows and/or our reputation.

Patents

- *Co-Aprovel® Patent Infringement Actions in Europe*

Sanofi has been involved since early 2012 in a number of legal proceedings involving generic companies that attempted to launch or launched generic versions of Sanofi s Co-Aprovel® in several European countries including United Kingdom, Belgium, France, Germany, the Netherlands, Italy and Norway. Sanofi filed for and was granted preliminary injunctions (PI) against several generic companies based on Sanofi s Supplemental Protection Certificate (SPC) covering Co-Aprovel® until October 15, 2013. The U.K. Court referred the question on the validity of the Co-Aprovel® SPC to the Court of Justice of the European Union (CJEU) in October 2012.

Following the CJEU decision on December 12, 2013, deciding the invalidity of Co-Aprovel® SPC, generic companies (which were withdrawn from the market due to national preliminary injunction or cross undertaking) have filed damages claims in several countries against Sanofi. The cases are currently pending. In the U.K., the cases have been settled with the generic companies in 2015.

- *Lantus® and Lantus® SoloSTAR® Patent Litigation (United States, France and Japan)*

In December 2013, January 2014 and May 2014, Sanofi received notifications from Eli Lilly and Company (Lilly), stating that it had filed two NDAs (505(b)(2) New Drug Application) with the FDA for two insulin glargine drug products. Lilly s NDAs also included Paragraph IV certifications directed to Sanofi patents listed in the FDA Orange Book for Sanofi s Lantus® and/or Lantus® SoloStar® products. In 2014, Sanofi filed patent infringement suits against Lilly in the United States District Court for the District of Delaware. The second of these two lawsuits was dismissed in May 2015 in light of Lilly s withdrawal of its second 505(b)(2) New Drug Application from FDA review.

In August 2014, Sanofi filed patent infringement law suits against Lilly in France, based on different patents (protecting the insulin glargine, a manufacturing process and a device).

In June 2015, Sanofi unilaterally withdrew the lawsuit in France against Lilly regarding the compound and the process patent.

On December 8, 2014, Sanofi filed a petition for a preliminary injunction against Lilly s insulin glargine biosimilar pre-loaded in its MirioPen® with the Tokyo District Court based on a Japanese device patent that Sanofi subsequently withdrew. In January 2015, Lilly filed an invalidation action concerning this Sanofi Japanese device patent with the Japanese Patent Office.

In September 2015, Sanofi entered into a settlement agreement with Lilly with respect to certain Sanofi patents relating to the Lantus® SoloStar® (insulin glargine) product. The settlement resolves the U.S. patent infringement lawsuit regarding Lilly s application for marketing approval for a competing product to Lantus® SoloStar®. Sanofi and Lilly agreed to dismiss this U.S. patent infringement lawsuit and to discontinue similar disputes worldwide. Under the terms of the settlement, Lilly will make royalty payments to Sanofi in exchange for a license to certain Sanofi patents. In the U.S. Lilly will not sell its insulin glargine product before December 15, 2016. The agreement does not extend to the Lantus® vial product, Toujeo® or combination products.

Following the settlement with Lilly, all of the U.S., French and Japanese disputes with Lilly with respect to Lantus® SoloStar® were discontinued.

- *Humalog® MirioPen® and Humulin® MirioPen® Patent Litigation (Japan)*

On October 7, 2014, Sanofi filed a patent infringement lawsuit against Lilly Japan at the Tokyo District Court claiming that Lilly s Humalog® MirioPen® and Humulin® MirioPen® products infringe a Japanese device patent. Sanofi sought damages from Lilly. Following the September 2015 settlement with Lilly (see above), this case is now closed.

- *Multaq® Patent Litigation (United States)*

From January 2014 to November 2014, several generic manufacturers notified Sanofi that they had filed Abbreviated New Drug Applications (ANDAs) seeking FDA approval to market generic versions of Multaq® (dronedarone hydrochloride) in the U.S. In April 2015, Sanofi received a tenth notice directed to Multaq from Lupin. The notices challenged some, but not all, of the patents listed by Sanofi in the FDA s Orange Book in connection with Multaq®. None of the ANDA filers challenged the patent directed to the active ingredient in Multaq®, U.S. Patent No. 5,223,510 (the 510 patent).

Sanofi brought suit against all of the ANDA filers in the United States District Court for the District of Delaware for patent infringement. Depending on the contents of the particular Paragraph IV Certification, Sanofi has brought suit

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Item 8. Financial Information

for infringement of at least three and sometimes four of its Orange Book listed patents. In all but two cases, the 30-month stay expires on the earlier of (1) January 1, 2017 or (2) a court decision in favor of one or more of the defendants on all patents that support the stay. In the Sandoz case, the 30-month stay expires on the earlier of (1) May 14, 2017 or (2) a court decision in favor of one or more of the defendants on all patents that support the stay. In the Lupin case, the 30-month stay expires on the earlier of (1) October 2017 or (2) a court decision in favor of one or more of the defendants on all patents that support the stay.

On October 13, 2015, Sanofi amended its complaint against Lupin to include U.S. Patent 9,107,900 which was listed in the Orange Book in September 2015. In December 2015, Sanofi filed separate patent infringement actions against six of the other defendants based on this patent.

- *Genzyme Myozyme®/Lumizyme® Patent Litigation (United States)*

BioMarin filed petitions with PTAB (*Patent Trial and Appeal Board)* requesting institution of an IPR (*Inter Partes Review IPR*) of the patentability of all claims of U.S. Patent No. 7,351,410 and all but one claims of U.S. Patent No. 7,655,226 regarding Myozyme®/Lumizyme®. Those petitions were granted. In February 2015, the PTAB ordered *inter alia* that claim 1 of the 410 patent and that claims 1 and 3-6 of the 226 patent are determined to be un-patentable. Genzyme filed a Notice of Appeal to the Federal Circuit in April 2015. The USPTO filed a Notice of Intervention in September 2015.

Government Investigations

From time to time, subsidiaries of Sanofi are subject to governmental investigations and information requests from regulatory authorities inquiring as to the practices of Sanofi with respect to the sales, marketing, and promotion of its products. For example, Sanofi is cooperating with the U.S. Department of Justice in its respective investigations into the promotion of Seprafilm® and Plavix®.

In December 2013, Genzyme entered into a settlement agreement to resolve civil claims arising out of the investigation into promotional practices of Seprafilm® and paid in that respect approximately $23 million. Discussions with the U.S. Government are ongoing to resolve the matter completely, including any potential criminal resolution. As part of this settlement, and as part of the settlement entered into by Sanofi U.S. in December 2012 relating to civil claims arising out of an investigation into sampling of its former product Hyalgan® for which Sanofi U.S. paid $109 million, the companies entered into a Corporate Integrity Agreement with the Office of the Inspector General of the United States Department of Health and Human Services in September 2015. Also in September 2015, Genzyme entered into a Deferred Prosecution

Agreement with the U.S. Department of Justice and paid in that respect approximately $33 million to resolve the Seprafilm® matter completely.

In June 2012, Sanofi U.S. became aware that the U.S. Department of Justice is investigating disclosures to the FDA regarding the variability of response to Plavix®. Sanofi U.S. is cooperating with the U.S. Department of Justice in this matter.

In France, in the claim concerning allegations that Sanofi s communication and promotional practices inhibited the entry on the market of generics of clopidogrel (the active ingredient of Plavix®), the French Antitrust Authority issued its decision on May 14, 2013, imposing on Sanofi a fine of 40.6 million. In December 2014, the Paris Court of Appeal rejected Sanofi s appeal and confirmed in totality the decision. Sanofi filed a *pourvoi* with the French Supreme Court (*Cour de Cassation*) in January 2015. As a consequence to the May 2013 ruling, claims were filed respectively by Sandoz in August 2014 and by Teva in September 2014 before the Commercial Court of Paris for compensation of their alleged damages: loss of margin and other ancillary damages (legal fees to external counsels, image and reputation).

Sanofi is engaged in discussions with the U.S. Department of Justice and the U.S. Securities and Exchange Commission regarding allegations that certain subsidiaries outside the United States made improper payments in connection with the sale of pharmaceutical products and whether those payments, if made, fall within the U.S. Foreign Corrupt Practices Act. Sanofi also received anonymous allegations of wrongdoing related to improper payments to healthcare professionals in connection with the sale of pharmaceutical products that may have occurred between 2007 and 2014 in certain parts of the Middle East and Africa. Sanofi proactively notified the U.S. Department of Justice and the U.S. Securities and Exchange Commission of all of the allegations. The Company has voluntarily provided and will continue to provide information to the DOJ and SEC, and will cooperate with the agencies reviews of these matters.

B. Significant Changes

An indemnity amount of approximately 200 million pursuant to a final arbitration was granted to Sanofi in February 2016 as consequence of a contractual dispute. Other details of the arbitration are confidential.

At its meeting held on March 3, 2016, the Board of Directors of Sanofi proposed the appointment of Diane Souza and Thomas Südhof, MD as new independent Directors during the General Shareholders meeting of May 4, 2016.

Diane D. Souza is the former CEO of UnitedHealthcare Specialty Benefits, an ancillary and voluntary health insurance business, which serves more than 75,000 employers and 21 million members. With over 25 years of

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managed care and health benefits experience, she led healthcare operations and business and large-scale systems transformation at UnitedHealthcare and Aetna, as well as delivery of the integrated market strategy for the Affordable Care Act. A certified public accountant, Ms. Souza was also Chief Financial Officer of Aetna s Guaranteed Products business, where she was regularly involved in complex financial transactions and dealings with the Securities and Exchange Commission. Diane has also held senior leadership positions at Deloitte and PricewaterhouseCoopers.

Thomas Südhof, MD, is the Avram Goldstein Professor in the School of Medicine of Stanford University, as well as a

Professor of Molecular & Cellular Physiology, Psychiatry, and Neurology. Prior to this position, he spent 25 years at the University of Texas, Southwestern, where he acted as Chairman of the Department of Neuroscience. Most of his research at that time focused on the mechanisms of synaptic information transmission which have pharmacological consequences for the treatment of neuro-degenerative and neuro-psychiatric diseases. Dr. Südhof won the Nobel Prize in Physiology or Medicine, (shared with James Rothman and Randy Shekman) in 2013, the Albert Lasker Medical Basic Research Award (together with Richard Scheller), as well as the Bernhard Katz Award of the Biophysical Society (shared with Reinhard Jahn).

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Item 9. The Offer and Listing

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A. Offer and Listing Details

We have one class of shares. Each American Depositary Share, or ADS, represents one-half of one share. The ADSs are evidenced by American Depositary Receipts, or ADRs, which are issued by JPMorgan Chase Bank, N.A.

Our shares trade on Compartment A of the regulated market of Euronext Paris, and our ADSs trade on the New York Stock Exchange, or NYSE.

In 2011, in connection with our acquisition of Genzyme, we issued contingent value rights (CVRs) under a CVR

agreement entered into by and between us and the American Stock Transfer & Trust Company, LLC, as trustee (see Item 10.C. Material Contracts The Contingent Value Rights Agreement). Our CVRs trade on the NASDAQ Global Market.

Trading History

The table below sets forth, for the periods indicated, the reported high and low market prices of our shares on Euronext Paris and our ADSs on the NYSE (source: Bloomberg).

	Shares, as traded on Euronext Paris		ADSs, as traded on the NYSE	
Calendar period	**High**	**Low**	**High**	**Low**
	(price per share in)		**(price per ADS in $)**	
Monthly				
February 2016	77.11	66.44	41.88	37.63
January 2016	79.13	70.94	42.34	38.58
December 2015	84.66	74.59	44.63	41.13
November 2015	93.82	79.81	50.95	42.79
October 2015	93.77	83.47	51.88	47.05
September 2015	91.81	82.01	51.35	46.02
2015				
First quarter	94.40	72.94	51.47	43.57
Second quarter	99.23	84.90	53.00	48.23
Third quarter	101.10	80.19	54.98	46.02
Fourth quarter	93.82	74.59	51.88	41.13
Full Year	101.10	72.94	54.98	41.13
2014				

First quarter	77.70	68.29	52.76	47.06
Second quarter	80.42	73.86	54.64	50.84
Third quarter	89.95	75.40	57.42	50.74
Fourth quarter	89.74	69.58	56.39	44.24
Full Year	89.95	68.29	57.42	44.24
2013				
Full Year	87.03	65.91	55.94	44.50
2012				
Full Year	72.38	53.20	47.97	33.03
2011				
Full Year	56.82	42.85	40.75	30.98

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Fluctuations in the exchange rate between the euro and the U.S. dollar will affect any comparisons of euro share prices and U.S. ADS prices.

B. Plan of Distribution

N/A

C. Markets

Shares and ADSs

Our shares are listed on Euronext Paris under the symbol SAN and our ADSs are listed on the NYSE under the symbol SNY .

As of the date of this annual report, our shares are included in a large number of indices, including the CAC 40 Index , the principal French index published by Euronext Paris. This index contains 40 stocks selected among the top 100 companies based on free-float capitalization and the most active stocks listed on the Euronext Paris market. The CAC 40 Index indicates trends in the French stock market as a whole and is one of the most widely followed stock price indices in France. Our shares are also included in the S&P Global 100 Index, the Dow Jones Euro STOXX 50, the Dow Jones STOXX 50, the FTS Eurofirst 100, the FTS Eurofirst 80 and the MSCI Pan-Euro Index, among other indices.

CVRs

Our CVRs trade on the NASDAQ Global Market under the symbol GCVRZ .

Trading by Sanofi in our own Shares

Under French law, a company may not issue shares to itself, but it may purchase its own shares in the limited cases described at Item 10. Additional Information B. Memorandum and Articles of Association Trading in Our Own Shares.

D. Selling Shareholders

N/A

E. Dilution

N/A

F. Expenses of the Issue

N/A

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Item 10. Additional Information

Item 10. Additional Information

A. Share Capital

N/A

B. Memorandum and Articles of Association

General

Our Company is a *société anonyme*, a form of limited liability company, organized under the laws of France.

In this section, we summarize material information concerning our share capital, together with material provisions of applicable French law and our Articles of Association (*statuts*), an English translation of which has been filed as an exhibit to this annual report. For a description of certain provisions of our Articles of Association relating to our Board of Directors and statutory auditors, see Item 6. Directors, Senior Management and Employees. You may obtain copies of our Articles of Association in French from the *greffe* (Clerk) of the *Registre du Commerce et des Sociétés de Paris* (Registry of Commerce and Companies of Paris, France, registration number: 395 030 844). Please refer to that full document for additional details.

Our Articles of Association specify that our corporate affairs are governed by:

- applicable laws and regulations (in particular, Title II of the French Commercial Code); and
- the Articles of Association themselves.

Article 3 of our Articles of Association specifies that the Company s corporate purpose, in France and abroad, is:

- acquiring interests and holdings, in any form whatsoever, in any company or enterprise, in existence or to be created, connected directly or indirectly with the health and fine chemistry sectors, human and animal therapeutics, nutrition and bio-industry;

in the following areas:

- purchase and sale of all raw materials and products necessary for these activities;
- research, study and development of new products, techniques and processes;
- manufacture and sale of all chemical, biological, dietary and hygiene products;

- obtaining or acquiring all intellectual property rights related to results obtained and, in particular, filing all patents, trademarks and models, processes or inventions;

- operating directly or indirectly, purchasing, and transferring for free or for consideration pledging or securing all intellectual property rights, particularly all patents, trademarks and models, processes or inventions;

- obtaining, operating, holding and granting all licenses;

- within the framework of a group-wide policy and subject to compliance with the relevant legislation, participating in treasury management transactions, whether as lead company or otherwise, in the form of centralized currency risk management or intra-group netting, or any other form permitted under the relevant laws and regulations;

and, more generally:

- all commercial, industrial, real or personal property, financial or other transactions, connected directly or indirectly, totally or partially, with the activities described above and with all similar or related activities or having any other purposes likely to encourage or develop the Company s activities.

Directors

Transactions in Which Directors Are Materially Interested

Under French law, any agreement entered into (directly or through an intermediary) between our Company and any one of the members of the Board of Directors that is not entered into (i) in the ordinary course of our business and (ii) under normal conditions is subject to the prior authorization of the disinterested members of the Board of Directors. The same provision applies to agreements between our Company and another company if one of the members of the Board of Directors is the owner, general partner, manager, director, general manager or member of the executive or supervisory board of the other company, as well as to agreements in which one of the members of the Board of Directors has an indirect interest.

The Board of Directors must also authorize any undertaking taken by our Company for the benefit of our Chairman, Chief Executive Officer (*directeur général*) or his delegates (*directeurs généraux délégués*) pursuant to which such persons will or may be granted compensation, benefit or any other advantage as a result of the termination of or a change in their offices or following such termination or change.

In addition, except with respect to any non-compete indemnity or certain pension benefits, any such termination package: (i) must be authorized by our shareholders through the adoption of a separate general shareholders meeting resolution for each such beneficiary, which authorization must be renewed at each renewal of such beneficiary s mandate, and (ii) cannot be paid to such beneficiary unless (a) the Board of Directors decides that such beneficiary has satisfied certain conditions, linked to such beneficiary s performance measured by our Company s performance, that must have been defined by the Board of Directors when granting such package, and (b) such decision is publicly disclosed.

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Item 10. Additional Information

Directors Compensation

The aggregate amount of attendance fees (*jetons de présence*) of the Board of Directors is determined at the Shareholders Ordinary General Meeting. The Board of Directors then divides this aggregate amount among its members by a simple majority vote. In addition, the Board of Directors may grant exceptional compensation (*rémunérations exceptionnelles*) to individual directors on a case-by-case basis for special assignments following the procedures described above at Transactions in Which Directors Are Materially Interested. The Board of Directors may also authorize the reimbursement of travel and accommodation expenses, as well as other expenses incurred by Directors in the corporate interest. See also Item 6. Directors, Senior Management and Employees.

Board of Directors Borrowing Powers

All loans or borrowings on behalf of the Company may be decided by the Board of Directors within the limits, if any, imposed by the Shareholders General Meeting. There are currently no limits imposed on the amounts of loans or borrowings that the Board of Directors may approve.

Directors Age Limits

For a description of the provisions of our Articles of Association relating to age limits applicable to our Directors, see Item 6. Directors, Senior Management and Employees.

Directors Share Ownership Requirements

Pursuant to the Board Charter, our Directors are required to hold at least 1,000 shares during the term of their appointment.

Share Capital

As of December 31, 2015, our share capital amounted to 2,611,393,518, divided into 1,305,696,759 outstanding shares with a par value of 2 per share. All of our outstanding shares are of the same class and are fully paid. Of these shares, we or entities controlled by us held 3,956,708 shares (or 0.30% of our outstanding share capital), as treasury shares as of such date. As of December 31, 2015, the carrying amount of such shares was 306 million.

At an extraordinary general meeting held on May 4, 2015, our shareholders authorized our Board of Directors to increase our share capital, through the issuance of shares or other securities giving access to the share capital with or without preemptive rights, by an aggregate maximum nominal amount of 1.3 billion. See Changes in Share Capital Increases in Share Capital, below.

The maximum total number of authorized but unissued shares as of December 31, 2015 was 160 million, reflecting the unused part of the May 3, 2013 and May 4, 2015

shareholder authorizations to issue shares without preemptive rights, outstanding options to subscribe for shares, and awards of shares.

Stock Options

Types of Stock Options

We have two types of stock options outstanding: options to subscribe for shares (*options de souscription d actions*) and options to purchase shares (*options d achat d actions*). Upon exercise of an option to subscribe for shares, we issue new shares, whereas upon exercise of an option to purchase shares, the option holder receives existing shares. We purchase our shares on the market prior to the vesting of the options to purchase in order to provide the option holder with shares upon exercise.

Because the exercise of options to purchase shares will be satisfied with existing shares repurchased on the market or held in treasury, the exercise of options to purchase shares has no impact on the amount of our share capital.

Stock Option Plans

Our combined general meeting held on May 3, 2013 authorized our Board of Directors for a period of 38 months to grant, on one or more occasions, options to subscribe for shares and options to purchase shares in favor of persons to be chosen by the Board of Directors from among the salaried employees and corporate officers of our Company or of companies or groupings of economic interest of the Group in accordance with Article L. 225-180 of the French Commercial Code.

The aggregate number of options to subscribe for shares and options to purchase shares that may be granted under this authorization may not give entitlement to a total number of shares exceeding 0.7% of the share capital as of the date of the decision by the Board of Directors to grant such options.

The Board of Directors sets the exercise price of options to subscribe for shares and options to purchase shares. However, the exercise price never incorporates a discount and must be at least equal to the average of the quoted market prices on the 20 trading sessions preceding the date of grant by the Board of Directors.

Stock option plans generally provide for a lock-up period of four years and have a duration of ten years.

Under such authorization the shareholders expressly waive, in favor of the grantees of options to subscribe for shares, their preemptive rights in respect of shares that are to be issued as and when options are exercised.

The Board of Directors is granted full power to implement this authorization and to set the terms and conditions on which options are granted and the arrangements with respect to the dividend entitlement of the shares.

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Item 10. Additional Information

See Item 6. Directors, Senior Management and Employees E. Share Ownership for a description of our option plans currently in force.

Awards of Shares

Our combined general meeting held on May 4, 2015 authorized our Board of Directors for a period of 38 months to allot, on one or more occasions, existing or new restricted shares in favor of persons to be chosen by the Board of Directors from among the salaried employees and corporate officers of our Company or of companies or economic interest groupings of the Group in accordance with Articles L. 225-197-1 *et seq*. of the French Commercial Code.

The existing or new shares allotted under this authorization may not represent more than 1.2% of our share capital as of the date of the decision by the Board of Directors to allot such shares.

The authorization provides that allotment of shares to the allottees will become irrevocable either (i) at the end of a minimum vesting period of three years, in which case the allottees will also be required to retain their shares for a minimum period of two years from the irrevocable allotment thereof, or (ii) after a minimum vesting period of four years, in which case allottees may not be subject to any minimum retention period.

In the case of newly issued shares, the authorization entails the express waiver by the shareholders, in favor of the allottees of restricted shares, of their preemptive rights in respect of shares that are to be issued as and when restricted shares vest.

The Board of Directors sets the terms on which restricted shares are granted and the arrangements with respect to the dividend entitlement of the shares.

See Item 6. Directors, Senior Management and Employees E. Share Ownership for a description of our restricted shares plans currently in force.

Changes in Share Capital in 2015

See Note D.15.1. to our consolidated financial statements included at Item 18 of this annual report.

Voting Rights

In general, each shareholder is entitled to one vote per share at any shareholders general meeting. Our Articles of Association do not provide for cumulative voting rights. However, our Articles of Association provide that any fully paid-up shares that have been held in registered form under the name of the same shareholder for at least two years acquire double voting rights. The double voting rights cease automatically for any share converted into bearer form or transferred from one owner to another, subject to certain exceptions permitted by law.

As of December 31, 2015, there were 143,355,987 shares that were entitled to double voting rights, representing 10.98% of our total share capital, and approximately 19.84% of the voting rights which can be cast at our shareholders general meeting as of that date.

Double voting rights are not taken into account in determining whether a quorum exists.

Under the French Commercial Code, treasury shares or shares held by entities controlled by that company are not entitled to voting rights and do not count for quorum purposes.

Our Articles of Association allow us to obtain from Euroclear France the name, nationality, address and number of shares held by holders of our securities that have, or may in the future have, voting rights. If we have reason to believe that a person on any list provided by Euroclear France holds securities on behalf of another person, our Articles of Association allow us to request information regarding beneficial ownership directly from such person. See B. Memorandum and Articles of Association Form, Holding and Transfer of Shares, below.

Our Articles of Association provide that Board members are elected on a rolling basis for a maximum tenure of four years.

Shareholders Agreement

We are not aware of any shareholder s agreement currently in force concerning our shares.

Shareholders Meetings

General

In accordance with the provisions of the French Commercial Code, there are three types of shareholders meetings: ordinary, extraordinary and special.

Ordinary general meetings of shareholders are required for matters such as:

- electing, replacing and removing directors;
- appointing independent auditors;
- approving the annual financial statements;
- declaring dividends or authorizing dividends to be paid in shares, provided the Articles of Association contain a provision to that effect; and
- approving share repurchase programs.

Extraordinary general meetings of shareholders are required for approval of matters such as amendments to our Articles of Association, including any amendment required in connection with extraordinary corporate actions. Extraordinary corporate actions include:

- changing our Company s name or corporate purpose;

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- increasing or decreasing our share capital;
- creating a new class of equity securities;
- authorizing the issuance of:
  - shares giving access to our share capital or giving the right to receive debt instruments, or
  - other securities giving access to our share capital;
- establishing any other rights to equity securities;
- selling or transferring substantially all of our assets; and
- the voluntary liquidation of our Company.

Special meetings of shareholders of a certain category of shares or shares with certain specific rights (such as shares with double voting rights) are required for any modification of the rights derived from that category of shares. The resolutions of the shareholders general meeting affecting these rights are effective only after approval by the relevant special meeting.

Annual Ordinary Meetings

The French Commercial Code requires the Board of Directors to convene an annual ordinary general shareholders meeting to approve the annual financial statements. This meeting must be held within six months of the end of each fiscal year. This period may be extended by an order of the President of the Commercial Court. The Board of Directors may also convene an ordinary or extraordinary general shareholders meeting upon proper notice at any time during the year. If the Board of Directors fails to convene a shareholders meeting, our independent auditors may call the meeting. In case of bankruptcy, the liquidator or court-appointed agent may also call a shareholders meeting in some instances. In addition, any of the following may request the court to appoint an agent for the purpose of calling a shareholders meeting:

- one or several shareholders holding at least 5% of our share capital;

- duly qualified associations of shareholders who have held their shares in registered form for at least two years and who together hold at least 1% of our voting rights;

- the works council in cases of urgency; or

- any interested party in cases of urgency.

Notice of Shareholders Meetings

All prior notice periods provided for below are minimum periods required by French law and cannot be shortened, except in case of a public tender offer for our shares.

We must announce general meetings at least thirty-five days in advance by means of a preliminary notice (*avis de réunion*), which is published in the *Bulletin des Annonces Légales Obligatoires*, or *BALO*. The preliminary notice must

first be sent to the French Financial markets authority (*Autorité des marchés financiers*, the AMF), with an indication of the date on which it will be published in the BALO. It must be published on our website at least twenty-one days prior to the general meeting. The preliminary notice must contain, among other things, the agenda, a draft of the resolutions to be submitted to the shareholders for consideration at the general meeting and a detailed description of the voting procedures (proxy voting, electronic voting or voting by mail), the procedures permitting shareholders to submit additional resolutions or items to the agenda and to ask written questions to the Board of Directors. The AMF also recommends that, prior to or simultaneously with the publication of the preliminary notice, we publish a summary of the notice indicating the date, time and place of the meeting in a newspaper of national circulation in France and on our website.

At least fifteen days prior to the date set for a first convening, and at least ten days prior to any second convening, we must send a final notice (*avis de convocation*) containing the final agenda, the date, time and place of the meeting and other information related to the meeting. Such final notice must be sent by mail to all registered shareholders who have held shares in registered form for more than one month prior to the date of the final notice and by registered mail, if shareholders have asked for it and paid the corresponding charges. The final notice must also be published in a newspaper authorized to publish legal announcements in the local administrative department (*département*) in which our Company is registered as well as in the *BALO*, with prior notice having been given to the AMF for informational purposes. Even if there are no proposals for new resolutions or items to be submitted to the shareholders at the meeting, we must publish a final notice in a newspaper authorized to publish legal announcements in the local administrative department (*département*) in with our Company is registered as well as in the *BALO*.

Other issues

In general, shareholders can only take action at shareholders meetings on matters listed on the agenda. As an exception to this rule, shareholders may take action with respect to the appointment and dismissal of directors even if this action has not been included on the agenda.

Additional resolutions to be submitted for approval by the shareholders at the shareholders meeting may be proposed to the Board of Directors, for recommendation to the shareholders at any time from the publication of the preliminary notice in the *BALO* until twenty-five days prior to the general meeting and in any case no later than twenty days following the publication of the preliminary notice in the *BALO* by:

- one or several shareholders together holding a specified percentage of shares;

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Item 10. Additional Information

- a duly qualified association of shareholders who have held their shares in registered form for at least two years and who together hold at least 1% of our voting rights; or

- the works council.

Within the same period, the shareholders may also propose additional items (*points*) to be submitted and discussed during the shareholders meeting, without a shareholders vote. The shareholders must substantiate the reasons for proposing their proposals of additional items.

The resolutions and the list of items added to the agenda of the shareholders meeting must be promptly published on our website.

The Board of Directors must submit the resolutions to a vote of the shareholders after having made a recommendation thereon. The Board of Directors may also comment on the items that are submitted to the shareholders meeting.

Following the date on which documents must be made available to the shareholders (including documents to be submitted to the shareholders meeting and resolutions proposed by the Board of Directors, which must be published on our website at least twenty-one days prior to the general meeting), shareholders may submit written questions to the Board of Directors relating to the agenda for the meeting until the fourth business day prior to the general meeting. The Board of Directors must respond to these questions during the meeting or may refer to a Q&A section located on our website in which the question submitted by a shareholder has already been answered.

Attendance at Shareholders Meetings; Proxies and Votes by Mail

In general, all shareholders may participate in general meetings either in person or by proxy. Shareholders may vote in person, by proxy or by mail.

The right of shareholders to participate in general meetings is subject to the recording (*inscription en compte*) of their shares on the second business day, zero hour (Paris time), preceding the general meeting:

- for holders of registered shares: in the registered shareholder account held by the Company or on its behalf by an agent appointed by it; and

- for holders of bearer shares: in the bearer shareholder account held by the accredited financial intermediary with whom such holders have deposited their shares; such financial intermediaries shall deliver to holders of bearer shares a shareholding certificate (*attestation de participation*) enabling them to participate in the general meeting.

Attendance in Person

Any shareholder may attend ordinary general meetings and extraordinary general meetings and exercise its voting rights subject to the conditions specified in the French Commercial Code and our Articles of Association.

Proxies and Votes by Mail

Proxies are sent to any shareholder upon a request received between the publication of the final notice of meeting and six days before the general meeting and must be made available on our website at least twenty-one days before the general meeting. In order to be counted, such proxies must be received at our registered office, or at any other address indicated on the notice of the meeting or by any electronic mail indicated on the notice of the meeting, prior to the date of the meeting (in practice, we request that shareholders return proxies at least three business days prior to

the meeting; electronic proxies must be returned before 3 p.m. Paris time, on the day prior to the general meeting). A shareholder may grant proxies to any natural person or legal entity. The agent may be required to disclose certain information to the shareholder or to the public.

Alternatively, the shareholder may send us a blank proxy without nominating any representative. In this case, the chairman of the meeting will vote the blank proxies in favor of all resolutions proposed or approved by the Board of Directors and against all others.

With respect to votes by mail, we must send shareholders a voting form upon request or must make available a voting form on our website at least twenty-one days before the general meeting. The completed form must be returned to us at least three days prior to the date of the shareholders meeting. For holders of registered shares, in addition to traditional voting by mail, instructions may also be given via the internet.

Quorum

The French Commercial Code requires that shareholders holding in the aggregate at least 20% of the shares entitled to vote must be present in person, or vote by mail or by proxy, in order to fulfill the quorum requirement for:

- an ordinary general meeting; and

- an extraordinary general meeting where the only resolutions pertain to either (a) a proposed increase in our share capital through incorporation of reserves, profits or share premium, or (b) the potential issuance of free share warrants in the event of a public tender offer for our shares (article L. 233-32 of the French Commercial Code).

For any other extraordinary general meeting the quorum requirement is at least 25% of the shares entitled to vote, held by shareholders present in person, voting by mail or by proxy.

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For a special meeting of holders of a certain category of shares, the quorum requirement is one third of the shares entitled to vote in that category, held by shareholders present in person, voting by mail or by proxy.

If a quorum is not present at a meeting, the meeting is adjourned. However, only questions that were on the agenda of the adjourned meeting may be discussed and voted upon once the meeting resumes.

When an adjourned meeting is resumed, there is no quorum requirement for meetings cited in the first paragraph of this *Quorum* section. In the case of any other reconvened extraordinary general meeting or special meeting, the quorum requirement is 20% of the shares entitled to vote (or voting shares belonging to the relevant category for special meetings of holders of shares of such specific category), held by shareholders present in person or voting by mail or by proxy. If a quorum is not met, the reconvened meeting may be adjourned for a maximum of two months with the same quorum requirement. No deliberation or action by the shareholders may take place without a quorum.

Votes Required for Shareholder Action

The affirmative vote of a simple majority of the votes cast may pass a resolution at either an ordinary general meeting or an extraordinary general meeting where the only resolution(s) pertain to either (a) a proposed increase in our share capital through incorporation of reserves, profits or share premium, or (b) the potential issuance of free share warrants in the event of a public tender offer for our shares (article L. 233-32 of the French Commercial Code). At any other extraordinary general shareholders meeting and at any special meeting of holders of a specific category of shares, the affirmative vote of two-thirds of the votes cast is required.

Abstention from voting by those present or those represented by proxy or voting by mail is counted as a vote against the resolution submitted to a shareholder vote.

Changes to Shareholders Rights

Under French law, the affirmative vote of two-thirds of the votes cast at an extraordinary shareholders meeting is required to change our Articles of Association, which set out the rights attached to our shares, except for capital increases through incorporation of reserves, profits or share premium, or through the issuance of free share warrants in the event of a public tender offer for our shares (article L. 233-32 of the French Commercial Code).

The rights of a class of shareholders can be amended only after a special meeting of the class of shareholders affected has taken place. The voting requirements applicable to this type of special meeting are the same as those applicable to an extraordinary general shareholders meeting. The quorum requirements for a special meeting are one-third of the voting shares, or 20% upon resumption of an adjourned meeting.

A unanimous shareholders vote is required to increase the liabilities of shareholders.

Financial Statements and Other Communications with Shareholders

In connection with any shareholders meeting, we must provide a set of documents which includes our annual report.

We must also provide on our website at least twenty-one days before a shareholders meeting certain information and a set of documents that includes the preliminary notice, the proxies and voting forms, the resolutions proposed by the Board of Directors, and the documents to be

submitted to the shareholders meeting pursuant to articles L. 225-115 and R. 225-83 of the French Commercial Code, etc. The resolutions and the list of items added to the agenda of the shareholders meeting must be promptly published on our website.

Dividends

We may only distribute dividends out of our distributable profits, plus any amounts held in our reserves that the shareholders decide to make available for distribution, other than those reserves that are specifically required by law or our Articles of Association. Distributable profits consist of our unconsolidated net profit in each fiscal year, as increased or reduced by any profit or loss carried forward from prior years, less any contributions to the reserve accounts pursuant to law or our Articles of Association.

Legal Reserve

The French Commercial Code requires us to allocate 5% of our unconsolidated net profit for each year to our legal reserve fund before dividends may be paid with respect to that year. Funds must be allocated until the amount in the legal reserve is equal to 10% of the aggregate par value of the issued and outstanding share capital. This restriction on the payment of dividends also applies to each of our French subsidiaries on an unconsolidated basis. At December 31, 2015, our legal reserve amounted to 282,280,863, representing 10.81% of the aggregate par value of our issued and outstanding share capital as of that date. The legal reserve of any company subject to this requirement may serve to allocate losses that may not be allocated to other reserves, or may be distributed to shareholders upon liquidation of the company.

Approval of Dividends

According to the French Commercial Code, our Board of Directors may propose a dividend for approval by shareholders at the annual general shareholders meeting. If we have earned distributable profits since the end of the preceding fiscal year, as reflected in an interim income statement certified by our independent auditors, our Board of Directors may distribute interim dividends to the extent of the

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distributable profits for the period covered by the interim income statement. Our Board of Directors exercises this authority subject to French law and regulations and may do so without obtaining shareholder approval.

Distribution of Dividends

Dividends are distributed to shareholders *pro rata* according to their respective holdings of shares. In the case of interim dividends, distributions are made to shareholders on the date set by our Board of Directors during the meeting in which the distribution of interim dividends is approved. The actual dividend payment date is decided by the shareholders at an ordinary general shareholders meeting or by our Board of Directors in the absence of such a decision by the shareholders. Shareholders that own shares on the actual payment date are entitled to the dividend.

Dividends may be paid in cash or, if the shareholders meeting so decides, in kind, provided that all shareholders receive a whole number of assets of the same nature paid in lieu of cash. Our Articles of Association provide that, subject to a decision of the shareholders meeting taken by ordinary resolution, each shareholder may be given the choice to receive his dividend in cash or in shares.

Timing of Payment

According to the French Commercial Code, we must pay any existing dividends within nine months of the end of our fiscal year, unless otherwise authorized by court order. Dividends on shares that are not claimed within five years of the date of declared payment revert to the French State.

Changes in Share Capital

Increases in Share Capital

As provided for by the French Commercial Code, our share capital may be increased only with shareholders approval at an extraordinary general shareholders meeting following the recommendation of our Board of Directors. The shareholders may delegate to our Board of Directors either the authority *(délégation de compétence)* or the power *(délégation de pouvoir)* to carry out any increase in share capital. Our Board of Directors may further delegate this power to our Chief Executive Officer or, subject to our Chief Executive Officer s approval, to his delegates *(directeurs généraux délégués).*

Increases in our share capital may be effected by:

- issuing additional shares;
- increasing the par value of existing shares;
- creating a new class of equity securities; or
- exercising the rights attached to securities giving access to the share capital.

Increases in share capital by issuing additional securities may be effected through one or a combination of the following:

- in consideration for cash;
- in consideration for assets contributed in kind;
- through an exchange offer;
- by conversion of previously issued debt instruments;
- by capitalization of profits, reserves or share premium; or
- subject to various conditions, in satisfaction of debt incurred by our Company.

Decisions to increase the share capital through the capitalization of reserves, profits and/or share premium or through the issuance of free share warrants in the event of a public tender offer for our shares (article L. 233-32 of the French Commercial Code) require shareholders approval at an extraordinary general shareholders meeting, acting under the quorum and majority requirements applicable to ordinary shareholders meetings. Increases effected by an increase in the par value of shares require unanimous approval of the shareholders, unless effected by capitalization of reserves, profits or share premium. All other capital increases require shareholders approval at an extraordinary general shareholders meeting acting under the regular quorum and majority requirements for such meetings. See Quorum and Votes Required for Shareholder Action above.

On May 4, 2015, our shareholders approved various resolutions delegating to the Board of Directors the authority to increase our share capital through the issuance of shares or securities giving access to the share capital, subject to an overall cap set at 1.3 billion. This cap applies to all the resolutions whereby the extraordinary shareholders meeting delegated to the Board of Directors the authority to increase the share capital, it being also specified that:

- the maximum aggregate par value of capital increases that may be carried out with preemptive rights maintained was set at 1.3 billion;
- the maximum aggregate par value of capital increases that may be carried out by public offering without preemptive rights was set at 260 million;
- the maximum aggregate par value of capital increases that may be carried out by private placement without preemptive rights was set at 260 million;
- capital increases resulting in the issuance of securities to members of employee savings plans are limited to 1% of the share capital as computed on the date of the Board of Directors decision to issue such securities, and such issuances may be made at a discount of 20% (or 30%) if certain French law restrictions on resales were to apply, i.e. a lock up period of five years (or 10 years).

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On May 4, 2015, our shareholders also approved resolutions delegating to the Board of Directors the authority to increase the share capital by granting existing or new restricted shares to our employees and/or corporate officers, subject to the overall cap mentioned above and under the following terms and conditions:

- the authorization is valid for a period of 38 months, and is subject to a limit of 1.2% of the share capital as computed on the date of the decision of the Board of Directors to allot such shares; see Awards of Shares above.

On May 3, 2013, our shareholders also approved resolutions delegating to the Board of Directors the authority to increase the share capital by granting options to our employees and/or corporate officers, subject to the overall cap mentioned above and under the following terms and conditions:

- the authorization is valid for a period of 38 months, and any options granted may not give entitlement to a total number of shares exceeding 0.7% of the share capital as computed on the date of the decision of the Board of Directors to grant such options; see Stock Options above;

See also Item 6. Directors, Senior Management and Employees E. Share Ownership .

Decreases in Share Capital

In accordance with the provisions of the French Commercial Code, any decrease in our share capital requires approval by the shareholders entitled to vote at an extraordinary general meeting. The share capital may be reduced either by decreasing the par value of the outstanding shares or by reducing the number of outstanding shares. The number of outstanding shares may be reduced either by an exchange of shares or by the repurchase and cancellation of shares. Holders of each class of shares must be treated equally unless each affected shareholder agrees otherwise.

In addition, specific rules exist to permit the cancellation of treasury shares, by which the shareholders meeting may authorize the cancellation of up to a maximum of 10% of a company s share capital within any 24-month period. On May 4, 2015, our shareholders delegated to our Board of Directors for 26 months the right to reduce our share capital by canceling our own shares.

Preemptive Rights

According to the French Commercial Code, if we issue additional securities to be paid in cash, current shareholders will have preemptive rights to these securities on a *pro rata* basis. These preemptive rights require us to give priority treatment to current shareholders. The rights entitle the individual or entity that holds them to subscribe to the issuance of any securities that may increase the share capital of our Company by means of a cash payment or a set-off of cash debts. Preemptive rights are transferable

during the subscription period relating to a particular offering. These rights may also be listed on Euronext Paris Stock Exchange.

Preemptive rights with respect to any particular offering may be waived by the affirmative vote of shareholders holding two-thirds of the shares entitled to vote at an extraordinary general meeting. Our Board of Directors and our independent auditors are required by French law to present

reports that specifically address any proposal to waive preemptive rights. In the event of a waiver, the issue of securities must be completed within the period prescribed by law. Shareholders may also notify us that they wish to waive their own preemptive rights with respect to any particular offering if they so choose.

The shareholders may decide at extraordinary general meetings to give the existing shareholders a non-transferable priority right to subscribe to the new securities, for a limited period of time.

In the event of a capital increase without preemptive rights to existing shareholders, French law requires that the capital increase be made at a price equal to or exceeding the weighted average market prices of the shares for the last three trading days on Euronext Paris Stock Exchange prior to the determination of the subscription price of the capital increase less 5%.

Form, Holding and Transfer of Shares

Form of Shares

Our Articles of Association provide that the shares may be held in either bearer form or registered form at the option of the holder.

Holding of Shares

In accordance with French law relating to the dematerialization of securities, shareholders ownership rights are represented by book entries instead of share certificates. We maintain a share account with Euroclear France (a French clearing system, which holds securities for its participants) for all shares in registered form, which is administered by BNP Paribas Securities Services. In addition, we maintain separate accounts in the name of each shareholder either directly or, at a shareholder s request, through the shareholder s accredited intermediary. Each shareholder account shows the name of the holder and the number of shares held. BNP Paribas Securities Services issues confirmations (*attestations d inscription en compte*) to each registered shareholder as to shares registered in the shareholder s account, but these confirmations are not documents of title.

Shares of a listed company may also be issued in bearer form. Shares held in bearer form are held and registered on the shareholder s behalf in an account maintained by an accredited financial intermediary and are credited to an

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account at Euroclear France maintained by such intermediary. Each accredited financial intermediary maintains a record of shares held through it and provides the account holder with a securities account statement. Transfers of shares held in bearer form may only be made through accredited financial intermediaries and Euroclear France.

Shares held by persons who are not domiciled in France may be registered in the name of intermediaries who act on behalf of one or more investors. When shares are so held, we are entitled to request from such intermediaries the names of the investors. Also, we may request any legal entity (*personne morale*) which holds more than 2.5% of our shares or voting rights to disclose the name of any person who owns, directly or indirectly, more than one-third of its share capital or of its voting rights. A person not providing the complete requested information in time, or who provides incomplete or false information, will be deprived of its voting rights at shareholders meetings and will have its payment of dividends withheld until it has provided the requested information in strict compliance with French law. If such person acted willfully, the person may be deprived by a French court of either its voting rights or its dividends or both for a period of up to five years.

Transfer of Shares

Our Articles of Association do not contain any restrictions relating to the transfer of shares.

Registered shares must be converted into bearer form before being transferred on the Euronext Paris Stock Exchange on the shareholders behalf and, accordingly, must be registered in an account maintained by an accredited financial intermediary on the shareholders behalf. A shareholder may initiate a transfer by giving instructions to the relevant accredited financial intermediary.

A fee or commission is payable to the broker involved in the transaction, regardless of whether the transaction occurs within or outside France. Registration duty is currently payable in France if a written deed of sale and purchase (*acte*) is executed in France or outside France with respect to the shares of the Company.

Redemption of Shares

Under French law, our Board of Directors is entitled to redeem a set number of shares as authorized by the extraordinary shareholders meeting. In the case of such an authorization, the shares redeemed must be cancelled within one month after the end of the offer to purchase such shares from shareholders. However, shares redeemed on the open market do not need to be cancelled if the company redeeming the shares grants options on or awards those shares to its employees within one year following the acquisition. See also Trading in Our Own Shares below.

Sinking Fund Provisions

Our Articles of Association do not provide for any sinking fund provisions.

Liability to Further Capital Calls

Shareholders are liable for corporate liabilities only up to the par value of the shares they hold; they are not liable to further capital calls.

Liquidation Rights

If we are liquidated, any assets remaining after payment of our debts, liquidation expenses and all of our remaining obligations will first be distributed to repay in full the par value of our shares. Any surplus will be distributed *pro rata* among shareholders in proportion to the par value of their shareholdings.

Requirements for Holdings Exceeding Certain Percentages

The French Commercial Code provides that any individual or entity, acting alone or in concert with others, that becomes the owner, directly or indirectly, of more than 5%, 10%, 15%, 20%, 25%, 30%, $33^{1}/_{3}$%, 50%, $66^{2}/_{3}$%, 90% or 95% of the outstanding shares or voting rights of a listed company in France, such as our Company, or that increases or decreases its shareholding or voting rights above or below any of those percentages, must notify the company, before the end of the fourth trading day following the date it crosses the threshold, of the number of shares it holds and their voting rights. The individual or entity must also notify the AMF before the end of the fourth trading day following the date it crosses any such threshold. The AMF makes the notice public.

Pursuant to the French Commercial Code and the AMF General Regulation, the participation thresholds shall be calculated on the basis of the shares and voting rights owned, and shall take into account the shares and voting rights which are deemed to be shares and voting rights owned, even if the individual or entity does not itself hold shares or voting rights. In accordance with this deemed ownership principle, the individual or entity must take into account specific situations where shares and voting rights are deemed to be shares and voting rights owned when calculating the number of shares owned to be disclosed in the notifications to the Company and to the AMF. It includes among others situations where an individual or entity is entitled to acquire issued shares at its own initiative, immediately or at the end of a maturity period, under an agreement or a financial instrument, without set-off against the number of shares that this individual or entity is entitled to sell under another agreement or financial instrument. The individual or entity required to make such notification shall also take into account issued shares covered by an agreement or cash-settled financial instrument and having

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an economic effect for said individual or entity that is equivalent to owning such shares. In the cases of deemed ownership described above, the notification shall mention the type of deemed ownership and include a description of the main characteristics of the financial instrument or agreement with specific details required by the AMF General Regulation.

The AMF General Regulation provides that shares and voting rights subject to multiple cases of deemed ownership shall only be counted once.

When an individual or entity modifies the allocation between the shares it owns and its financial instruments or agreements deemed to be owned shares, it must disclose that change in a new notification. However, the change must only be disclosed if the acquisition of owned shares due to the settlement of the financial instruments or agreements causes the investor to cross a threshold.

Subject to certain limited exceptions, French law and AMF regulations impose additional reporting requirements on persons who acquire more than 10%, 15%, 20%, or 25% of the outstanding shares or voting rights of a company listed in France. These persons must file a report with the company and the AMF before the end of the fifth trading day following the date they cross any such threshold.

In the report, the acquirer will have to specify its intentions for the following six months including:

- whether it acts alone or in concert with others;
- the means of financing of the acquisition (the notifier shall indicate in particular whether the acquisition is being financed with equity or debt, the main features of that debt, and, where applicable, the main guarantees given or received by the notifier. The notifier shall also indicate what portion of its holding, if any, it obtained through securities loans);
- whether or not it intends to continue its purchases;
- whether or not it intends to acquire control of the company in question;
- the strategy it contemplates *vis-à-vis* the issuer;
- the way it intends to implement its strategy, including: (i) any plans for a merger, reorganization, liquidation, or partial transfer of a substantial part of the assets of the issuer or of any other entity it controls within the meaning of article L. 233-3 of the French Commercial Code, (ii) any plans to modify the business of the issuer, (iii) any plans to modify articles of association of the issuer, (iv) any plans to delist a category of the issuer s financial instruments, and (v) any plans to issue the issuer s financial instruments;
- any agreement for the temporary transfer of shares or voting rights of the issuer;

- the way it intends to settle its agreements or instruments on the shares or voting rights of the issuer mentioned in Article L. 233- 9,4° and 4° bis of the French Commercial Code; and

- whether it seeks representation on the Board of Directors.

The AMF makes the report public. Upon any change of intention within the six-month period following the filing of the report, it will have to file a new report for the following six-month period.

In order to enable shareholders to give the required notice, we must each month publish on our website and send the AMF a written notice setting forth the total number of our shares and voting rights (including treasury shares) whenever they vary from the figures previously published.

If any shareholder fails to comply with an applicable legal notification requirement, the shares in excess of the relevant threshold will be deprived of voting rights for all shareholders meetings until the end of a two-year period following the date on which the owner complies with the notification requirements. In addition, any shareholder who fails to comply with these requirements may have all or part of its voting rights suspended for up to five years by the Commercial Court at the request of our Chairman, any shareholder or the AMF, and may be subject to criminal fines.

Under AMF regulations, and subject to limited exemptions granted by the AMF, any person or entity, acting alone or in concert, that crosses the threshold of 30% of the share capital or voting rights of a French listed company must initiate a public tender offer for the balance of the shares and securities giving access to the share capital or voting rights of such company. Cash-settled derivative instruments or agreements mentioned in Article L. 233-9, 4° bis of the French Commercial Code are not included in the calculation of the number of shares related to the mandatory public tender offer.

In addition, our Articles of Association provide that any person or entity, acting alone or in concert with others, who becomes the owner of 1%, or any multiple of 1% of our share capital or our voting rights, even beyond the minimum declaration limits permitted by the legal and regulatory provisions, must notify us by certified mail, return receipt requested, within five trading days, of the total number of shares and securities giving access to our share capital and voting rights that such person then owns. The same provisions of our Articles of Association apply whenever such owner increases or decreases its ownership of our share capital or our voting rights to such extent that it goes above or below one of the thresholds described in the preceding sentence. Any person or entity that fails to comply with such notification requirement will, upon the request of one or more shareholders holding at least 5% of our share capital or of our voting rights made at the general

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shareholders meeting, be deprived of voting rights with respect to the shares in excess of the relevant threshold for all shareholders meetings until the end of a two-year period following the date on which such person or entity complies with the notification requirements.

Change in Control/Anti-takeover

There are no provisions in our Articles of Association that would have the effect of delaying, deferring or preventing a change in control of our Company or that would operate only with respect to a merger, acquisition or corporate restructuring involving our Company or any of our subsidiaries. Further, there are no provisions in our Articles of Association that allow the issuance of preferred stock upon the occurrence of a takeover attempt or the addition of other anti-takeover measures without a shareholder vote.

Our Articles of Association do not include any provisions discriminating against any existing or prospective holder of our securities as a result of such shareholder owning a substantial number of shares.

Trading in Our Own Shares

Under French law, Sanofi may not issue shares to itself. However, we may, either directly or through a financial intermediary acting on our behalf, acquire up to 10% of our issued share capital within a maximum period of 18 months, provided our shares are listed on a regulated market. Prior to acquiring our shares, we must publish a description of the share repurchase program (*descriptif du programme de rachat d actions*).

We may not cancel more than 10% of our issued share capital over any 24-month period. Our repurchase of shares must not result in our Company holding, directly or through a person acting on our behalf, more than 10% of our issued share capital. We must hold any shares that we repurchase in registered form. These shares must be fully paid up. Shares repurchased by us continue to be deemed issued under French law but are not entitled to dividends or voting rights so long as we hold them directly or indirectly, and we may not exercise the preemptive rights attached to them.

The shareholders, at an extraordinary general shareholders meeting, may decide not to take these shares into account in determining the preemptive rights attached to the other shares. However, if the shareholders decide to take them into account, we must either sell the rights attached to the shares we hold on the market before the end of the subscription period or distribute them to the other shareholders on a *pro rata* basis.

On May 4, 2015, our shareholders approved a resolution authorizing us to repurchase up to 10% of our shares over an 18-month period. Under this authorization, the purchase price for each Sanofi ordinary share may not be greater than 120.00 and the maximum amount that Sanofi may pay for the repurchases is 12,248,051,000. This authorization was granted for a period of 18 months from May 4, 2015 and

cancelled and replaced the authorization granted to the Board of Directors by the combined general meeting held on May 5, 2014. A description of this share repurchase program as adopted by the combined general meeting held on May 4, 2015 (*descriptif du programme de rachat d actions*) was published on March 11, 2015.

Purposes of Share Repurchase Programs

Under the European regulation 2273/2003, dated December 22, 2003 (which we refer to in this section as the Regulation), in application of European directive 2003/6/EC, dated January 28, 2003, known as the Market Abuse Directive , an issuer will benefit from a safe harbor for share transactions that comply with certain conditions relating in particular to the pricing, volume and timing of transactions (see below) and that are made in connection with a share repurchase program the purpose of which is:

- to reduce the share capital through the cancellation of treasury shares; and/or

- to meet obligations arising from debt instruments exchangeable into equity instruments and/or the implementation of employee share option programs or other employee share allocation plans.

Safe harbor transactions will by definition not be considered market abuses under the Regulation. Transactions that are carried out for other purposes than those mentioned above do not qualify for the safe harbor. However, as permitted by the Directive, which provides for the continuation of existing practices that do not constitute market manipulation and that conform with certain criteria set forth in European directive 2004/72, dated April 29, 2004, the AMF published exceptions on March 22, 2005, October 1, 2008, March 21, 2011, March 10, 2012, and April 24, 2013 to permit the following existing market practices:

- transactions pursuant to a liquidity agreement entered into with a financial services intermediary that complies with the ethical code (*charte de déontologie*) approved by the AMF; and

- the purchase of shares that are subsequently used as acquisition currency in a business combination transaction.

The AMF confirmed that all transactions directed at maintaining the liquidity of an issuer s shares must be conducted pursuant to a liquidity agreement with a financial services intermediary acting independently.

Pricing, Volume and Other Restrictions

In order to qualify for the safe harbor, the issuer must generally comply with the following pricing and volume restrictions:

- a share purchase must not be made at a price higher than the higher of the price of the last independent trade and the highest current independent bid on the trading venues where the purchase is carried out;

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- subject to certain exceptions for illiquid securities, the issuer must not purchase more than 25% of the average daily volume of the shares in any one day on the regulated market on which the purchase is carried out. The average daily volume figure must be based on the average daily volume traded in the month preceding the month of public disclosure of the share repurchase program and fixed on that basis for the authorized period of that program. If the program does not make reference to this volume, the average daily volume figure must be based on the average daily volume traded in the 20 trading days preceding the date of purchase.

In addition, an issuer must not:

- sell treasury shares during the period of the repurchase program (without prejudice to the right of the issuer to meet its obligations under employee share option programs or other employee share allocation plans or to use shares as acquisition currency as mentioned above); it being further specified that such prohibition is not applicable in the event of off-market block trades or if the share repurchase program is implemented by a financial services intermediary pursuant to a liquidity agreement as mentioned above; and

- effect any transaction during a blackout period imposed by the applicable law of the Member State in which the transaction occurs (i.e., under French law, during the period between the date on which the company has knowledge of insider information and the date on which such information is made public and during the 30-day period preceding the date of publication of annual and half-year financial statements and the 15-day period preceding the date of publication of quarterly financial information), without prejudice to transactions carried out pursuant to a liquidity agreement as mentioned above; or

- effect any transaction in securities with respect to which the issuer has decided to defer disclosure of any material, non-public information.

Use of Share Repurchase Programs

Pursuant to the AMF rules, issuers must immediately allocate the repurchased shares to one of the purposes provided for in the Regulation and must not subsequently use the shares for a different purpose. As an exception to the foregoing, shares repurchased with a view to covering stock option plans may, if no longer needed for this purpose, be re-allocated for cancellation or sold in compliance with AMF requirements relating in particular to blackout periods. Shares repurchased in connection with one of the market practices authorized by the AMF (see above) may also be re-allocated to one of the purposes contemplated by the Regulation or sold in compliance with AMF requirements. Shares repurchased with a view to their cancellation must be cancelled within 24 months following their acquisition.

During the year ended December 31, 2015, we used the authority delegated by our shareholders to repurchase our shares on the stock market.

Pursuant to our share repurchase programs authorized by our shareholders on May 5, 2014 and on May 4, 2015, we repurchased 20,275,940 of our shares for a weighted average price of 87.67, i.e. a total cost of 1,779 million. Brokerage fees and financial transaction taxes (net of income taxes) amounted to 2.4 million.

On April 29, 2015, the Board of Directors cancelled 18,482,786 treasury shares repurchased between November 2014 and March 2015 pursuant to the share repurchase program of the Company.

On October 29, 2015, the Board of Directors cancelled 7,259,200 treasury shares repurchased between April 2015 and August 2015 pursuant to the share repurchase program of the Company.

During 2015, pursuant to the liquidity contract, Exane BNP Paribas purchased 3,416,317 of our shares at an average weighted price of 88.15 for a total amount of 301,137,412 and sold 3,416,317 of our shares at an average weighted price of 88.18 for a total amount of 301,266,554.

In 2015, of the 193,331 shares allocated to stock purchase option plans outstanding at December 31, 2014, 33,480 shares were transferred to grantees of options.

As a result, as of December 31, 2015, out of the 3,956,708 treasury shares, representing 0.30% of our share capital, 159,851 were allocated to outstanding stock purchase option plans and 3,796,857 were allocated to the purpose of cancellation. At the same date, none of the shares was allocated to the liquidity account, even though the liquidity contract was outstanding.

As of December 31, 2015, we directly owned 3,956,708 Sanofi shares with a par value of 2 representing around 0,30% of our share capital and with an estimated value of 306 million, based on the share price at the time of purchase.

Reporting Obligations

Pursuant to the AMF Regulation and the French Commercial Code, issuers trading in their own shares are subject to the following reporting obligations:

- issuers must report all transactions in their own shares on their web site within seven trading days of the transaction in a prescribed format, unless such transactions are carried out pursuant to a liquidity agreement that complies with the ethical code approved by the AMF; and

- issuers must declare to the AMF on a monthly basis all transactions completed under the share repurchase program unless they provide the same information on a weekly basis.

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Ownership of Shares by Non-French Persons

The French Commercial Code and our Articles of Association currently do not limit the right of non-residents of France or non-French persons to own or, where applicable, to vote our securities. However, non-residents of France must file an administrative notice with the French authorities in connection with certain direct and indirect investments in us, including the acquisition of a controlling interest in our Company. Under existing administrative rulings, ownership of $33^{1}/_{3}$% or more of our share capital or voting rights is regarded as a controlling interest, but a lower percentage might be held to be a controlling interest in certain circumstances depending upon factors such as:

- the acquiring party s intentions;
- the acquiring party s ability to elect directors; or
- financial reliance by the company on the acquiring party.

Moreover, certain foreign investments in companies incorporated under French laws are subject to the prior authorization from the French Minister of the Economy, where all or part of the target s business and activity relate to a strategic sector, such as energy, transportation, public health, telecommunications, etc.

Enforceability of Civil Liabilities

We are a limited liability company (*société anonyme*) organized under the laws of France, and most of our officers and directors reside outside the United States. In addition, a substantial portion of our assets is located in France.

As a result, investors may find it difficult or be unable to effect service of process within the United States upon or obtain jurisdiction over our Company or our officers and directors in U.S. courts in actions predicated on the civil liability provisions of U.S. securities law. It may also be difficult to enforce against them, either inside or outside the United States, judgments obtained against them in U.S. courts, or to enforce in U.S. courts, judgments obtained against them in courts in jurisdictions outside the United States, in any action based on civil liabilities under the U.S. federal securities laws. There is doubt as to the enforceability against such persons in France, whether in original actions or in actions to enforce judgments of U.S. courts, of liabilities based solely on the U.S. federal securities laws. In addition, actions in the United States under the U.S. federal securities laws could be affected under certain circumstances by the French law No. 68-678 of July 26, 1968 as amended by French Law No. 80-538 of July 16, 1980, which may preclude or restrict the obtaining of evidence in France or from French persons in connection with those actions. Additionally, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in France.

C. Material Contracts

The Contingent Value Rights Agreement

In connection with its acquisition of Genzyme Corporation, now a wholly-owned subsidiary of Sanofi, Sanofi issued one CVR per Genzyme share. On March 30, 2011, Sanofi and American Stock Transfer & Trust Company, LLC, as trustee, entered into a Contingent Value Rights agreement (the CVR Agreement) governing the terms of the CVRs.

Pursuant to the terms of the CVR Agreement, a holder of a CVR is entitled to cash payments upon the achievement of contractually defined milestones.

The two first milestones (related, respectively, to manufacturing of Cerezyme® and Fabrazyme® and U.S. regulatory approval on or before March 31, 2014 of Lemtrada® for the treatment of MS (the Approval Milestone)) were not met and therefore lapsed. Based upon actual sales trends to date, Sanofi does not expect that Product Sales Milestone #1, pursuant to which a holder of a CVR would be entitled to receive $2 per CVR if Lemtrada® sales (as defined in the CVR Agreement) post launch equals or exceeds a total of $400 million within certain specified periods and territories, will be met.

The remaining milestone payments will be triggered on achievement of certain Lemtrada® sales thresholds within certain defined periods, as summarized below:

- *Product Sales Milestone #2 Payment.* $3 per CVR upon the first instance in which Lemtrada® sales (as defined in the CVR Agreement) for a four calendar quarter period are equal to or in excess of $1.8 billion. Given that the Approval Milestone was not achieved, an additional $1 per CVR will be paid should Product Sales Milestone #2 be achieved, totaling $4 per CVR.

- *Product Sales Milestone #3 Payment.* $4 per CVR upon the first instance in which Lemtrada® sales (as defined in the CVR Agreement) for a four calendar quarter period are equal to or in excess of $2.3 billion (however, no quarter in which Lemtrada® sales (as defined in the CVR Agreement) were used to determine the achievement of Product Sales Milestone #1 or #2 shall be included in the calculation of sales for determining whether Product Sales Milestone #3 has been achieved).

- *Product Sales Milestone #4 Payment.* $3 per CVR upon the first instance in which Lemtrada® sales (as defined in the CVR Agreement) for a four calendar quarter period are equal to or in excess of $2.8 billion (however, no quarter in which Lemtrada® sales (as defined in the CVR Agreement) were used to determine the achievement of Product Sales Milestone #1, #2 or #3 shall be included in the calculation of sales for determining whether Product Sales Milestone #4 has been achieved).

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The CVR Agreement will terminate on the earlier of (a) December 31, 2020 and (b) the date that Product Sales Milestone #4 is paid (the Termination Date), provided that if any milestone has been achieved prior to the Termination Date, but the associated CVR payment has not been paid on or prior to the Termination Date, the CVR Agreement shall not terminate until such payment has been paid in full in accordance with the terms of the CVR Agreement.

Sanofi has agreed to use diligent efforts (as defined in the CVR Agreement), until the CVR Agreement is terminated, to achieve each of the remaining milestones. However, we are not required to take all possible actions to achieve these goals. Based upon actual sales trends to date, Sanofi does not expect that Product Sales Milestone #1 will be met. There can be no assurance that the other product sales milestones will be achieved. Sanofi has also agreed to use its commercially reasonable efforts to maintain a listing for trading of the CVRs on the NASDAQ market.

For more information on Lemtrada® see Item 4.B Business Overview Pharmaceutical Products Multiple Sclerosis .

The CVR Agreement does not prohibit Sanofi or any of its subsidiaries or affiliates (as defined in the CVR Agreement) from acquiring the CVRs, whether in open market transactions, private transactions or otherwise. Sanofi has certain disclosure obligations in connection with such acquisitions under the CVR Agreement. On or after April 1, 2017, Sanofi may also, subject to certain terms and conditions as set forth in the CVR Agreement, optionally purchase and cancel all (but not less than all) of the outstanding CVRs at a cash price as set forth in the CVR Agreement if (i) the volume-weighted average price paid per CVR for all CVRs traded over the forty-five trading days prior to such date is less than fifty cents and (ii) Lemtrada® sales (as defined in the CVR Agreement) in the four calendar quarters ended immediately prior to such date are less than $1 billion in the aggregate.

A copy of the form of 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. Reference is made to such exhibit for a more complete description of the terms and conditions of the CVR Agreement, and the foregoing summary of such terms and conditions is qualified in its entirety by such exhibit.

D. Exchange Controls

French exchange control regulations currently do not limit the amount of payments that we may remit to non-residents of France. Laws and regulations concerning foreign exchange controls do require, however, that all payments or transfers of funds made by a French resident to a non-resident be handled by an accredited intermediary.

E. Taxation

General

The following generally summarizes the material French and U.S. federal income tax consequences to U.S. holders (as defined below) of purchasing, owning and disposing of our ADSs and ordinary shares (collectively the Securities). This discussion is intended only as a descriptive summary and does not purport to be a complete analysis or listing of all potential tax effects of the purchase, ownership or disposition of our Securities. All of the following is subject to change. Such changes could apply retroactively and could affect the consequences described below.

This summary does not constitute a legal opinion or tax advice. Holders are urged to consult their own tax advisers regarding the tax consequences of the purchase, ownership and disposition of Securities in light of their particular circumstances, including the effect of any U.S. federal, state, local or other national tax laws.

A set of tax rules is applicable to French assets that are held by or in foreign trusts. These rules provide *inter alia* for the inclusion of trust assets in the settlor s net assets for purpose of applying the French wealth tax, for the application of French gift and death duties to French assets held in trust, for a specific tax on capital on the French assets of foreign trusts not already subject to the French wealth tax and for a number of French tax reporting and disclosure obligations. The following discussion does not address the French tax consequences applicable to Securities held in trusts. *If Securities are held in trust, the grantor, trustee and beneficiary are urged to consult their own tax adviser regarding the specific tax consequences of acquiring, owning and disposing of Securities.*

The description of the French and U.S. federal income tax consequences set forth below is based on the laws (including, for U.S. federal income tax purposes, the Internal Revenue Code of 1986, as amended (the Code), final, temporary and proposed U.S. Treasury Regulations promulgated thereunder and administrative and judicial interpretations thereof) in force as of the date of this annual report, the Convention Between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income and Capital of August 31, 1994 (the Treaty), which entered into force on December 30, 1995 (as amended by any subsequent protocols, including the protocol of January 13, 2009), and the tax regulations issued by the French tax authorities within the *Bulletin Officiel des Finances Publiques- Impôts* (the Regulations) in force as of the date of this report. *U.S. holders are advised to consult their own tax advisers regarding their eligibility for Treaty benefits, especially with regard to the Limitations on Benefits provision, in light of their own particular circumstances.*

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Item 10. Additional Information

For the purposes of this discussion, a U.S. holder is a beneficial owner of Securities that is (i) an individual who is a U.S. citizen or resident for U.S. federal income tax purposes, (ii) a U.S. domestic corporation or certain other entities created or organized in or under the laws of the United States or any state thereof, including the District of Colombia, or (iii) otherwise subject to U.S. federal income taxation on a net income basis in respect of Securities. A non-U.S. holder is a person other than a U.S. holder.

If a partnership holds Securities, the tax treatment of a partner generally will depend upon the status of the partner and the activities of the partnership. *If a U.S. holder is a partner in a partnership that holds Securities, the holder is urged to consult its own tax adviser regarding the specific tax consequences of acquiring, owning and disposing of Securities.*

This discussion is intended only as a general summary and does not purport to be a complete analysis or listing of all potential tax effects of the acquisition, ownership or disposition of the Securities to any particular investor, and does not discuss tax considerations that arise from rules of general application or that are generally assumed to be known by investors. The discussion applies only to investors that hold our Securities as capital assets that have the U.S. dollar as their functional currency, that are entitled to Treaty benefits under the Limitation on Benefits provision contained in the Treaty, and whose ownership of the Securities is not effectively connected to a permanent establishment or a fixed base in France. Certain holders (including, but not limited to, U.S. expatriates, partnerships or other entities classified as partnerships for U.S. federal income tax purposes, banks, insurance companies, regulated investment companies, tax-exempt organizations, financial institutions, persons subject to the alternative minimum tax, persons who acquired the Securities pursuant to the exercise of employee stock options or otherwise as compensation, persons that own (directly, indirectly or by attribution) 5% or more of our voting stock or 5% or more of our outstanding share capital, dealers in securities or currencies, persons that elect to mark their securities to market for U.S. federal income tax purposes, persons that acquire ADSs in pre-release transactions (*i.e.*, prior to deposit of the relevant ordinary shares) and persons holding Securities as a position in a synthetic security, straddle or conversion transaction) may be subject to special rules not discussed below. *Holders of Securities are advised to consult their own tax advisers with regard to the application of French tax law and U.S. federal income tax law to their particular situations, as well as any tax consequences arising under the laws of any state, local or other foreign jurisdiction.*

French Taxes

Estate and Gift Taxes and Transfer Taxes

In general, a transfer of Securities by gift or by reason of death of a U.S. holder that would otherwise be subject to French gift or inheritance tax, respectively, will not be subject to such French tax by reason of the Convention between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Estates, Inheritances and Gifts, dated November 24, 1978, unless the donor or the transferor is domiciled in France at the time of making the gift or at the time of his or her death, or the Securities were used in, or held for use in, the conduct of a business through a permanent establishment or a fixed base in France.

Pursuant to Article 235 ter ZD of the French General Tax Code, purchases of Securities are subject to a 0.2% French tax on financial transactions (the FTFF) provided that Sanofi s market capitalization exceeds 1 billion euros as of December 1 of the year preceding the taxation year. A list of companies whose market capitalization exceeds 1 billion euros as of December 1 of the year preceding the taxation year used to be published annually by the French Ministry of Economy. It is now published by the French tax authorities, and could be amended at any time. Pursuant to Regulations BOI-ANNX-000467-20151221 issued on December 21, 2015, purchases of Sanofi s Securities in 2016 should be subject to the FTFF as the market capitalization of Sanofi exceeded 1 billion euros as of December 1, 2015. In accordance with Article 726-II of the French General Tax Code, purchases which are subject to the FTFF should however not be subject to transfer taxes (*droits d enregistrement*) in France.

Wealth Tax

The French wealth tax *impôt de solidarité sur la fortune* applies only to individuals and does not generally apply to the Securities if the holder is a U.S. resident, as defined pursuant to the provisions of the Treaty, provided that the individual does not own directly or indirectly a shareholding exceeding 25% of the financial rights.

U.S. Taxes

Ownership of the Securities

Deposits and withdrawals by a U.S. holder of ordinary shares in exchange for ADSs, will not be taxable events for U.S. federal income tax purposes. For U.S. tax purposes, holders of ADSs will be treated as owners of the ordinary shares represented by such ADSs. Accordingly, the discussion that follows regarding the U.S. federal income tax consequences of acquiring, owning and disposing of ordinary shares is equally applicable to ADSs.

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Information Reporting and Backup Withholding Tax

Distributions made to holders and proceeds paid from the sale, exchange, redemption or disposal of Securities may be subject to information reporting to the Internal Revenue Service. Such payments may be subject to backup withholding taxes unless the holder (i) is a corporation or other exempt recipient or (ii) provides a taxpayer identification number and certifies that no loss of exemption from backup withholding has occurred. Holders that are not U.S. persons generally are not subject to information reporting or backup withholding. However, such a holder may be required to provide a certification of its non-U.S. status in connection with payments received within the United States or through a U.S.-related financial intermediary to establish that it is an exempt recipient. Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a holder s U.S. federal income tax liability. A holder may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the Internal Revenue Service and furnishing any required information.

Foreign Asset Reporting

In addition, a U.S. holder that is an individual (and, to the extent provided in future regulations, an entity), may be subject to recently-enacted reporting obligations with respect to ordinary shares and ADSs if the aggregate value of these and certain other specified foreign financial assets exceeds $50,000. If required, this disclosure is made by filing Form 8938 with the U.S. Internal Revenue Service. Significant penalties can apply if holders are required to make this disclosure and fail to do so. In addition, a U.S. holder should consider the possible obligation to file online a FinCEN Form 114 Foreign Bank and Financial Accounts Report as a result of holding ordinary shares or ADSs. Holders are encouraged to consult their U.S. tax advisors with respect to these and other reporting requirements that may apply to their acquisition of ordinary shares and ADSs.

State and Local Taxes

In addition to U.S. federal income tax, U.S. holders of Securities may be subject to U.S. state and local taxes with respect to such Securities. *Holders of Securities are advised to consult their own tax advisers with regard to the application of U.S. state and local income tax law to their particular situation.*

ADSs-Ordinary Shares

French Taxes

Taxation of Dividends

Under French law, dividends paid by a French corporation, such as Sanofi, to non-residents of France are generally

subject to French withholding tax at a rate of 30% (21% for distributions made to individuals that are resident in the European Economic Area, and 15% for distributions made to not-for-profit organizations with a head office in a Member State of the European Economic Area which would be subject to the tax regime set forth under article 206-5 of the French General Tax Code if its head office were located in France and which meet the criteria set forth in the administrative guidelines BOI-RPPM-RCM-30- 30-10-70-20120912, nº 130). Dividends paid by a French corporation, such as Sanofi, towards non-cooperative States or territories, as defined in Article 238-0 A of the French General Tax Code, will generally be subject to French withholding tax at a rate of 75%, irrespective of the tax residence of the beneficiary of the dividends if the

dividends are received in such States or territories; however, eligible U.S. holders entitled to Treaty benefits under the Limitation on Benefits provision contained in the Treaty who are U.S. residents, as defined pursuant to the provisions of the Treaty and who receive dividends in non-cooperative States or territories, will not be subject to this 75% withholding tax rate.

Under the Treaty, the rate of French withholding tax on dividends paid to an eligible U.S. holder who is a U.S. resident as defined pursuant to the provisions of the Treaty and whose ownership of the ordinary shares or ADSs is not effectively connected with a permanent establishment or fixed base that such U.S. holder has in France, is reduced to 15%, or to 5% if such U.S. holder is a corporation and owns directly or indirectly at least 10% of the share capital of the issuing company; such U.S. holder may claim a refund from the French tax authorities of the amount withheld in excess of the Treaty rates of 15% or 5%, if any. For U.S. holders that are not individuals but are U.S. residents, as defined pursuant to the provisions of the Treaty, the requirements for eligibility for Treaty benefits, including the reduced 5% or 15% withholding tax rates contained in the Limitation on Benefits provision of the Treaty, are complicated, and certain technical changes were made to these requirements by the protocol of January 13, 2009. U.S. holders are advised to consult their own tax advisers regarding their eligibility for Treaty benefits in light of their own particular circumstances.

Dividends paid to an eligible U.S. holder may immediately be subject to the reduced rates of 5% or 15% provided that such holder establishes before the date of payment that it is a U.S. resident under the Treaty by completing and providing the depositary with a treaty form (Form 5000). Dividends paid to a U.S. holder that has not filed the Form 5000 before the dividend payment date will be subject to French withholding tax at the rate of 30% and then reduced at a later date to 5% or 15%, provided that such holder duly completes and provides the French tax authorities with the treaty forms Form 5000 and Form 5001 before December 31 of the second calendar year following the year during which the dividend is paid. Pension funds and certain other tax-exempt entities are subject to the same general filing

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Item 10. Additional Information

requirements as other U.S. holders except that they may have to supply additional documentation evidencing their entitlement to these benefits.

The depositary agrees to use reasonable efforts to follow the procedures established, or that may be established, by the French tax authorities (i) to enable eligible U.S. holders to qualify for the reduced withholding tax rate provided by the Treaty, if available at the time the dividends are paid, or (ii) to recover any excess French withholding taxes initially withheld or deducted with respect to dividends and other distributions to which such U.S. holders may be eligible from the French tax authorities and (iii) to recover any other available tax credits. In particular, associated forms (including Form 5000 and Form 5001, together with their instructions), will be made available by the depositary to all U.S. holders registered with the depositary, and are also generally available from the U.S. Internal Revenue Service.

The withholding tax refund, if any, ordinarily is paid within 12 months of filing the applicable French Treasury Form, but not before January 15 of the year following the calendar year in which the related dividend is paid.

Tax on Sale or Other Disposition

In general, under the Treaty, a U.S. holder who is a U.S. resident for purposes of the Treaty will not be subject to French tax on any capital gain from the redemption (other than redemption proceeds characterized as dividends under French domestic law), sale or exchange of ordinary shares or ADSs unless the ordinary shares or the ADSs form part of the business property of a permanent establishment or fixed base that the U.S. holder has in France. Special rules apply to holders who are residents of more than one country.

U.S. Taxes

Taxation of Dividends

For U.S. federal income tax purposes, the gross amount of any distribution paid to U.S. holders (that is, the net distribution received plus any tax withheld therefrom) will be treated as ordinary dividend income to the extent paid or deemed paid out of the current or accumulated earnings and profits of Sanofi (as determined under U.S. federal income tax principles). Dividends paid by Sanofi will not be eligible for the dividends-received deduction generally allowed to corporate U.S. holders.

Subject to certain exceptions for short-term and hedged positions, the U.S. dollar amount of dividends received by an individual U.S. holder with respect to the ADSs or our ordinary shares is currently subject to taxation at a maximum rate of 20% if the dividends are qualified dividends . Dividends paid on the ordinary shares or ADSs will be treated as qualified dividends if (i) the issuer is eligible for the benefits of a comprehensive income tax treaty with the United States that the Internal Revenue Service has

approved for the purposes of the qualified dividend rules and (ii) the issuer was not, in the year prior to the year in which the dividend was paid, and is not, in the year in which the dividend is paid, a passive foreign investment company (PFIC). The Treaty has been approved for the purposes of the qualified dividend rules. Based on our audited financial statements and relevant market and shareholder data, we believe Sanofi was not a PFIC for U.S. federal income tax purposes with respect to its 2014 taxable year. In addition, based on its current expectations regarding the value and nature of its assets, the sources and nature of its income, and relevant market and shareholder data, we do not anticipate that Sanofi will become a PFIC for its 2015 taxable year. *Holders of ordinary shares and ADSs should consult their own tax advisers regarding the availability of the reduced dividend tax rate in light of their own particular circumstances.*

If you are a U.S. holder, dividend income received by you with respect to ADSs or ordinary shares generally will be treated as foreign source income for foreign tax credit purposes. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. Distributions out of earnings and profits with respect to the ADSs or ordinary shares generally will be treated as passive category income (or, in the case of certain U.S. holders, general category income). Subject to certain limitations, French income tax withheld in connection with any distribution with respect to the ADSs or ordinary shares may be claimed as a credit against the U.S. federal income tax liability of a U.S. holder if such U.S. holder elects for that year to credit all foreign income taxes. Alternatively, such French withholding tax

may be taken as a deduction against taxable income. Foreign tax credits will not be allowed for withholding taxes imposed in respect of certain short-term or hedged positions in Securities and may not be allowed in respect of certain arrangements in which a U.S. holder s expected economic profit is insubstantial. *The U.S. federal income tax rules governing the availability and computation of foreign tax credits are complex. U.S. holders should consult their own tax advisers concerning the implications of these rules in light of their particular circumstances.*

To the extent that an amount received by a U.S. holder exceeds the allocable share of our current and accumulated earnings and profits, such excess will be applied first to reduce such U.S. holder s tax basis in its ordinary shares or ADSs and then, to the extent it exceeds the U.S. holder s tax basis, it will constitute capital gain from a deemed sale or exchange of such ordinary shares or ADSs (see Tax on Sale or Other Disposition , below).

The amount of any distribution paid in euros will be equal to the U.S. dollar value of the euro amount distributed, calculated by reference to the exchange rate in effect on the date the dividend is received by a U.S. holder of ordinary shares (or by the depositary, in the case of ADSs) regardless of whether the payment is in fact converted into

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U.S. dollars on such date. *U.S. holders should consult their own tax advisers regarding the treatment of foreign currency gain or loss, if any, on any euros received by a U.S. holder that are converted into U.S. dollars on a date subsequent to receipt.*

Distributions to holders of additional ordinary shares (or ADSs) with respect to their ordinary shares (or ADSs) that are made as part of a pro rata distribution to all ordinary shareholders generally will not be subject to U.S. federal income tax. However, if a U.S. holder has the option to receive a distribution in shares (or ADSs) or to receive cash in lieu of such shares (or ADSs), the distribution of shares (or ADSs) will be taxable as if the holder had received an amount equal to the fair market value of the distributed shares (or ADSs), and such holder s tax basis in the distributed shares (or ADSs) will be equal to such amount.

Tax on Sale or Other Disposition

In general, for U.S. federal income tax purposes, a U.S. holder that sells, exchanges or otherwise disposes of its ordinary shares or ADSs will recognize capital gain or loss in an amount equal to the U.S. dollar value of the difference between the amount realized for the ordinary shares or ADSs and the U.S. holder s adjusted tax basis (determined in U.S. dollars and under U.S. federal income tax rules) in the ordinary shares or ADSs. Such gain or loss generally will be U.S.-source gain or loss, and will be treated as long term capital gain or loss if the U.S. holder s holding period in the ordinary shares or ADSs exceeds one year at the time of disposition. If the U.S. holder is an individual, any capital gain generally will be subject to U.S. federal income tax at preferential rates (currently a maximum of 20%) if specified minimum holding periods are met. The deductibility of capital losses is subject to significant limitations.

Medicare Tax

Certain U.S. holders who are individuals, estates or trusts are now required to pay a Medicare tax of 3.8% (in addition

to taxes they would otherwise be subject to) on their net investment income which would include, among other things, dividends and capital gains from the ordinary shares and ADSs.

F. Dividends and Paying Agents

N/A

G. Statement by Experts

N/A

H. Documents on Display

We are subject to the information requirements of the U.S. Securities Exchange Act of 1934, as amended, or Exchange Act, and, in accordance therewith, we are required to file reports, including this annual report on Form 20-F, and other information with the U.S. Securities and Exchange Commission, or Commission, by electronic means.

You may review a copy of our filings with the Commission, as well as other information furnished to the Commission, including exhibits and schedules filed with it, at the Commission s public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Please call the SEC at 1-800-SEC- 0330 for further information. In addition, the Commission maintains an Internet site at http://www.sec.gov that contains reports and other information regarding issuers that file electronically with the Commission (these documents are not incorporated by reference

in this annual report).

I. Subsidiary Information

N/A

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Item 11. Quantitative and Qualitative Disclosures about Market Risk

Item 11. Quantitative and Qualitative Disclosures about Market Risk (1)

General Policy

Liquidity risk, foreign exchange risk and interest rate risk, as well as related counterparty risks, are managed centrally by our dedicated treasury team within the Group Finance Department. Where it is not possible to manage those risks centrally in particular due to regulatory restrictions (such as foreign exchange controls) or local tax restrictions credit facilities and/or currency lines, guaranteed whenever necessary by the parent company, are contracted by our subsidiaries locally with banks, under the supervision of the central treasury team.

Our financing and investment strategies, and our interest rate and currency hedging strategies, are reviewed monthly by the Group Finance Department.

Our policy prohibits the use of derivatives for speculative purposes.

Liquidity Risk

We operate a centralized treasury platform whereby all surplus cash and financing needs of our subsidiaries are invested with or funded by the parent company (where permitted by local legislation). The central treasury department manages the Group s current and projected financing, and ensures that the Group is able to meet its financial commitments by maintaining sufficient cash and confirmed credit facilities for the size of our operations and the maturity of our debt (see Notes D.17.c and D.17.g to the consolidated financial statements).

We diversify our short-term investments with leading counterparties using money-market products with instant access or with a maturity of less than three months. As of December 31, 2015, cash and cash equivalents amounted to 9,148 million, and our short-term investments predominantly comprised:

- collective investments in short-term money market and money market euro-denominated funds based on the European classification used by the *Autorité des Marchés Financiers*. All such funds can be traded on a daily basis and the amount invested in each fund may not exceed 10% of the aggregate amount invested in such funds;
- amounts invested directly with banks in the form of instant access deposits, term deposits, and certificates of deposit with a maturity of no more than three months;
- amounts invested directly with non-financial institutions in the form of commercial paper and euro commercial paper with a maturity of no more than three months.

As of December 31, 2015, the Group also had 8 billion of undrawn general corporate purpose confirmed credit facilities, expiring December 2020. Those credit facilities are not subject to financial covenant ratios.

Our policy is to diversify our sources of funding through public or private issuances of debt securities, in the United States (shelf registration statement) and Europe (Euro Medium Term Note program). In addition, our A-1+/P-1 short-term rating gives us access to commercial paper programs in the United States and, to a lesser extent, in France. The average maturity of our total debt was 4.5 years as of December 31, 2015, compared with 4.6 years as of December 31, 2014. During 2015, we did not draw down on our French commercial paper program. Average drawdowns under the U.S. commercial paper program during 2015 were 2.1 billion (maximum 3.7 billion); the average maturity of those drawdowns was two months. As of December 31, 2015, neither of those programs was being utilized.

In the event of a liquidity crisis, we could be exposed to difficulties in calling up our available cash, a scarcity of sources of funding including the above-mentioned programs, and/or a deterioration in their terms. This situation could damage our capacity to refinance our debt or to issue new debt on reasonable terms.

Interest Rate Risk

We manage our net debt mainly in two currencies: the euro and the U.S. dollar (see note D.17 to the consolidated financial statements). The floating-rate portion of this debt exposes the Group to rises in interest rates, primarily in the Eonia and Euribor benchmark rates (for the euro) and in the U.S. Libor and Federal Fund Effective rates (for the U.S. dollar). To optimize (or reduce the volatility of) our cost of debt, we use interest rate swaps, cross-currency swaps and where appropriate interest rate options, that alter the fixed/floating rate split of our debt. Those derivative instruments are predominantly denominated in euros and in U.S. dollars.

(1) The disclosures in this section supplement those provided in Note B.8.8. to the consolidated financial statements as regards the disclosure requirements of IFRS 7, and are covered by the statutory auditors opinion on the consolidated financial statements.

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The projected full-year sensitivity to interest rate fluctuations of our debt, net of cash and cash equivalents for 2016 is as follows:

Change in EUR and USD short-term interest rates	**Impact on pre-tax net income (million)**	**Impact on pre-tax income/(expense) recognized directly in equity (million)**
+100 bp	32	9
+25 bp	8	2
-25 bp	(8)	(2)
-100 bp	(32)	(9)

Foreign Exchange Risk

a. Operating Foreign Exchange Risk

A substantial portion of our net sales is generated in countries where the euro, which is our reporting currency, is not the functional currency. In 2015, for example, 36% of our aggregate net sales were generated in the United States, 32% in Emerging Markets (including countries that are, or may in future become, subject to exchange controls), and 6% in Japan. Although we also incur expenses in those countries, the impact of those expenses is not enough wholly to offset the impact of exchange rates on our net sales. Consequently, our operating income may be materially affected by fluctuations in exchange rates between the euro and other currencies.

We operate a foreign exchange risk hedging policy to reduce the exposure of our operating income to exchange rate

movements. This policy involves regular assessments of our worldwide foreign currency exposure, based on foreign-currency transactions carried out by the parent company and its subsidiaries. Those transactions mainly comprise sales, purchases, research costs, co-marketing and co-promotion expenses, and royalties. To reduce the exposure of those transactions to exchange rate movements, we contract hedges using liquid derivative instruments, mainly forward currency purchases and sales, and also currency swaps.

The table below shows operating currency hedging instruments in place as of December 31, 2015, with the notional amount translated into euros at the relevant closing exchange rate (see Note D.20. to the consolidated financial statements for the accounting classification of those instruments as of December 31, 2015).

Operating foreign exchange derivatives as of December 31, 2015

(million)	**Notional amount**	**Fair value**

Forward currency sales	**2,142**	**27**
of which U.S. dollar	672	(2)
of which Chinese yuan renminbi	339	1
of which Japanese yen	159	(1)
of which Russian rouble	130	22
of which Singapore dollar	114	
Forward currency purchases	**905**	**(11)**
of which U.S. dollar	204	
of which Russian rouble	109	(9)
of which Singapore dollar	104	(1)
of which Hungarian forint	90	(1)
of which Chinese yuan renminbi	86	2
Total	**3,047**	**16**

The above positions mainly hedge future material foreign-currency cash flows arising after the end of the

reporting period in relation to transactions carried out during the year ended December 31, 2015 and recognized in the

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Item 11. Quantitative and Qualitative Disclosures about Market Risk

balance sheet at that date. Gains and losses on hedging instruments (forward contracts) have been and will continue to be calculated and recognized in parallel with the recognition of gains and losses on the hedged items. Due to this hedging relationship, the commercial foreign exchange gain or loss on these items (hedging instruments and hedged transactions) will be immaterial in 2016.

b. Financial Foreign Exchange Risk

The cash pooling arrangements for our foreign subsidiaries outside the euro zone, and some of our financing activities, expose certain of our entities to financial foreign exchange risk (i.e., the risk of changes in the value of borrowings and loans denominated in a currency other than the functional currency of the borrower or lender). That foreign exchange

exposure is hedged by the parent company using firm financial instruments (usually currency swaps or forward contracts) contracted with banking counterparties.

Although we incur more of our costs in euros than in any other currency, the U.S. dollar accounts for a higher proportion of our revenues than any other currency. Consequently, we maintain a significant portion of our indebtedness in U.S. dollars.

The table below shows financial currency hedging instruments in place as of December 31, 2015, with the notional amounts translated into euros at the relevant closing exchange rate (see also Note D.20 to the consolidated financial statements for the accounting classification of these instruments as of December 31, 2015).

Financial foreign exchange derivatives as of December 31, 2015

(million)	Notional amount	Fair value	Expiry
Forward currency sales	**3,472**	**(44)**	
of which U.S. dollar	2,171	(30)	2016
of which Japanese yen	612	(9)	2016
of which Australian dollar	266	(4)	2016
Forward currency purchases	**2,623**	**9**	
of which U.S. dollar[(1)]	610	5	2016
of which Swiss franc	363	(1)	2016
of which Singapore dollar	310		2016
Total	**6,095**	**(35)**	

(1) Includes U.S.$84 million designated as a cash flow hedge as of December 31, 2015.

These forward currency contracts generate a net financial foreign exchange gain or loss arising from the interest rate differential between the hedged currency and the euro, given that the foreign exchange gain or loss on the foreign-currency borrowing and loans is offset by the change in the intrinsic value of the hedging instruments.

We may also hedge some future foreign-currency investment or divestment cash flows.

c. Other Foreign Exchange Risks

A significant proportion of our net assets is denominated in U.S. dollars (see Note D.35. to the consolidated financial statements). As a result, any fluctuation in the exchange rate of the U.S. dollar against the euro automatically impacts the amount of our equity as expressed in euros. As of December 31, 2015, we had no derivative instruments in place to limit the effect of such fluctuations, but a significant proportion of our debt is still denominated in U.S. dollars.

In addition, we use the euro as our reporting currency. Consequently, if one or more European Union member states were to abandon the euro as a currency, the resulting economic upheavals in particular, fluctuations in exchange rates could have a significant impact on the terms under which we can obtain financing and on our financial results, the extent and consequences of which are not currently foreseeable.

Counterparty Risk

Our financing and investing transactions, and our currency and interest rate hedges, are contracted with leading counterparties. We set limits for investment and derivative transactions with individual financial institutions, depending on the rating of each institution. Compliance with these limits, which are based on notional amounts weighted by the residual maturity and the nature of the commitment, is monitored on a daily basis.

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The table below shows our total exposure as of December 31, 2015 by rating and in terms of our percentage exposure to the dominant counterparty.

(million)	**Cash and cash equivalents (excluding mutual funds)(1)**	**Notional amounts of currency hedges(2)**	**Notional amounts of interest rate hedges(2)**	**General corporate purpose credit facilities**
AA-	4	922	392	500
A+	1,337	1,076	1,818	1,500
A	1,848	4,632	1,507	3,500
A	320	1,840	400	1,500
BBB+	257	451	546	1,000
BBB	170			
Unallocated	170	223		
Total	4,106	9,144	4,663	8,000
% / rating of dominant counterparty	20% / A+	13% / A	26% / A+	6% / BBB+

(1) Cash equivalents include mutual fund investments of 5,042 million.

(2) The notional amounts are translated into euros at the relevant closing exchange rate as of December 31, 2015.

As of December 31, 2015, we held investments in short-term money market and money market euro-denominated funds based on the European classification used by the *Autorité des Marchés Financiers*. Those instruments have low volatility, low sensitivity to interest rate risk, and a very low probability of loss of principal. The depositary banks of the mutual funds, and of Sanofi itself, have a long-term rating of at least A.

Realization of counterparty risk could impact our liquidity in certain circumstances.

Stock Market Risk

It is our policy not to trade on the stock market for speculative purposes.

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Item 12. Description of Securities other than Equity Securities

Item 12. Description of Securities other than Equity Securities

12.A Debt Securities

Not applicable.

12.B Warrants and Rights

Not applicable.

12.C Other Securities

Not applicable.

12.D American Depositary Shares

General

JPMorgan Chase Bank, N.A. (JPMorgan), as depositary, issues Sanofi ADSs in certificated form (evidenced by an ADR) or book-entry form. Each ADR is a certificate evidencing a specific number of Sanofi ADSs. Each Sanofi ADS represents one-half of one Sanofi ordinary share (or the right to receive one-half of one Sanofi ordinary share) deposited with the Paris, France office of BNP Paribas, as custodian. Each Sanofi ADS also represents an interest in any other securities, cash or other property that may be held by the depositary under the deposit agreement. The depositary s office is located at 4 New York Plaza, 12th Floor, New York, New York 10004.

A holder may hold Sanofi ADSs either directly or indirectly through his or her broker or other financial institution. The following description assumes holders hold their Sanofi ADSs directly, in certificated form evidenced by ADRs. Holders who hold the Sanofi ADSs indirectly must rely on the procedures of their broker or other financial institution to assert the rights of ADR holders described in this section. Holders should consult with their broker or financial institution to find out what those procedures are.

Holders of Sanofi ADSs do not have the same rights as holders of Sanofi shares. French law governs shareholder rights. The rights of holders of Sanofi ADSs are set forth in the deposit agreement between Sanofi and JPMorgan and in the ADR. New York law governs the deposit agreement and the ADRs.

The following is a summary of certain terms of the deposit agreement, as amended. Our form of second amended and restated deposit agreement was filed as an exhibit to our Post-Effective Amendment No. 1 to Form F-6 filed on February 13, 2015. To the extent any portion of the amendment and restatement would prejudice any substantial existing right of holders of ADSs under the first amended and restated deposit agreement, such portion shall not

become effective as to such holders until 30 days after holders have received notice thereof. For more complete information, holders should read the entire second amended and restated deposit agreement and the ADR itself. Holders may also inspect a copy of the current deposit agreement at the depositary s office.

Share Dividends and Other Distributions

Receipt of dividends and other distributions

The depositary has agreed to pay to holders of Sanofi ADSs the cash dividends or other distributions that it or the custodian receives on the deposited Sanofi ordinary shares and other deposited securities after deducting its fees and expenses. Holders of Sanofi ADSs will receive these distributions in proportion to the number of Sanofi ADSs that they hold.

Cash. The depositary will convert any cash dividend or other cash distribution paid on the shares into U.S. dollars if, in its judgment, it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If the depositary determines that such a conversion and transfer is not possible, or if any approval from the French government is needed and cannot be obtained within a reasonable period, then the depositary may (1) distribute the foreign currency received by it to the holders of Sanofi ADSs or (2) hold the foreign currency distribution (uninvested and without liability for any interest) for the account of holders of Sanofi ADSs.

In addition, if any conversion of foreign currency, in whole or in part, cannot be effected to some holders of Sanofi ADSs, the deposit agreement allows the depositary to distribute the dividends only to those ADR holders to whom it is possible to do so. It will hold the foreign currency it cannot convert into U.S. dollars for the account of the ADR holders who have not been paid. It will not invest the funds it holds and it will not be liable for any interest.

Before making a distribution, any withholding taxes that must be paid under French law will be deducted. The depositary will distribute only whole U.S. dollars and cents and will round fractional cents down to the nearest whole cent. ***Exchange rate fluctuations during a period when the depositary cannot convert euros into U.S. dollars may result in holders losing some or all of the value of a distribution.***

Shares. The depositary may, and at our request will, distribute new ADRs representing any shares we distribute as a dividend or free distribution, if we furnish it promptly with satisfactory evidence that it is legal to do so. At its option, the depositary may distribute fractional Sanofi ADSs. If the depositary does not distribute additional Sanofi ADSs, the outstanding ADRs will also represent the new shares. The depositary may withhold any tax or other governmental charges, or require the payment of any required fees and expenses, prior to making any distribution of additional Sanofi ADSs.

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Rights to Receive Additional Shares. If we offer holders of Sanofi ordinary shares any rights to subscribe for additional shares or any other rights, the depositary, after consultation with us, will, in its discretion, either (1) make these rights available to holders or (2) dispose of such rights on behalf of holders and make the net proceeds available to holders. The depositary may make rights available to certain holders but not others if it determines it is lawful and feasible to do so. However, if, under the terms of the offering or for any other reason, the depositary may not make such rights available or dispose of such rights and make the net proceeds available, it will allow the rights to lapse. In that case, holders of Sanofi ADSs will receive no value for them.

In circumstances where rights would not otherwise be distributed by the depositary to holders of Sanofi ADSs, a holder of Sanofi ADSs may nonetheless request, and will receive from the depositary, any instruments or other documents necessary to exercise the rights allocable to that holder if the depositary first receives written notice from Sanofi that (1) Sanofi has elected, in its sole discretion, to permit the rights to be exercised and (2) such holder has executed the documents Sanofi has determined, in its sole discretion, are reasonably required under applicable law.

If the depositary makes rights available to holders of Sanofi ADSs, upon instruction from such holders, it will exercise the rights and purchase the shares on such holder s behalf. The depositary will then deposit the shares and deliver ADRs to such holders. It will only exercise rights if holders of Sanofi ADSs pay it the exercise price and any other charges the rights require such holders to pay.

U.S. securities laws may restrict the sale, deposit, cancellation or transfer of ADRs issued upon exercise of rights. For example, holders of Sanofi ADSs may not be able to trade Sanofi ADSs freely in the United States. In this case, the depositary may deliver Sanofi ADSs under a separate restricted deposit agreement that will contain the same provisions as the deposit agreement, except for changes needed to implement the required restrictions.

Other Distributions. The depositary will distribute to holders of Sanofi ADSs anything else we may distribute on deposited securities (after deduction or upon payment of fees and expenses or any taxes or other governmental charges) by any means it thinks is legal, equitable and practical. If, for any reason, it cannot make the distribution in that way, the depositary may sell what we distributed and distribute the net proceeds of the sale in the same way it distributes cash dividends, or it may choose any other method to distribute the property it deems equitable and practicable.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of Sanofi ADSs. We have no obligation to register Sanofi ADSs, shares, rights or other securities under the U.S. Securities Act of 1933, as amended. We also have no

obligation to take any other action to permit the distribution of ADRs, shares, rights or anything else to holders of Sanofi ADSs. This means that holders may not receive the distribution we make on our shares or any value for them if it is illegal or impractical for the depositary to make them available to such holders.

Elective Distributions. Whenever we intend to distribute a dividend payable at the election of shareholders either in cash or in additional shares, we will give prior notice thereof to the depositary and will indicate whether we wish the elective distribution to be made available to holders of Sanofi ADSs. In that case, we will assist the depositary in determining whether that distribution is lawful and reasonably practicable. The depositary will make the election available to holders of Sanofi ADSs only if it is reasonably practicable and if we have provided all the documentation contemplated in the deposit agreement. In that case, the depositary will establish procedures to enable holders of Sanofi ADSs to elect to receive either cash or additional ADSs, in each case as described in the deposit agreement. If the election is not made available to holders of Sanofi ADSs, such holders will receive either cash or additional Sanofi ADSs, depending on what a shareholder in France would receive for failing to make an election, as more fully described in the deposit agreement.

Deposit, Withdrawal and Cancellation

Delivery of ADRs

The depositary will deliver ADRs if the holder or his or her broker deposit shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of Sanofi ADSs in the names the holder requests and will deliver the ADRs to the persons the holder requests at its office.

Obtaining Sanofi ordinary shares

A holder may turn in his or her ADRs at the depositary s office. Upon payment of its fees and expenses and any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver (1) the underlying shares to an account designated by the holder and (2) any other deposited securities underlying the ADR at the office of a custodian or, at the holder s request, risk and expense, the depositary will deliver the deposited securities at its office.

Voting Rights

A holder may instruct the depositary to vote the Sanofi ordinary shares underlying his or her Sanofi ADSs at any meeting of Sanofi shareholders, but only if we request that the depositary ask for holder instructions. Otherwise, holders will not be able to exercise their right to vote unless they withdraw the underlying ordinary shares from the ADR

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Item 12. Description of Securities other than Equity Securities

program and vote as an ordinary shareholder. However, holders may not know about the meeting sufficiently in advance to timely withdraw the underlying ordinary shares.

If we ask for holder instructions in connection with a meeting of Sanofi shareholders, the depositary will provide materials to holders of Sanofi ADSs in the manner described under the heading Notices and Reports; Rights of Holders to Inspect Books below. For any instructions to be valid, the depositary must receive them on or before the date specified in the materials distributed by the depositary. The depositary will endeavor, in so far as practical, subject to French law and the provisions of our *statuts*, to vote or to have its agents vote the shares or other deposited securities as holders may validly instruct. The depositary will only vote or attempt to vote shares as holders validly instruct.

We cannot guarantee holders that they will receive the voting materials with sufficient time to enable them to return any voting instructions to the depositary in a timely manner to vote their shares. As long as they act in good faith, neither the depositary nor its agents will be responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. ***This means that holders may not be able to exercise their right to vote and there may be nothing holders can do if their shares are not voted as they requested.***

Similar to our shares, Sanofi ADSs evidenced by ADRs that are registered in the name of the same owner for at least two (2) years are eligible for double voting rights so long as certain procedures are followed, as set out in the deposit agreement. For additional information regarding double voting rights, see Item 10. Additional Information B. Memorandum and Articles of Association Voting Rights .

The deposit agreement allows the depositary and Sanofi to change the voting procedures or require additional voting procedures in addition to the ones described above if necessary or appropriate. ***For example, holders might be required to arrange to have their Sanofi ADSs deposited in a blocked account for a specified period of time prior to a shareholders meeting in order to be allowed to give voting instructions.***

Notices and Reports; Rights of Holders to Inspect Books

On or before the first date on which we give notice, by publication or otherwise, of any meeting of holders of shares or other deposited securities, or of any adjourned meeting of such holders, or of the taking of any action in respect of any

cash or other distributions or the offering of any rights, we will transmit to the depositary a copy of the notice.

Upon notice of any meeting of holders of shares or other deposited securities, if requested in writing by Sanofi, the depositary will, as soon as practicable, mail to the holders of Sanofi ADSs a notice, the form of which is in the discretion of the depositary, containing (1) a summary in English of the information contained in the notice of meeting provided by Sanofi to the depositary, (2) a statement that the holders as of the close of business on a specified record date will be entitled, subject to any applicable provision of French law and of our *statuts*, to instruct the depositary as to the exercise of the voting rights, if any, pertaining to the amount of shares or other deposited securities represented by their respective ADSs and (3) a statement as to the manner in which such instructions may be given. Notwithstanding the above, the depositary may, to the extent not prohibited by law or regulations, or by the requirements of the NYSE, in lieu of distribution of the materials provided to the depositary as described above, distribute to the holders a notice that provides holders with, or otherwise publicizes to holders, instructions on how to retrieve such materials or receive such materials upon request (i.e., by reference to a website containing the materials for retrieval or a contact for requesting copies of the materials).

The depositary will make available for inspection by ADS holders at the depositary s office any reports and communications, including any proxy soliciting material, received from us that are both (1) received by the depositary as the holder of the deposited securities and (2) made generally available to the holders of such deposited securities by us. The depositary will also, upon written request, send to ADS holders copies of such reports when furnished by us pursuant to the deposit agreement. Any such reports and communications, including any such proxy soliciting material, furnished to the depositary by us will be furnished in English to the extent such materials are required to be translated into English pursuant to any regulations of the SEC.

The depositary will keep books for the registration of ADRs and transfers of ADRs that at all reasonable times will be open for inspection by the holders provided that such inspection is not for the purpose of communicating with holders in the interest of a business or object other than our business or a matter related to the deposit agreement or the ADRs.

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Item 12. Description of Securities other than Equity Securities

Fees and Expenses

Fees Payable By ADS Holders

Pursuant to the deposit agreement, holders of our ADSs may have to pay to JPMorgan, either directly or indirectly, fees or charges up to the amounts set forth in the table below.

Associated Fee	Depositary Action
$5.00 or less per 100 ADSs (or portion thereof)	Execution and delivery of ADRs for distributions and dividends in shares and rights to subscribe for additional shares or rights of any other nature and surrender of ADRs for the purposes of withdrawal, including the termination of the deposit agreement
$0.05 or less per ADS (or portion thereof)	Any cash distribution made pursuant to the deposit agreement, including, among other things: · cash distributions or dividends, · distributions other than cash, shares or rights, · distributions in shares, and · rights of any other nature, including rights to subscribe for additional shares.
Registration fees in effect for the registration of transfers of shares generally on the share register of the company or foreign registrar and applicable to transfers of shares to or from the name of JPMorgan or its nominee to the custodian or its nominee on the making of deposits and withdrawals	As applicable
A fee equal to the fee for the execution and delivery of ADSs which would have been charged as a result of the deposit of such securities	Distributions of securities other than cash, shares or rights
A fee for the reimbursement of such fees, charges and expenses as are incurred by JPMorgan, its agents (and their agents), including BNP Paribas, as custodian (by deductions from cash dividends or other cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them)	Compliance with foreign exchange control regulations or any law or regulation relating to foreign investment, servicing of shares or other deposited securities, sale of securities, delivery of deposited securities or otherwise
Expenses incurred by JPMorgan	· Cable, telex and facsimile transmission (where expressly provided for in the deposit agreement) · Foreign currency conversion into U.S. dollars

In addition to the fees outlined above, each holder will be responsible for any taxes or other governmental charges payable on his or her Sanofi ADSs or on the deposited securities underlying his or her Sanofi ADSs. The depositary may refuse to transfer a holder s Sanofi ADSs or allow a holder to withdraw the deposited securities underlying his or her Sanofi ADSs until such taxes or other charges are paid. It may apply payments owed to a holder or sell deposited securities underlying a holder s Sanofi ADSs to pay any taxes owed, and the holder will remain liable for any deficiency. If it sells deposited securities, it will, if appropriate, reduce the number of Sanofi ADSs to reflect the sale and pay to the holder any

proceeds, or send to the holder any property, remaining after it has paid the taxes. For additional information regarding taxation, see Item 10. Additional Information E. Taxation .

Fees Paid to Sanofi by the Depositary

JPMorgan, as depositary, has agreed to reimburse Sanofi for certain expenses (subject to certain limits) Sanofi incurs relating to legal fees, investor relations servicing, investor-related presentations, ADR-related advertising and public relations in those jurisdictions in which the ADRs may be listed or otherwise quoted, investor relations channel, perception studies, accountants fees in relation to our annual report on Form 20-F or any other expenses directly or indirectly relating to managing the program or servicing the ADR holders. The depositary has also agreed to provide additional amounts to us based on certain performance indicators relating to the ADR facility and fees collected by it. From January 1, 2015 to December 31, 2015, we received a total amount of $16,159,254 from JPMorgan. In addition to these payments, JPMorgan has agreed to waive servicing

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Item 12. Description of Securities other than Equity Securities

fees we may incur in connection with routine corporate actions such as annual general meetings and dividend distributions, as well as for other assistance JPMorgan may provide to us, such as preparation of tax and regulatory compliance documents for holders and investor relations advisory services.

Changes Affecting Deposited Securities

If we:

- change the nominal or par value of our Sanofi ordinary shares;
- recapitalize, reorganize, merge or consolidate, liquidate, sell assets, or take any similar action;
- reclassify, split up or consolidate any of the deposited securities; or
- distribute securities on the deposited securities that are not distributed to holders;

then either:

- the cash, shares or other securities received by the depositary will become deposited securities and each Sanofi ADS will automatically represent its equal share of the new deposited securities; or
- the depositary may, and will if we ask it to, distribute some or all of the cash, shares or other securities it receives. It may also deliver new ADRs or ask holders to surrender their outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

Disclosure of Interests

The obligation of a holder or other person with an interest in our shares to disclose information under French law and under our *statuts* also applies to holders and any other persons, other than the depositary, who have an interest in the Sanofi ADSs. The consequences for failing to comply with these provisions are the same for holders and any other persons with an interest as a holder of our ordinary shares. For additional information regarding these obligations, see Item 10. Additional Information B. Memorandum and Articles of Association Requirements for Holdings Exceeding Certain Percentages .

Amendment and Termination

We may agree with the depositary to amend the deposit agreement and the ADRs without the consent of the ADS holders for any reason. If the amendment adds or increases fees or charges, except for taxes and other governmental charges or registration fees, cable, telex or facsimile transmission costs, delivery costs or other such expenses, or prejudices a substantial right of holders of Sanofi ADSs, it will only become effective 30 days after the depositary notifies such holders of the amendment. However, we may not be

able to provide holders of Sanofi ADSs with prior notice of the effectiveness of any modifications or supplements that are required to accommodate compliance with applicable provisions of law, whether or not those modifications or supplements could be considered to be materially prejudicial to the substantial rights of holders of Sanofi ADSs. ***At the time an amendment becomes effective, such holders will be considered, by continuing to hold their ADR, to have agreed to the amendment and to be bound by the ADR and the deposit agreement as amended.***

The depositary will terminate the agreement if we ask it to do so. The depositary may also terminate the agreement if the depositary has told us that it would like to resign and we have not appointed a new depositary bank within 90 days. In both cases, the depositary must notify holders of Sanofi ADSs at least 30 days before termination.

After termination, the depositary and its agents will be required to do only the following under the deposit agreement: (1) collect distributions on the deposited securities, (2) sell rights and other property as provided in the deposit agreement and (3) deliver shares and other deposited securities upon cancellation of ADRs. Six months or more after termination, the depositary may sell any remaining deposited securities by public or private sale. After that, the depositary will hold the money it receives on the sale, as well as any other cash it is holding under the deposit agreement, for the pro rata benefit of the holders of Sanofi ADSs that have not surrendered their Sanofi ADSs. It will have no liability for interest. Upon termination of the deposit agreement, the depositary s only obligations will be to account for the proceeds of the sale and other cash and with respect to indemnification. After termination, our only obligation will be with respect to indemnification and to pay certain amounts to the depositary.

Limitations on Obligations and Liability to Holders of Sanofi ADSs

The deposit agreement expressly limits our obligations and the obligations of the depositary, and it limits our liability and the liability of the depositary. In particular, please note the following:

- we and the depositary are obligated only to take the actions specifically set forth in the deposit agreement without gross negligence or bad faith;
- we and the depositary are not liable if either is prevented or delayed by law or circumstances beyond its control from performing its obligations under the deposit agreement;
- we and the depositary are not liable if either exercises, or fails to exercise, any discretion permitted under the deposit agreement;
- we and the depositary have no obligation to become involved in a lawsuit or other proceeding related to the

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Sanofi ADSs or the deposit agreement on holders behalf or on behalf of any other party, unless indemnity satisfactory to it against all expense and liability is furnished as often as may be required;

- we and the depositary are not liable for the acts or omissions made by, or the insolvency of, any securities depository, clearing agency or settlement system or the custodian, subject to certain exceptions and to the extent the custodian is not a branch or affiliate of JPMorgan;

- the depositary is not liable for the price received in connection with any sale of securities, the timing thereof or any delays, acts, omissions to act, errors, defaults or negligence on the part of the party so retained in connection with any such sale or proposed sale;

- we and the depositary may rely without any liability upon any written notice, request, direction, instruction or other document believed by either of us to be genuine and to have been signed or presented by the proper parties; and

- we and the depositary are not liable for any action or nonaction taken in reliance upon the advice of or information from legal counsel, accountants, any person presenting ordinary shares for deposit, any ADS holder, or any other person believed in good faith to be competent to give such advice or information.

In addition, the depositary will not be liable for any acts or omissions made by a successor depositary. Moreover, neither we nor the depositary nor any of our respective agents will be liable to any holder of Sanofi ADSs for any indirect, special, punitive or consequential damages.

Pursuant to the terms of the deposit agreement, we and the depositary have agreed to indemnify each other under certain circumstances.

Requirements for Depositary Actions

Before the depositary will deliver or register the transfer of Sanofi ADSs, make a distribution on Sanofi ADSs or process a withdrawal of shares, the depositary may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;

- production of satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and

- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver Sanofi ADSs, register transfers of Sanofi ADSs or permit withdrawals of shares when the transfer books of the depositary or our transfer books are closed, or at any time if the depositary or we think it advisable to do so.

Right to Receive the Shares Underlying the Sanofi ADSs

Holders have the right to cancel their Sanofi ADSs and withdraw the underlying Sanofi ordinary shares at any time except:

- when temporary delays arise when we or the depositary have closed our transfer books or the deposit of shares in connection with voting at a shareholders meeting, or the payment of dividends;

- when the holder or other holders of Sanofi ADSs seeking to withdraw shares owe money to pay fees, taxes and similar charges; or

- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to Sanofi ADSs or to the withdrawal of shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Pre-Release of Sanofi ADSs

Unless we instruct the depositary not to, the deposit agreement permits the depositary to deliver Sanofi ADSs before deposit of the underlying shares. This is called a pre-release of the Sanofi ADSs. The depositary may also deliver shares upon cancellation of pre-released Sanofi ADSs (even if the Sanofi ADSs are cancelled before the pre-release transaction has been closed out). A pre-release is closed out as soon as the underlying shares are delivered to the depositary. The depositary may receive Sanofi ADSs instead of shares to close out a pre-release. Unless otherwise agreed in writing, the depositary may pre-release Sanofi ADSs only under the following conditions: (1) before or at the time of the pre-release, the person to whom the pre-release is being made must represent to the depositary in writing that it or its customer (i) owns the shares or Sanofi ADSs to be deposited, (ii) assigns all beneficial rights, title and interest in such shares or ADRs to the depositary in its capacity as depositary and (iii) will not take any action with respect to such shares or ADRs that is inconsistent with the transfer of beneficial ownership, other than in satisfaction of such pre-release; (2) the pre-release must be fully collateralized with cash, U.S. government securities or other collateral that the depositary considers appropriate; (3) the depositary must be able to close out the pre-release on not more than five business days notice; and (4) the depositary may require such further indemnities and credit regulations as it deems appropriate. In addition, the depositary will limit the number of Sanofi ADSs that may be outstanding at any time as a result of pre-release, although the depositary may disregard the limit from time to time, if it thinks it is appropriate to do so. The depositary may retain for its own account any compensation received by it in connection with the foregoing. Any holder of pre-release ADRs should consult its tax and other advisors about the implications of pre-release for its particular situation.

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Item 13. Defaults, Dividend Arrearages and Delinquencies

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies

N/A

Item 14. Material Modifications to the Rights of Security Holders

N/A

Item 15. Controls and Procedures

(a) Our Chief Executive Officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) as of the end of the period covered by this Form 20-F, have concluded that, as of such date, our disclosure controls and procedures were effective to ensure that material information relating to Sanofi was timely made known to them by others within the Group.

(b) Report of Management on Internal Control Over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Management assessed the effectiveness of internal control over financial reporting as of December 31, 2015 based on the framework in Internal Control Integrated Framework (2013 framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Based on that assessment, management has concluded that the Company s internal control over financial reporting was effective as of December 31, 2015 to provide reasonable assurance regarding the reliability of its financial reporting and the preparation of its financial statements for external purposes, in accordance with generally accepted accounting principles.

Due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements, and can only provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The effectiveness of the Company s internal control over financial reporting has been audited by PricewaterhouseCoopers Audit and Ernst & Young et Autres, independent registered public accounting firms, as stated in their report on the Company s internal control over financial reporting as of December 31, 2015, which is included herein. See paragraph (c) of the present Item 15, below.

(c) See report of PricewaterhouseCoopers Audit and Ernst & Young et Autres, independent registered public accounting firms, included under Item 18. Financial Statements on page F-3.

(d) There were no changes to our internal control over financial reporting that occurred during the period covered by this Form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 16.

[Reserved]

Item 16A. Audit Committee Financial Expert

Our Board of Directors has determined that Robert Castaigne, Fabienne Lecorvaisier and Christian Mulliez, directors serving on the Audit Committee, are independent

financial experts within the meaning of paragraph 407 of the Sarbanes-Oxley Act of 2002.

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Item 16A. Audit Committee Financial Expert

The Board of Directors determined that Robert Castaigne qualifies as a financial expert based on his education and his experience as Chief Financial Officer of Total, a major corporation. The Board of Directors deemed Fabienne Lecorvaisier to be a financial expert taking into account her experience in corporate finance in various international banks and as Chief Financial Officer of Essilor and now Air Liquide. The Board of Directors deemed Christian Mulliez to be a financial expert taking into account his experience as Vice President, General Manager Administration and

Finance of L Oréal and graduate of the *Ecole Supérieure des Sciences Economiques et Commerciales* (ESSEC).

The Board of Directors has determined that all four directors meet the independence criteria of U.S. Securities and Exchange Commission Rule 10A- 3, although only Robert Castaigne Fabienne Lecorvaisier and Carole Piwnica meet the French AFEP-MEDEF Code criteria of independence applied by the Board of Directors for general corporate governance purposes (see Item 16G, below).

Item 16B. Code of Ethics

We have adopted a financial code of ethics, as defined in Item 16B. of Form 20-F under the Exchange Act. Our financial code of ethics applies to our Chief Executive Officer, Chief Financial Officer, Chief Accounting Officer and other officers performing similar functions, as designated from time to time. Our financial code of ethics is available on our Website at www.sanofi.com (information on our website

is not incorporated by reference in this annual report). A copy of our financial code of ethics may also be obtained without charge by addressing a written request to the attention of Individual Shareholder Relations at our headquarters in Paris. We will disclose any amendment to the provisions of such financial code of ethics on our website.

Item 16C. Principal Accountants Fees and Services

See Note E. to our consolidated financial statements included at Item 18 of this annual report.

Item 16D. Exemptions from the Listing Standards for Audit Committees

N/A

Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

In 2015, Sanofi made the following purchases of its ordinary shares.

Period	(a) Total Number of Shares Purchased	(b) Average Price Paid per Share	(c) Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs[1]	(d) Approximate Value of Shares that May Yet Be Purchased Under the Plans or Programs[2]
January 2015	2,729,605	75.95	2,729,605	12,041
February 2015	250,000	81.15	250,000	12,021
March 2015	6,240,278	90.58	6,240,278	11,456
April 2015	4,528,689	96.00	4,528,689	11,022
June 2015	150,000	89.61	150,000	11,009
July 2015	1,270,000	89.32	1,270,000	10,896
August 2015	1,310,511	93.95	1,310,511	10,773
December 2015	3,796,857	79.01	3,796,857	10,474

(1) The Company was authorized to repurchase up to 12,248,051,000 of shares for a period of eighteen months (i.e., through November 4, 2016) by the Annual Shareholders Meeting held on May 4, 2015.

(2) Millions of euros.

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Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

This schedule does not include purchases and sales conducted by Exane under a liquidity contract entered into in 2010 and that is still in effect. For more information see

Item 10.B *Memorandum and Articles of Association Use of Share Repurchase Programs.*

Item 16F. Change in Registrant s Certifying Accountant

N/A

Item 16G. Corporate Governance

Sanofi is incorporated under the laws of France, with securities listed on regulated public markets in the United States (New York Stock Exchange) and France (Euronext Paris). Consequently, as described further in our annual report, our corporate governance framework reflects the mandatory provisions of French corporate law, the securities laws and regulations of France and the United States and the rules of the aforementioned public markets. In addition, we generally follow the AFEP-MEDEF corporate governance recommendations for French listed issuers (hereafter referred to as the AFEP-MEDEF Code). As a result, our corporate governance framework is similar in many respects to, and provides investor protections that are comparable to or in some cases, more stringent than the corresponding rules of the New York Stock Exchange. Nevertheless, there are important differences to keep in mind.

In line with New York Stock Exchange rules applicable to domestic issuers, Sanofi maintains a board of directors of which at least half of the members are independent. Sanofi evaluates the independence of members of our Board of Directors using the standards of the French AFEP-MEDEF Code as the principal reference. We believe that AFEP-MEDEF s overarching criteria for independence no relationship of any kind whatsoever with the Company, its group or the management of either that is such as to color a Board member s judgment are on the whole consistent with the goals of the New York Stock Exchange s rules although the specific tests proposed under the two standards may vary on some points. We have complied with the audit committee independence and other requirements of the Rule 10A-3 under the U.S. Securities Exchange Act of 1934, as amended, adopted pursuant to the Sarbanes-Oxley Act of 2002. Our Compensation Committee includes one non-independent member, Christian Mulliez, which is permitted under the AFEP-MEDEF Code but would not be compliant with the rules of the New York Stock Exchange for domestic issuers.

Under French law, the committees of our Board of Directors are advisory only, and where the New York Stock Exchange Listed Company Manual would vest certain decision-making powers with specific committees by delegation (*e.g.,* appointment or audit committees), under French law our Board of Directors remains the only competent body to

take such decisions, albeit taking into account the recommendation of the relevant committees. Additionally, under French corporate law, it is the Shareholders General Meeting of Sanofi that is competent to appoint our auditors upon the proposal of our Board of Directors, although our Board Charter provides that the Board of Directors will make its proposal on the basis of the recommendation of our Audit Committee. We believe that this requirement of French law, together with the additional legal requirement that two sets of statutory auditors be appointed, share

the New York Stock Exchange s underlying goal of ensuring that the audit of our accounts be conducted by auditors independent from company management.

In addition to the oversight role of our Compensation Committee for questions of management compensation including by way of equity, under French law any option or restricted share plans or other share capital increases, whether for the benefit of senior management or employees, may only be adopted by the Board of Directors pursuant to and within the limits of a shareholder resolution approving the related capital increase and delegating to the Board the authority to implement such operations.

As described above, a number of issues, which could be resolved directly by a board or its committees in the United States, require the additional protection of direct shareholder consultation in France. Our Audit Committee is entirely composed of independent directors as that term is defined in Rule 10A-3 under the U.S. Securities Exchange Act of 1934, as amended, adopted pursuant to the Sarbanes-Oxley Act of 2002. The composition of our Audit Committee, Compensation Committee, and Appointments and Governance Committee includes directors who are also officers of our largest shareholder.

As a foreign private issuer under the U.S. securities laws, our Chief Executive Officer and our Chief Financial Officer issue the certifications required by §302 and §906 of the Sarbanes Oxley Act of 2002 on an annual basis (with the filing of our annual report on U.S. Form 20-F) rather than on a quarterly basis as would be the case of a U.S. corporation filing quarterly reports on U.S. Form 10-Q.

French corporate law provides that the Board of Directors must vote to approve a broadly defined range of transactions that could potentially create conflicts of interest between

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Sanofi on the one hand and its Directors and Chief Executive Officer on the other hand, which are then presented to shareholders for approval at the next annual meeting. This legal safeguard provides shareholders with an

opportunity to approve significant aspects of the Chief Executive Officer s compensation package, and it operates in place of certain provisions of the NYSE Listed Company Manual.

Item 16H. Mine Safety Disclosure

N/A

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Item 17. Financial Statements

PART III

Item 17. Financial Statements

See Item 18.

Item 18. Financial Statements

See pages F-1 through F-108 incorporated herein by reference.

Item 19. Exhibits

1.1 Articles of association (*statuts*) of Sanofi (English translation)

1.2 Board Charter (*Règlement Intérieur*) of Sanofi (English translation)

2. The total amount of long-term debt securities authorized under any instrument does not exceed 10% of the total assets of the Company and its subsidiaries on a consolidated basis. We here by agree to furnish to the SEC, upon its request, a copy of any instrument defining the rights of holders of long-term debt of the Company or of its subsidiaries for which consolidated or unconsolidated financial statements are required to befiled.

4.1 Form of Contingent Value Rights Agreement by and among Sanofi and Trustee (*on file with the SEC as Annex B to Amendment No.2 to the Registration Statement on Form F-4 filed on March 24, 2011)*

8.1 List of significant subsidiaries, see Item 4. Information on the Company C. Organizational Structure of this Form 20-F.

12.1 Certification by Olivier Brandicourt, Chief Executive Officer, required by Section 302 of the Sarbanes-Oxley Act of 2002

12.2 Certification by Jérôme Contamine, Principal Financial Officer, required by Section 302 of the Sarbanes-Oxley Act of 2002

13.1 Certification by Olivier Brandicourt, Chief Executive Officer, required by Section 906 of the Sarbanes-Oxley Act of 2002

13.2 Certification by Jérôme Contamine, Principal Financial Officer, required by Section 906 of the Sarbanes-Oxley Act of 2002

23.1 Consent of Ernst & Young et Autres dated March 3, 2016

23.2 Consent of PricewaterhouseCoopers Audit dated March 3, 2016

99.1 Report of the Chairman of the Board of Directors for 2015 as required by Art. L. 225- 37 paragraph 6 of the French Commercial Code

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SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Sanofi
By: /s/ OLIVIER BRANDICOURT
Name: **Olivier Brandicourt**
Title: **Chief Executive Officer**

Date: March 3, 2016

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2015 ANNUAL CONSOLIDATED FINANCIAL STATEMENTS

The financial statements are presented in accordance with

International Financial Reporting Standards (IFRS).

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRMS

To the Board of Directors and Shareholders of Sanofi,

We have audited the accompanying consolidated balance sheets of Sanofi and its subsidiaries (together the Group) as of December 31, 2015, 2014 and 2013, and the related consolidated statements of income, comprehensive income, changes in equity and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Group s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board of the United States of America (the PCAOB). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Group as of December 31, 2015, 2014 and 2013, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

We also have audited, in accordance with the standards of the PCAOB, the effectiveness of the Group s internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) and our report dated March 3, 2016 expressed an unqualified opinion thereon.

Neuilly-sur-Seine and Paris-La Défense, March 3, 2016

PricewaterhouseCoopers Audit		Ernst & Young et Autres
/s/ Philippe Vogt	/s/ François Guillon	/s/ Nicolas Pfeuty

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRMS

SANOFI

To the Board of Directors and Shareholders of Sanofi,

We have audited internal control over financial reporting of Sanofi and its subsidiaries (together the Group) as of December 31, 2015, based on criteria established in **Internal Control-Integrated Framework** issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) (the COSO criteria). The Group s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Report of Management on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board of the United States of America (the PCAOB). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Group maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the COSO criteria.

We also have audited, in accordance with the standards of the PCAOB, the consolidated balance sheets of the Group as of December 31, 2015, 2014 and 2013, and the related consolidated statements of income, comprehensive income, changes in equity and cash flows for each of the three years in the period ended December 31, 2015 and our report dated March 3, 2016 expressed an unqualified opinion thereon.

Neuilly-sur-Seine and Paris-La Défense, March 3, 2016

PricewaterhouseCoopers Audit
/s/ Philippe Vogt /s/ François Guillon

Ernst & Young et Autres
/s/ Nicolas Pfeuty

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CONSOLIDATED BALANCE SHEETS ASSETS

(million)	Note	December 31, 2015	December 31, 2014	December 31, 2013
Property, plant and equipment	D.3.	9,943	10,396	10,182
Goodwill	D.4.	39,557	39,197	37,134
Other intangible assets	D.4.	12,026	14,543	15,395
Investments in associates and joint ventures	D.6.	2,676	2,384	448
Other non-current assets	D.7.	2,725	2,575	4,826
Deferred tax assets	D.14.	4,714	4,860	4,144
Non-current assets		**71,641**	**73,955**	**72,129**
Inventories	D.9.	6,516	6,562	6,352
Accounts receivable	D.10.	7,386	7,149	6,831
Other current assets	D.11.	1,767	2,157	2,287
Current financial assets	D.12.	111	218	185
Cash and cash equivalents	D.13. - D.17.	9,148	7,341	8,257
Current assets		**24,928**	**23,427**	**23,912**
Assets held for sale or exchange	D.8. - D.36.	5,752	10	14
TOTAL ASSETS		**102,321**	**97,392**	**96,055**

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CONSOLIDATED BALANCE SHEETS LIABILITIES AND EQUITY

(million)	Note	December 31, 2015	December 31, 2014	December 31, 2013
Equity attributable to equity holders of Sanofi	D.15.	58,049	56,120	56,904
Equity attributable to non-controlling interests	D.15.10.	161	148	129
Total equity		**58,210**	**56,268**	**57,033**
Long-term debt	D.17.	13,118	13,276	10,414
Non-current liabilities relating to business combinations and to non-controlling interests	D.18.	1,121	1,133	884
Provisions and other non-current liabilities	D.19.	9,169	9,578	8,735
Deferred tax liabilities	D.14.	2,895	4,105	5,060
Non-current liabilities		**26,303**	**28,092**	**25,093**
Accounts payable		3,817	3,651	3,003
Other current liabilities	D.19.4.	9,442	7,712	6,725
Current liabilities relating to business combinations and to non-controlling interests	D.18.	130	131	24
Short-term debt and current portion of long-term debt	D.17.	3,436	1,538	4,176
Current liabilities		**16,825**	**13,032**	**13,928**
Liabilities related to assets held for sale or exchange	D.8. - D.36.	983	-	1
TOTAL LIABILITIES AND EQUITY		**102,321**	**97,392**	**96,055**

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CONSOLIDATED INCOME STATEMENTS

(million)	Note	2015[1]	2014[1]	2013[1]
Net sales	**D.35.1.**	**34,542**	**31,694**	**30,966**
Other revenues		319	305	325
Cost of sales		(10,919)	(10,230)	(10,302)
Gross profit		**23,942**	**21,769**	**20,989**
Research and development expenses		(5,082)	(4,667)	(4,605)
Selling and general expenses		(9,382)	(8,425)	(7,950)
Other operating income	**D.25.**	254	301	691
Other operating expenses	**D.26.**	(462)	(157)	(240)
Amortization of intangible assets		(2,137)	(2,081)	(2,527)
Impairment of intangible assets	**D.5.**	(767)	31	(1,387)
Fair value remeasurement of contingent consideration liabilities	**D.18.**	53	(303)	314
Restructuring costs	**D.27.**	(795)	(404)	(303)
Other gains and losses, and litigation	**D.28.**	-	-	-
Operating income		**5,624**	**6,064**	**4,982**
Financial expenses	**D.29.**	(559)	(598)	(609)
Financial income	**D.29.**	178	192	111
Income before tax and associates and joint ventures	**D.35.1.**	**5,243**	**5,658**	**4,484**
Income tax expense	**D.30.**	(709)	(1,214)	(726)
Share of profit/(loss) of associates and joint ventures	**D.31.**	(22)	(52)	39
Net income excluding the held-for-exchange Animal Health business		**4,512**	**4,392**	**3,797**
Net income/(loss) of the held-for-exchange Animal Health business	**D.36.**	(124)	117	77
Net income		**4,388**	**4,509**	**3,874**
Net income attributable to non-controlling interests	**D.32.**	101	119	158
Net income attributable to equity holders of Sanofi		**4,287**	**4,390**	**3,716**
Average number of shares outstanding (million)	**D.15.9.**	1,306.2	1,315.8	1,323.1
Average number of shares outstanding after dilution (million)	**D.15.9.**	1,320.7	1,331.1	1,339.1
Basic earnings per share (in euros)		3.28	3.34	2.81
Basic earnings per share (in euros) excluding the held-for-exchange Animal Health business		3.38	3.25	2.75
Diluted earnings per share (in euros)		3.25	3.30	2.77
Diluted earnings per share (in euros) excluding the held-for-exchange Animal Health business		3.34	3.21	2.72

(1) The results of the Animal Health business are reported separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations); see Notes D.2.1. and D.36.

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CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(million)	Note	2015	2014	2013
Net income		**4,388**	**4,509**	**3,874**
Attributable to equity holders of Sanofi		*4,287*	*4,390*	*3,716*
Attributable to non-controlling interests		*101*	*119*	*158*
Other comprehensive income:				
· Actuarial gains/(losses)	**D.15.7.**	652	(869)	810
· Tax effects	**D.15.7.**	(187)	303	(152)
Sub-total: items not subsequently reclassifiable to profit or loss (a)		**465**	**(566)**	**658**
· Available-for-sale financial assets		(37)	(2,760)	1,208
· Cash flow hedges		(3)	-	(3)
· Change in currency translation differences	**D.15.7.**	1,915	2,506	(1,804)
· Tax effects	**D.15.7.**	20	250	(208)
Sub-total: items subsequently reclassifiable to profit or loss (b)		**1,895**	**(4)**	**(807)**
Other comprehensive income for the period, net of taxes (a+b)		**2,360**	**(570)**	**(149)**
Comprehensive income		**6,748**	**3,939**	**3,725**
Attributable to equity holders of Sanofi		*6,641*	*3,810*	*3,581*
Attributable to non-controlling interests		*107*	*129*	*144*

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CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

(*million*)	Share capital	Additional paid-in capital and retained earnings	Treasury shares	Stock options and other share-based payment	Other comprehensive income	Attributable to equity-holders of Sanofi	Non-controlling interests	Total equity
Balance at January 1, 2013 per the published financial statements	**2,653**	**52,916**	**(207)**	**2,160**	**(170)**	**57,352**	**134**	**57,486**
Other comprehensive income for the period	-	658	-	-	(793)	(135)	(14)	(149)
Net income for the period	-	3,716	-	-	-	3,716	158	3,874
Comprehensive income for the period	**-**	**4,374**	**-**	**-**	**(793)**	**3,581**	**144**	**3,725**
Dividend paid out of 2012 earnings (2.77 per share)	-	(3,638)	-	-	-	(3,638)	-	(3,638)
Payment of dividends to non-controlling interests	-	-	-	-	-	-	(140)	(140)
Share repurchase program[1]	-	-	(1,641)	-	-	(1,641)	-	(1,641)
Reduction in share capital[1]	(42)	(1,560)	1,602	-	-	-	-	-
Share-based payment plans:								
· Exercise of stock options[1]	31	875	-	-	-	906	-	906
· Issuance of restricted shares[1]	4	(4)	-	-	-	-	-	-
· Employee share ownership plans[1]	3	95	-	-	-	98	-	98
· Proceeds from sale of treasury shares on exercise of stock options	-	-	2	-	-	2	-	2
· Value of services obtained from employees	-	-	-	200	-	200	-	200
· Tax effects of the exercise of stock options	-	-	-	30	-	30	-	30
Changes in non-controlling interests without loss of control	-	14	-	-	-	14	(9)	5
Balance at December 31, 2013	**2,649**	**53,072**	**(244)**	**2,390**	**(963)**	**56,904**	**129**	**57,033**
Other comprehensive income for the period	-	(566)	-	-	(14)	(580)	10	(570)
Net income for the period	-	4,390	-	-	-	4,390	119	4,509
Comprehensive income for the period	**-**	**3,824**	**-**	**-**	**(14)**	**3,810**	**129**	**3,939**
Dividend paid out of 2013 earnings (2.80 per share)	-	(3,676)	-	-	-	(3,676)	-	(3,676)
Payment of dividends to non-controlling interests	-	-	-	-	-	-	(125)	(125)
Share repurchase program[1]	-	-	(1,801)	-	-	(1,801)	-	(1,801)
Reduction in share capital[1]	(36)	(1,314)	1,350	-	-	-	-	-
Share-based payment plans:								
· Exercise of stock options[1]	22	658	-	-	-	680	-	680
· Issuance of restricted shares[1]	4	(4)	-	-	-	-	-	-
· Proceeds from sale of treasury shares on exercise of stock options	-	-	1	-	-	1	-	1
· Value of services obtained from employees	-	-	-	202	-	202	-	202
· Tax effects of the exercise of stock options	-	-	-	7	-	7	-	7
Change in non-controlling interests without loss of control	-	(7)	-	-	-	(7)	15	8
Balance at December 31, 2014	**2,639**	**52,553**	**(694)**	**2,599**	**(977)**	**56,120**	**148**	**56,268**

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CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY (CONTINUED)

(*million*)	Share capital	Additional paid-in capital and retained earnings	Treasury shares	Stock options and other share-based payment	Other comprehensive income	Attributable to equity-holders of Sanofi	Non-controlling interests	Total equity
Balance at December 31, 2014	**2,639**	**52,553**	**(694)**	**2,599**	**(977)**	**56,120**	**148**	**56,268**
Other comprehensive income for the period	-	465	-	-	1,889	2,354	6	2,360
Net income for the period	-	4,287	-	-	-	4,287	101	4,388
Comprehensive income for the period	**-**	**4,752**	**-**	**-**	**1,889**	**6,641**	**107**	**6,748**
Dividend paid out of 2014 earnings (2.85 per share)	-	(3,694)	-	-	-	(3,694)	-	(3,694)
Payment of dividends to non-controlling interests	-	-	-	-	-	-	(110)	(110)
Share repurchase program[1]	-	-	(1,781)	-	-	(1,781)	-	(1,781)
Reduction in share capital[1]	(52)	(2,124)	2,176	-	-	-	-	-
Share-based payment plans:								
· Exercise of stock options[1]	18	555	-	-	-	573	-	573
· Issuance of restricted shares[1]	6	(6)	-	-	-	-	-	-
· Proceeds from sale of treasury shares on exercise of stock options	-	-	1	-	-	1	-	1
· Value of services obtained from employees	-	-	-	205	-	205	-	205
· Tax effects of the exercise of stock options	-	-	-	10	-	10	-	10
Change in non-controlling interests without loss of control	-	(26)	-	-	-	(26)	16	(10)
Balance at December 31, 2015	**2,611**	**52,010**	**(298)**	**2,814**	**912**	**58,049**	**161**	**58,210**

(1) See Notes D.15.1., D.15.3., D.15.4. and D.15.5.

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CONSOLIDATED STATEMENTS OF CASH FLOWS

(*million*)	Note	2015[1]	2014[1]	2013[1]
Net income attributable to equity holders of Sanofi		**4,287**	**4,390**	**3,716**
Net (income)/loss from the held-for-exchange Animal Health business		124	(117)	(77)
Non-controlling interests, excluding BMS[2]	**D.32.**	7	10	17
Share of undistributed earnings of associates and joint ventures		115	142	(2)
Depreciation, amortization and impairment of property, plant and equipment and intangible assets[3]		4,276	3,280	5,095
Gains and losses on disposals of non-current assets, net of tax[4]		(136)	(249)	(276)
Net change in deferred taxes		(1,253)	(1,151)	(901)
Net change in provisions[5]		(13)	(374)	(1,333)
Cost of employee benefits (stock options and other share-based payments)	**D.15.2. - D.15.3. - D.15.8.**	193	192	192
Impact of the workdown of acquired inventories remeasured at fair value	**D.35.1.**	-	-	8
Unrealized (gains)/losses recognized in income		(365)	134	(76)
Operating cash flow before changes in working capital and excluding the held-for-exchange Animal Health business		**7,235**	**6,257**	**6,363**
(Increase)/decrease in inventories		(466)	(8)	(48)
(Increase)/decrease in accounts receivable		(493)	(20)	133
Increase/(decrease) in accounts payable		241	459	(124)
Net change in other current assets, current financial assets and other current liabilities[6]		1,773	477	234
Net cash provided by/(used in) operating activities excluding the held-for-exchange Animal Health business		**8,290**	**7,165**	**6,558**
Net cash provided by/(used in) operating activities of the held-for-exchange Animal Health business[6]		**630**	**525**	**396**
Acquisitions of property, plant and equipment and intangible assets	**D.3.-D.4.**	(2,772)	(1,453)	(1,306)
Acquisitions of investments in consolidated undertakings, net of cash acquired[7]	**D.1. - D.18.**	(220)	(1,723)	(235)
Acquisitions of available-for-sale financial assets	**D.7.**	(142)	(571)	(18)
Proceeds from disposals of property, plant and equipment, intangible assets and other non-current assets, net of tax[8]		211	262	408
Net change in loans and other financial assets		(88)	128	(27)
Net cash provided by/(used in) investing activities excluding the held-for-exchange Animal Health business		**(3,011)**	**(3,357)**	**(1,178)**
Net cash provided by/(used in) investing activities of the held-for-exchange Animal Health business		**(246)**	**(103)**	**(95)**

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CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)

(*million*)	Note	2015[1]	2014[1]	2013[1]
Issuance of Sanofi shares	D.15.1.	573	680	1,004
Dividends paid:				
· to shareholders of Sanofi		(3,694)	(3,676)	(3,638)
· to non-controlling interests, excluding BMS[2]		(12)	(10)	(12)
Transactionswith non-controlling interests, other than dividends		(8)	2	(40)
Additional long-term debt contracted	D.17.	2,253	2,980	3,119
Repayments of long-term debt	D.17.	(708)	(3,032)	(2,822)
Net change in short-term debt		(199)	(338)	271
Acquisition of treasury shares	D.15.4.	(1,784)	(1,801)	(1,641)
Disposals of treasury shares, net of tax	D.15.	1	1	2
Net cash provided by/(used in) financing activities excluding the held-for-exchange Animal Health business		**(3,578)**	**(5,194)**	**(3,757)**
Net cash provided by/(used in) financing activities of the held-for-exchange Animal Health business		**(23)**	**14**	**31**
Impact of exchange rates on cash and cash equivalents		**(232)**	**34**	**(79)**
Impact on cash and cash equivalents of the reclassification of the Animal Health business to Assets held for sale or exchange[9]	D.36.	**(23)**	**-**	**-**
Net change in cash and cash equivalents excluding the Animal Health business		**1,469**	**(1,352)**	**1,544**
Net change in cash and cash equivalents of the Animal Health business		**361**	**436**	**332**
Net change in cash and cash equivalents		**1,807**	**(916)**	**1,876**
Cash and cash equivalents, beginning of period		**7,341**	**8,257**	**6,381**
Cash and cash equivalents, end of period	D.13.	**9,148**	**7,341**	**8,257**

(1) Cash flows of the Animal Health business are presented separately in accordance with IFRS 5 (Non-current Assets Held for Sale and Discontinued Operations).

(2) See Note C.2.

(3) In 2014, this line item includes 356 million for the partial reversal of the impairment loss taken against Lemtrada® in 2013 (see Note D.5.).

(4) Includes available-for-sale financial assets.

(5) This line item includes contributions paid to pension funds (see Note D.19.1.).

(6) Including:

Income tax paid	(1,784)	(2,697)	(2,370)
Interest paid (excluding cash flows on derivative instruments used to hedge debt)	(415)	(445)	(491)
Interest received (excluding cash flows on derivative instruments used to hedge debt)	58	68	49
Dividends received from non-consolidated entities	10	5	5

(7) This line item includes payments made in respect of contingent consideration identified and recognized as a liability in business combinations.

(8) This line item includes proceeds from disposals of investments in consolidated entities and of other non-current financial assets.

(9)

Cash and cash equivalents of the Animal Health business are presented within the line item ***Cash and cash equivalents*** for 2014 and 2013, and within the line item ***Assets held for sale or exchange*** *for 2015.*

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

YEAR ENDED DECEMBER 31, 2015

Sanofi, together with its subsidiaries (collectively Sanofi or the Group), is a global healthcare leader engaged in the research, development and marketing of therapeutic solutions focused on patient needs.

Sanofi is listed in Paris (Euronext: SAN) and New York (NYSE: SNY).

The consolidated financial statements for the year ended December 31, 2015, and the notes thereto, were signed off by the Sanofi Board of Directors on February 8, 2016.

A/ Basis of preparation

A.1. INTERNATIONAL FINANCIAL REPORTING STANDARDS (IFRS)

The consolidated financial statements cover the twelve-month periods ended December 31, 2015, 2014 and 2013.

In accordance with Regulation No. 1606/2002 of the European Parliament and Council of July 19, 2002 on the application of international accounting standards, Sanofi has presented its consolidated financial statements in accordance with IFRS since January 1, 2005. The term IFRS refers collectively to international accounting and financial reporting standards (IASs and IFRSs) and to interpretations of the interpretations committees (SIC and IFRIC) with mandatory application as of December 31, 2015.

The consolidated financial statements of Sanofi as of December 31, 2015 have been prepared in compliance with IFRS as issued by the International Accounting Standards Board (IASB) and with IFRS as endorsed by the European Union as of December 31, 2015.

IFRS as endorsed by the European Union as of December 31, 2015 are available under the heading IFRS Financial Statements via the following web link:

http://ec.europa.eu/internal_market/accounting/ias/index_en.htm

The consolidated financial statements have been prepared in accordance with the IFRS general principles of fair presentation, going concern, accrual basis of accounting, consistency of presentation, materiality, and aggregation.

New standards, amendments and interpretations applicable in 2015 with an impact on the consolidated financial statements are described in Note A.2. For standards, amendments and interpretations issued by the IASB that apply from 2016 onwards, refer to Note B.28.

A.2. NEW STANDARDS, AMENDMENTS AND INTERPRETATIONS APPLICABLE IN 2015

There are no new standards, amendments to standards, or interpretations applicable with effect from the 2015 financial year that have an impact on the consolidated financial statements or on their presentation.

IFRIC 21 (Levies) has been applied by the Group since 2014.

A.3. USE OF ESTIMATES AND JUDGMENTS

The preparation of financial statements requires management to make reasonable estimates and assumptions based on information available at the date of the finalization of the financial statements. Those estimates and assumptions may affect the reported amounts of assets, liabilities, revenues and expenses in the financial statements, and disclosures of contingent assets and contingent liabilities as of the date of the review of the financial statements. Examples of estimates and assumptions include:

- amounts deducted from sales for projected sales returns, chargeback incentives, rebates and price reductions (see Notes B.14. and D.23.);
- impairment of property, plant and equipment, intangible assets, and investments in associates and joint ventures (see Notes B.6. and D.5.);
- the valuation of goodwill and the valuation and useful life of acquired intangible assets (see Notes B.3., B.4.3., D.4. and D.5.);
- the amount of post-employment benefit obligations (see Notes B.23. and D.19.1.);
- the amount of provisions for restructuring, litigation, tax risks and environmental risks (see Notes B.12., B.22., D.19. and D.22.);
- the amount of deferred tax assets resulting from tax losses available for carry-forward and deductible temporary differences (see Notes B.22. and D.14.);
- the measurement of contingent consideration (see Notes B.3. and D.18.); and
- which exchange rate to use at the end of the reporting period for the translation of accounts denominated in foreign currencies, and of financial statements of foreign subsidiaries, in cases where more than one exchange rate exists for a given currency (see Note A.4.).

Actual results could differ from these estimates.

Management is also required to exercise judgment in assessing whether the criteria specified in IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations) are met, and hence whether a non-current asset or asset group should be classified as held for sale or exchange and whether a discontinued operation should be reported separately. Such assessments are reviewed at each reporting date based on the facts and circumstances.

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A.4. CONSOLIDATION AND FOREIGN CURRENCY TRANSLATION OF THE FINANCIAL STATEMENTS OF VENEZUELAN SUBSIDIARIES

In 2015, the Group continued to account for subsidiaries based in Venezuela using the full consolidation method, on the basis that the criteria for control as specified in IFRS 10 (Consolidated Financial Statements) are met.

As of December 31, 2015, the foreign exchange system consists of three exchange rates:

- an official exchange rate remaining unchanged (the CENCOEX rate) at a fixed rate of 6.3 bolivars per U.S. dollar, which is restricted to essential goods;
- an administered exchange rate (the SICAD rate), which was 13.5 bolivars per U.S. dollar as of December 31, 2015 and is applied to certain specific business sectors;
- the SIMADI rate, of approximately 200 bolivars per U.S. dollar, which is applied to specified transactions.

For the purposes of preparing the consolidated financial statements as of December 31, 2015, the financial statements of the Venezuelan subsidiaries were translated into euros using the SICAD official exchange rate, which is the estimated rate at which the profits generated by the operations of those subsidiaries will be remitted to the parent. This estimate reflects transactions carried out in the fourth quarter of 2015 that were translated into euros on the basis of a rate close to the SICAD rate. Previously, the Group used the official CENCOEX rate, which was the rate mainly applied early in 2015 to settle transactions with other consolidated Group entities.

In 2015, the Venezuelan subsidiaries contributed 455 million to consolidated net sales, including the restatement made in respect of the application of a general price index in accordance with IAS 29. The net cash position as of December 31, 2015 was 95 million, of which 90 million was subject to exchange controls compared with 242 million as of December 31, 2014 (see Note D.13.). The net foreign exchange loss recognized in 2015 was 240 million. That loss arose mainly on the settlement and remeasurement of foreign currency liabilities of the Venezuelan subsidiaries.

The Group continues to be exposed to a risk of devaluation of the Venezuelan bolivar. The table below shows, for information purposes, the amounts that would have been reported for consolidated net sales and the net cash position if the SIMADI rate had been applied in translating the local financial statements for the purpose of preparing the consolidated financial statements:

Estimated amounts in millions of euros based on an application of SIMADI exchange rate (200 bolivars per U.S. dollar)	**2015**
Contribution to consolidated net sales	37
Cash	11

In February 2016, the Venezuelan government announced changes to the foreign exchange system, which now consists of only two categories:

- essential goods, involving an exchange rate of one U.S. dollar for 10 bolivars (as opposed to 6.3 previously);

- all other transactions, for which a floating exchange rate between the U.S. dollar and the bolivar will apply (as opposed to the fixed rate of 200 bolivars per U.S. dollar previously applied).

B/ Summary of significant accounting policies

B.1. BASIS OF CONSOLIDATION

In accordance with IFRS 10 (Consolidated Financial Statements), the consolidated financial statements of Sanofi include the financial statements of entities that the Group controls directly or indirectly, regardless of the level of the Group s equity interest in the entity. An entity is controlled when the Group has power over the entity, exposure or rights to variable returns from its involvement with the entity, and the ability to affect those returns through its power over the entity. In determining whether control exists, potential voting rights must be taken into account if those rights are substantive, in other words they can be exercised on a timely basis when decisions about the relevant activities of the entity are to be taken.

Entities consolidated by the Group are referred to as subsidiaries . Entities that the Group controls by means other than voting rights are referred to as consolidated structured entities .

In accordance with IFRS 11 (Joint Arrangements), Sanofi classifies its joint arrangements (i.e. arrangements in which Sanofi exercises joint control with one or more other parties) either as a joint operation or a joint venture. In the case of a joint operation, Sanofi recognizes the assets and liabilities of the operation in proportion to its rights and obligations relating to those assets and liabilities. Joint ventures are accounted for by the equity method.

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Sanofi exercises joint control over a joint arrangement when decisions relating to the relevant activities of the arrangement require the unanimous consent of Sanofi and the other parties with whom control is shared.

Sanofi exercises significant influence over an entity when it has the power to participate in the financial and operating policy decisions of that entity, but does not have the power to exercise control or joint control over those policies.

In accordance with IAS 28 (Investments in Associates and Joint Ventures), the equity method is used to account for joint ventures (i.e. entities over which Sanofi exercises joint control) and for associates (i.e. entities over which Sanofi exercises significant influence).

Under the equity method, the investment is initially recognized at cost, and subsequently adjusted to reflect changes to the net assets of the associate or joint venture. IAS 28 does not specify the treatment to be adopted on first-time application of the equity method to an investee following a step acquisition. Consequently, by reference to paragraph 10 of IAS 28, Sanofi has opted to apply the cost method, whereby the carrying amount of the investment represents the sum of the historical cost amounts for each step in the acquisition. As of the date on which the equity method was first applied, goodwill (which is included in the carrying amount of the investment) is determined for each acquisition step. The same applies to subsequent increases in the percentage interest in the associate or joint venture.

Material transactions between consolidated companies are eliminated, as are intragroup profits.

A list of the principal companies included in the consolidation as of December 31, 2015 is presented in Note F to the consolidated financial statements.

B.2. FOREIGN CURRENCY TRANSLATION

B.2.1. Accounting for foreign currency transactions in the financial statements of consolidated entities

Non-current assets (other than receivables) and inventories acquired in foreign currencies are translated into the functional currency using the exchange rate prevailing at the acquisition date.

Monetary assets and liabilities denominated in foreign currencies are translated using the exchange rate prevailing at the end of the reporting period. The gains and losses resulting from foreign currency translation are recorded in the income statement. However, foreign exchange gains and losses arising from the translation of advances between consolidated subsidiaries for which settlement is neither planned nor likely to occur in the foreseeable future are recognized in equity, in the line item ***Change in currency translation difference***.

B.2.2. Foreign currency translation of the financial statements of foreign entities

Sanofi presents its consolidated financial statements in euros ( ). In accordance with IAS 21 (The Effects of Changes in Foreign Exchange Rates), each Group subsidiary accounts for its transactions in the currency that is most representative of its economic environment (the functional currency).

All assets and liabilities are translated into euros using the exchange rate of the subsidiary s functional currency prevailing at the end of the reporting period. Income statements are translated using a weighted average exchange rate for the period, except in the case of foreign subsidiaries in a hyperinflationary economy. The resulting currency translation difference is recognized as a separate component of equity in the

consolidated statement of comprehensive income, and is recognized in the income statement only when the subsidiary is sold or is wholly or partially liquidated.

B.3. BUSINESS COMBINATIONS AND TRANSACTIONS WITH NON-CONTROLLING INTERESTS

B.3.1. Accounting for business combinations, transactions with non-controlling interests and loss of control

Business combinations are accounted for in accordance with IFRS 3 (Business Combinations) and IFRS 10 (Consolidated Financial Statements).

Business combinations are accounted for using the acquisition method. Under this method, the acquiree s identifiable assets and liabilities that satisfy the recognition criteria of IFRS 3 (Business Combinations) are measured initially at their fair values as of the date of acquisition, except for (i) non-current assets classified as held for sale (which are measured at fair value less costs to sell) and (ii) assets and liabilities that fall within the scope of IAS 12 (Income Taxes) and IAS 19 (Employee Benefits). Restructuring liabilities are recognized as a liability of the acquiree only if the acquiree has an obligation as of the acquisition date to carry out the restructuring.

The principal accounting rules applicable to business combinations and transactions with non-controlling interests include:

- acquisition-related costs are recognized as an expense on the acquisition date, as a component of ***Operating income****;*
- contingent consideration is recognized in equity if the contingent payment is settled by delivery of a fixed number of the acquirer s equity instruments; otherwise, it is recognized in Liabilities related to business combinations. Contingent consideration is recognized at

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fair value at the acquisition date irrespective of the probability of payment. If the contingent consideration was originally recognized as a liability, subsequent adjustments to the liability are recognized in profit or loss in the line item ***Fair value remeasurement of contingent consideration liabilities***, unless the adjustment is made within the twelve months following the acquisition date and relates to facts and circumstances existing as of that date. Subsequent contingent consideration adjustments in respect of business combinations completed before January 1, 2010 continue to be accounted for in accordance with the pre-revision IFRS 3 (i.e. through goodwill);

- in the case of a step acquisition, the previously-held equity interest is remeasured at its acquisition-date fair value. The difference between this fair value and the carrying amount is recorded in profit or loss, along with any gains or losses relating to the previously-held interest that were recognized in other comprehensive income and are reclassifiable to profit or loss;

- goodwill may be calculated on the basis of either (i) the entire fair value of the acquiree, or (ii) a share of the fair value of the acquiree proportionate to the interest acquired. This option may be elected for each acquisition individually;

- the effects of (i) a buyout of non-controlling interests in a subsidiary already controlled by the Group, and (ii) a decrease of a percentage interest without loss of control, are recognized in equity;

- in a partial disposal resulting in loss of control, the retained equity interest is remeasured at fair value at the date of loss of control. The gain or loss recognized on the disposal includes the effect of that remeasurement, and items that were initially recognized in equity and are required to be reclassified to profit or loss;

- adjustments to the values of assets and liabilities initially determined provisionally (pending the results of independent valuations or further analysis) are recognized as a retrospective adjustment to goodwill if they are made within twelve months of the acquisition date. Once this twelve-month period has elapsed, the effects of any adjustments are recognized directly in profit or loss, unless they qualify as an error correction.

Purchase price allocations are performed under the responsibility of management, with assistance from an independent valuer in the case of major acquisitions. The revised IFRS 3 does not specify an accounting treatment for contingent consideration arising from a business combination made by an entity prior to the acquisition of control in that entity and carried as a liability in the acquired entity s balance sheet. The accounting treatment applied by the Group to such a liability is to measure it at fair value as of the acquisition date and to report it in the lines items

Liabilities related to business combinations and to non-controlling interests, with subsequent remeasurements recognized in profit or loss. This treatment is consistent with the accounting applied to contingent consideration in the books of the acquirer.

B.3.2. Goodwill

The excess of the cost of an acquisition over the Group s interest in the fair value of the identifiable assets and liabilities of the acquiree is recognized as goodwill at the date of the business combination.

Goodwill arising on the acquisition of subsidiaries is shown as a separate line on the balance sheet whereas goodwill arising on the acquisition of associates and joint ventures is recorded in ***Investments in associates and joint ventures***.

Goodwill arising on the acquisition of foreign entities is measured in the functional currency of the acquired entity and translated into euros using the exchange rate prevailing at the end of the reporting period.

In accordance with IAS 36 (Impairment of Assets), goodwill is carried at cost less accumulated impairment (see Note B.6.).

Goodwill is tested for impairment annually for each cash-generating unit (CGU) and whenever events or circumstances indicate that impairment might exist. Such events or circumstances include significant changes more likely than not to have an other-than-temporary impact on the substance of the original investment.

B.4. OTHER INTANGIBLE ASSETS

Other intangible assets are initially measured at acquisition cost or production cost, including any directly attributable costs of preparing the asset for its intended use, or (in the case of assets acquired in a business combination) at fair value as of the date of the business combination. Intangible assets are amortized on a straight line basis over their useful lives.

The useful lives of other intangible assets are reviewed at the end of each reporting period. The effect of any adjustment to useful lives is recognized prospectively as a change in accounting estimate.

Amortization of other intangible assets is recognized in the income statement within ***Amortization of intangible assets*** except for amortization charged against (i) acquired or internally-developed software and (ii) other rights of an industrial or operational nature, which is recognized in the relevant classification of expense by function.

The Group does not own any other intangible assets with an indefinite useful life.

Intangible assets (other than goodwill) are carried at cost less accumulated amortization and accumulated impairment, if any, in accordance with IAS 36 (see Note B.6.).

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B.4.1. Research and development not acquired in a business combination

Internally generated research and development

Under IAS 38, research expenses are recognized in profit or loss when incurred.

Internally generated development expenses are recognized as an intangible asset if, and only if, all the following six criteria can be demonstrated: (a) the technical feasibility of completing the development project; (b) the Group s intention to complete the project; (c) the Group s ability to use the project; (d) the probability that the project will generate future economic benefits; (e) the availability of adequate technical, financial and other resources to complete the project; and (f) the ability to measure the development expenditure reliably.

Due to the risks and uncertainties relating to regulatory approval and to the research and development process, the six criteria for capitalization are usually considered not to have been met until the product has obtained marketing approval from the regulatory authorities. Consequently, internally generated development expenses arising before marketing approval has been obtained, mainly the cost of clinical trials, are generally expensed as incurred within ***Research and development expenses***.

Some industrial development expenses (such as those incurred in developing a second-generation synthesis process) are incurred after marketing approval has been obtained, in order to improve the industrial process for an active ingredient. To the extent that the six IAS 38 criteria are considered as having been met, such expenses are recognized as an asset on the balance sheet within ***Other intangible assets*** as incurred. Similarly, some clinical trials, for example those undertaken to obtain a geographical extension for a molecule that has already obtained marketing approval in a major market, may in certain circumstances meet the six capitalization criteria under IAS 38, in which case the related expenses are recognized as an asset on the balance sheet within ***Other intangible assets.***

Separately acquired research and development

Payments for separately acquired research and development are capitalized within ***Other intangible assets*** provided that they meet the definition of an intangible asset: a resource that is (i) controlled by the Group, (ii) expected to provide future economic benefits for the Group, and (iii) identifiable (i.e. it is either separable or arises from contractual or legal rights). Under paragraph 25 of IAS 38, the first condition for capitalization (the probability that the expected future economic benefits from the asset will flow to the entity) is considered to be satisfied for separately acquired research and development. Because the amount of the payments is determinable, the second condition for

capitalization (the cost can be measured reliably) is also met. Consequently, upfront and milestone payments to third parties related to pharmaceutical products for which regulatory marketing approval has not yet been obtained are recognized as intangible assets, and amortized on a straight line basis over their useful lives beginning when regulatory approval is obtained.

Payments under research and development arrangements relating to access to technology or to databases and payments made to purchase generics files are also capitalized, and amortized over the useful life of the intangible asset.

Subcontracting arrangements, payments for research and development services, and continuous payments under research and development collaborations which are unrelated to the outcome of that collaboration, are expensed over the service term.

B.4.2. Other intangible assets not acquired in a business combination

Licenses other than those related to pharmaceutical products and research projects, in particular software licenses, are capitalized at acquisition cost, including any directly attributable cost of preparing the software for its intended use. Software licenses are amortized on a straight line basis over their useful lives for the Group (three to five years).

Internally generated costs incurred to develop or upgrade software are capitalized if the IAS 38 recognition criteria are satisfied, and amortized on a straight line basis over the useful life of the software from the date on which the software is ready for use.

B.4.3. Other intangible assets acquired in a business combination

Other intangible assets acquired in a business combination which relate to in-process research and development and currently marketed products and are reliably measurable are identified separately from goodwill, measured at fair value and capitalized within ***Other intangible assets*** in accordance with IFRS 3 (Business Combinations) and IAS 38 (Intangible Assets). The related deferred tax liability is also recognized if a deductible or taxable temporary difference exists.

In-process research and development acquired in a business combination is amortized on a straight line basis over its useful life from the date of receipt of regulatory approval.

Rights to products currently marketed by the Group are amortized on a straight line basis over their useful lives, determined based on cash flow forecasts which take into account the patent protection period of the marketed product.

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B.5. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment is initially measured and recognized at acquisition cost, including any directly attributable cost of preparing the asset for its intended use, or (in the case of assets acquired in a business combination) at fair value as of the date of the business combination. The component-based approach to accounting for property, plant and equipment is applied. Under this approach, each component of an item of property, plant and equipment with a cost which is significant in relation to the total cost of the item and which has a different useful life from the other components must be depreciated separately.

After initial measurement, property, plant and equipment is carried at cost less accumulated depreciation and impairment, except for land which is carried at cost less impairment.

Subsequent costs are not recognized as assets unless (i) it is probable that future economic benefits associated with those costs will flow to the Group and (ii) the costs can be measured reliably.

Day-to-day maintenance costs of property, plant and equipment are expensed as incurred.

Borrowing costs attributable to the financing of items of property, plant and equipment, and incurred during the construction period, are capitalized as part of the acquisition cost of the item.

Government grants relating to property, plant and equipment are deducted from the acquisition cost of the asset to which they relate.

In accordance with IAS 17 (Leases), items of property, plant and equipment leased by Sanofi as lessee under finance leases are recognized as an asset on the balance sheet, with the related lease obligation recognized as a liability. A lease qualifies as a finance lease if it transfers substantially all of the risks and rewards of ownership of the asset to the Group. Assets held under finance leases are carried at the lower of the fair value of the leased asset or the present value of the minimum lease payments, and are depreciated over the shorter of the useful life of the asset or the term of the lease.

The depreciable amount of items of property, plant and equipment, net of any residual value, is depreciated on a straight line basis over the useful life of the asset. The useful life of an asset is usually equivalent to its economic life.

The useful lives of property, plant and equipment are as follows:

Buildings	15 to 40 years
Fixtures	10 to 20 years
Plant and equipment	5 to 15 years
Other property, plant and equipment	3 to 15 years

Useful lives and residual values of property, plant and equipment are reviewed annually. The effect of any adjustment to useful lives or residual values is recognized prospectively as a change in accounting estimate.

Depreciation of property, plant and equipment is recognized as an expense in the income statement, in the relevant classification of expense by function.

B.6. IMPAIRMENT OF PROPERTY, PLANT AND EQUIPMENT, INTANGIBLE ASSETS, AND INVESTMENTS IN ASSOCIATES AND JOINT VENTURES

B.6.1. Impairment of property, plant and equipment and intangible assets

In accordance with IAS 36 (Impairment of Assets), assets that generate separate cash flows and assets included in cash-generating units (CGUs) are assessed for impairment when events or changes in circumstances indicate that the asset or CGU may be impaired.

A CGU is the smallest identifiable group of assets that generates cash inflows that are largely independent of the cash inflows from other assets or groups of assets.

Under IAS 36, each CGU to which goodwill is allocated must (i) represent the lowest level within the entity at which the goodwill is monitored for internal management purposes, and (ii) not be larger than an operating segment determined in accordance with IFRS 8 (Operating Segments), before application of the IFRS 8 aggregation criteria. Consequently, the CGUs used by the Group to test goodwill for impairment correspond to the geographical sub-segments of each operating segment.

Quantitative and qualitative indications of impairment (primarily relating to the status of the research and development portfolio, pharmacovigilance, patent litigation, and the launch of competing products) are reviewed at the end of each reporting period. If there is any internal or external indication of impairment, the Group estimates the recoverable amount of the asset or CGU.

Other intangible assets not yet available for use (such as capitalized in-process research and development), and CGUs that include goodwill, are tested for impairment annually whether or not there is any indication of impairment, and more frequently if any event or circumstance indicates that they might be impaired. Such assets are not amortized.

When there is an internal or external indication of impairment, the Group estimates the recoverable amount of the asset and recognizes an impairment loss if the carrying amount of the asset exceeds its recoverable amount. The recoverable amount of the asset is the higher of its fair value less costs to sell or its value in use. To determine value in use, the Group uses estimates of future cash flows generated by the asset or CGU, prepared using the same methods as those used in the initial measurement of the asset or CGU on the basis of medium-term plans.

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In the case of goodwill, estimates of future cash flows are based on a medium-term strategic plan, an extrapolation of the cash flows beyond the plan, and a terminal value. In the case of other intangible assets, the period used is based on the economic life of the asset.

Estimated cash flows are discounted at long-term market interest rates that reflect the best estimate by Sanofi of the time value of money, the risks specific to the asset or CGU, and economic conditions in the geographical regions in which the business activity associated with the asset or CGU is located.

Certain assets and liabilities that are not directly attributable to a specific CGU are allocated between CGUs on a basis that is reasonable, and consistent with the allocation of the corresponding goodwill.

Impairment losses arising on property, plant and equipment, on software and on intangible assets of an industrial or operational nature are recognized in the relevant classification of expense by function.

Impairment losses arising on other intangible assets are recognized within ***Impairment of intangible assets*** on the income statement.

B.6.2. Impairment of investments in associates and joint ventures

In accordance with IAS 28 (Investments in Associates), the Group applies the criteria specified in IAS 39 (Financial Instruments: Recognition and Measurement) to determine whether an investment in an associate or joint venture may be impaired (see Note B.8.2.). If an investment is impaired, the amount of the impairment loss is determined by applying IAS 36 (see Note B.6.1.) and recognized in ***Share of profit/(loss) of associates and joint ventures***.

B.6.3. Reversals of impairment losses charged against property, plant and equipment, intangible assets, and investments in associates and joint ventures

At the end of each reporting period, the Group assesses whether events or changes in circumstances indicate that an impairment loss recognized in a prior period in respect of an asset (other than goodwill) or an investment in an associate or joint venture can be reversed. If this is the case, and the recoverable amount as determined based on the new estimates exceeds the carrying amount of the asset, the Group reverses the impairment loss only to the extent of the carrying amount that would have been determined had no impairment loss been recognized for the asset.

Reversals of impairment losses in respect of other intangible assets are recognized in the income statement line item ***Impairment of intangible assets***, while reversals of impairment losses in respect of investments in associates and joint ventures are recognized in the income statement line item ***Share of profit/(loss) of associates and joint ventures***. Impairment losses taken against goodwill are never reversed, unless the goodwill is part of the carrying amount of an investment in an associate or joint venture.

B.7. ASSETS HELD FOR SALE OR EXCHANGE AND LIABILITIES RELATED TO ASSETS HELD FOR SALE OR EXCHANGE

In accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations), non-current assets and groups of assets are classified as held for sale in the balance sheet if their carrying amount will be recovered principally through a sale transaction rather than through continuing use. Within the meaning of IFRS 5, the term sale also includes exchanges for other assets.

Non-current assets or asset groups held for sale must be available for immediate sale in their present condition, subject only to terms that are usual and customary for sales of such assets, and a sale must be highly probable. Criteria used to determine whether a sale is highly probable include:

- the appropriate level of management must be committed to a plan to sell;
- an active program to locate a buyer and complete the plan must have been initiated;
- the asset must be actively marketed for sale at a price that is reasonable in relation to its current fair value;
- completion of the sale should be foreseeable within the twelve months following the date of reclassification as held for sale or exchange;
- and actions required to complete the plan should indicate that it is unlikely that significant changes to the plan will be made or that the plan will be withdrawn.

Before initial reclassification of the non-current asset (or asset group) as held for sale or exchange, the carrying amounts of the asset (or of all the assets and liabilities in the asset group) must be measured in accordance with the applicable standards.

Subsequent to reclassification as held for sale or exchange, the non-current asset (or asset group) is measured at the lower of carrying amount or fair value less costs to sell, with any write-down recognized by means of an impairment loss. Once a non-current asset has been reclassified as held for sale or exchange, it is no longer depreciated or amortized.

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In a disposal of an equity interest leading to loss of control, all the assets and liabilities of the entity involved are classified as held for sale assets or liabilities within the balance sheet line items ***Assets held for sale or exchange*** or ***Liabilities related to assets held for sale or exchange***, provided that the disposal satisfies the IFRS 5 classification criteria.

The profit or loss generated by a held for sale asset group is reported on a separate line in the income statement for the current period and for the comparative periods presented, provided that the asset group:

- represents a separate major line of business or geographical area of operations; or,
- is part of a single coordinated plan to dispose of a separate major line of business or geographical area of operations; or,
- is a subsidiary acquired exclusively with a view to resale.

Events or circumstances beyond the Group s control may extend the period to complete the sale or exchange beyond one year without precluding classification of the asset (or disposal group) in ***Assets held for sale or exchange*** provided that there is sufficient evidence that the Group remains committed to the planned sale or exchange.

Finally, in the event of changes to a plan of sale that require an asset no longer to be classified as held for sale, IFRS 5 specifies the following treatment:

- the assets and liabilities previously classified as held for sale are reclassified to the appropriate balance sheet line items, with no restatement of comparative periods;
- each asset is measured at the lower of (a) its carrying amount before the asset was reclassified as held for sale, adjusted for any depreciation, amortization or revaluation that would have been recognized if the asset had not been reclassified as held for sale, or (b) its recoverable amount at the date of the reclassification;
- the backlog of depreciation, amortization and impairment not recognized while non-current assets were classified as held for sale must be reported in the same income statement line item that was used to report impairment losses arising on initial reclassification of assets as held for sale and gains or losses arising on the sale of such assets. In the consolidated income statement, these impacts are reported in the line item ***Other gains and losses, and litigation***;
- the net income of a business previously classified as discontinued or held for exchange and reported on a separate line in the income statement must be reclassified and included in net income from continuing operations, for all periods presented;
- in addition, segment information relating to the income statement and the statement of cash flows (acquisitions of

non-current assets) must be disclosed in the notes to the financial statements in accordance with IFRS 8 (Operating Segments), and must also be restated for all prior periods presented.

B.8. FINANCIAL INSTRUMENTS

B.8.1. Non-derivative financial assets

In accordance with IAS 39 (Financial Instruments: Recognition and Measurement) and IAS 32 (Financial Instruments: Presentation), Sanofi has adopted the following classification for non-derivative financial assets, based on the type of asset and on management intention at the date of initial recognition. The designation and classification of such financial assets are subsequently reassessed at the end of each reporting period.

Non-derivative financial assets are recognized on the date when Sanofi becomes party to the contractual terms of the asset. On initial recognition, financial assets are measured at fair value, plus direct transaction costs in the case of financial assets not classified as fair value through profit or loss.

Classification, presentation and subsequent measurement of non-derivative financial assets are as follows:

Financial assets at fair value through profit or loss

These assets are classified on the balance sheet in the line items ***Other non-current assets***, ***Current financial assets*** and ***Cash and cash equivalents***.

Financial assets at fair value through profit or loss comprise assets held for trading (financial assets acquired principally for the purpose of reselling them in the near term, usually within less than 12 months), and financial instruments designated as fair value through profit and loss on initial recognition in accordance with the conditions for application of the fair value option.

Such financial assets are carried at fair value without any deduction for transaction costs that may be incurred on sale. Realized and unrealized gains and losses resulting from changes in the fair value of these assets are recognized in the income statement, in ***Financial income*** or ***Financial expenses***.

Realized and unrealized foreign exchange gains and losses on financial assets in currencies other than the euro are recognized in the income statement in ***Financial income*** or ***Financial expenses***.

Available-for-sale financial assets

Available-for-sale financial assets are non-derivative financial assets that are (i) designated by management as available-for-sale or (ii) not classified as financial assets at fair value through profit or loss, held-to-maturity

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investments or loans and receivables . This category includes equity interests in quoted or unquoted companies other than investments in associates and joint ventures. Available-for-sale financial assets are classified in ***Other non-current assets***.

Available-for-sale financial assets are measured at fair value without any deduction for transaction costs that may be incurred on sale. Gains and losses arising from changes in the fair value of these assets, including unrealized foreign exchange gains and losses, are recognized directly in equity in the consolidated statement of comprehensive income in the period in which they occur, except for impairment losses and foreign exchange gains and losses on debt instruments. On derecognition of an available-for-sale financial asset, or on recognition of an impairment loss on such an asset, the cumulative gains and losses previously recognized in equity are recognized in the income statement for the period within ***Financial income*** or ***Financial expenses***.

Interest income and dividends on equity instruments are recognized in the income statement within ***Financial income*** when the Group is entitled to receive payment.

Available-for-sale financial assets in the form of equity interests in companies not quoted in an active market are measured at cost if their fair value cannot be measured reliably; an impairment loss is recognized when there is objective evidence that such an asset is impaired.

Held-to-maturity investments

Held-to-maturity investments are non-derivative financial assets with fixed or determinable payments and fixed maturities that the Group has the positive intention and ability to hold to maturity.

Such investments are measured at amortized cost using the effective interest method.

Sanofi did not hold any such investments during the years ended December 31, 2015, 2014 or 2013.

Loans and receivables

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They are presented in current assets, within ***Other current assets*** in the case of loans and ***Accounts receivable*** in the case of trade receivables. Loans with a maturity of more than 12 months are presented in Long-term loans and advances within ***Other non-current assets***. Those financial assets are measured at amortized cost using the effective interest method.

B.8.2. Impairment of non-derivative financial assets

Indicators of impairment are reviewed for all non-derivative financial assets at the end of each reporting period. Such indicators include default in contractual payments, significant financial difficulties of the issuer or debtor, probability of

bankruptcy, or a prolonged or significant decline in quoted market price. An impairment loss is recognized in the income statement if there is objective evidence of impairment resulting from one or more events after the initial recognition of the asset (a loss event) and that loss event has a reliably measurable impact on the estimated future cash flows of the financial asset (or group of financial assets).

The impairment loss on loans and receivables, which are measured at amortized cost, is the difference between the carrying amount of the asset and the present value of estimated future cash flows discounted at the financial asset s original effective interest rate.

When an impairment loss is identified on an available-for-sale financial asset, the cumulative losses previously recognized directly in equity are recorded in the income statement. The loss recognized in the income statement is the difference between the acquisition cost (net of principal repayments and amortization) and the fair value at the time of impairment, less any impairment loss previously recognized in the income statement.

The impairment loss on investments in companies not quoted in an active market and measured at cost is the difference between the carrying amount of the investment and the present value of its estimated future cash flows, discounted at the current market interest rate for similar financial assets.

Impairment losses in respect of loans are recognized within ***Financial expenses*** in the income statement.

Impairment losses in respect of trade receivables are recognized within ***Selling and general expenses*** in the income statement.

Impairment losses on investments in companies that are not quoted in an active market and are measured at cost, and on equity instruments classified as available-for-sale financial assets, cannot be reversed through the income statement.

B.8.3. Derivative instruments

Derivative instruments that do not qualify for hedge accounting are initially and subsequently measured at fair value, with changes in fair value recognized on the income statement in ***Other operating income*** or in ***Financial income*** or ***Financial expenses***, depending on the nature of the underlying economic item which is hedged.

Derivative instruments that qualify for hedge accounting are measured in accordance with the hedge accounting requirements of IAS 39 (see Note B.8.4.).

IFRS 13 (Fair Value Measurement) requires counterparty credit risk to be taken into account when measuring the fair value of financial instruments. This risk is estimated on the basis of observable, publicly-available statistical data.

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Policy on offsetting

In order for a financial asset and a financial liability to be presented as a net amount on the balance sheet under IAS 32, there must be (a) a legally enforceable right to offset and (b) the intention either to settle on a net basis, or to realize the asset and settle the liability simultaneously.

In addition, IFRS 7 (Financial Instruments: Disclosures) requires the notes to the financial statements to include a schedule showing a list of any offsets recognized under IAS 32 and of transactions for which only criterion (a) is met, i.e. potential offsets such as those specified in close out netting agreements (positions offset only in the event of default, as specified in the International Swaps and Derivatives Association (ISDA)).

B.8.4. Hedging

Hedging involves the use of derivative financial instruments. Changes in the fair value of such instruments are intended to offset the exposure of the hedged items to changes in fair value.

As part of its overall interest rate risk and foreign exchange risk management policy, the Group enters into various transactions involving derivative instruments. Derivative instruments used in connection with the Group s hedging policy may include forward exchange contracts, currency options, interest rate swaps and interest rate options.

Derivative financial instruments qualify as hedging instruments for hedge accounting purposes when (a) at the inception of the hedge there is formal designation and documentation of the hedging relationship and of the risk management strategy and objective; (b) the hedge is expected by management to be highly effective in offsetting the risk; (c) the forecast transaction being hedged is highly probable and presents an exposure to variations in cash flows that could ultimately affect profit or loss; (d) the effectiveness of the hedge can be reliably measured; and (e) the effectiveness of the hedge is assessed on an ongoing basis and the hedge is determined actually to have been highly effective throughout the reporting periods for which the hedge was designated.

Those criteria are applied when the Group uses derivative instruments designated as a fair value hedge, a cash flow hedge or a hedge of a net investment in a foreign operation.

Fair value hedge

A fair value hedge is a hedge of the exposure to changes in fair value of a recognized asset or liability or unrecognized firm commitment that could affect profit or loss.

Changes in fair value of the hedging instrument and changes in fair value of the hedged item attributable to the hedged

risk are recognized in the income statement, within ***Other operating income*** for hedges of operating activities, and within ***Financial income*** or ***Financial expenses*** for hedges of investing or financing activities.

Cash flow hedge

A cash flow hedge is a hedge of the exposure to variability in cash flows attributable to a particular risk associated with a recognized asset or liability, or a highly probable forecast transaction, which could affect profit or loss.

Changes in fair value of the hedging instrument attributable to the effective portion of the hedge are recognized directly in equity in the consolidated statement of comprehensive income. Changes in fair value attributable to the ineffective portion of the hedge are recognized in the income statement within ***Other operating income*** for hedges of operating activities, and within ***Financial income*** or ***Financial expenses*** for hedges of investing or financing activities.

Cumulative changes in fair value of the hedging instrument previously recognized in equity are reclassified to the income statement when the hedged transaction affects profit or loss. These transferred gains and losses are recorded within ***Other operating income*** for hedges of operating activities, and within ***Financial income*** or ***Financial expenses*** for hedges of investing or financing activities.

When a forecast transaction results in the recognition of a non-financial asset or liability, cumulative changes in the fair value of the hedging instrument previously recognized in equity are included in the initial measurement of that asset or liability.

When the hedging instrument expires or is sold, terminated or exercised, the cumulative gain or loss previously recognized in equity remains separately recognized in equity and is not reclassified to the income statement until the forecast transaction occurs. However, if the Group no longer expects the forecast transaction to occur, the cumulative gain or loss previously recognized in equity is recognized immediately in profit or loss.

Hedge of a net investment in a foreign operation

In a hedge of a net investment in a foreign operation, changes in the fair value of the hedging instrument attributable to the effective portion of the hedge are recognized directly in equity in the consolidated statement of comprehensive income. Changes in fair value attributable to the ineffective portion of the hedge are recognized in the income statement within ***Financial income*** or ***Financial expenses***. When the investment in the foreign operation is sold, the changes in the fair value of the hedging instrument previously recognized in equity are reclassified to the income statement within ***Financial income*** or ***Financial expenses***.

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Discontinuation of hedge accounting

Hedge accounting is discontinued when (a) the hedging instrument expires or is sold, terminated or exercised, or (b) the hedge no longer meets the criteria for hedge accounting, or (c) the Group revokes the hedge designation, or (d) management no longer expects the forecast transaction to occur.

B.8.5. Non-derivative financial liabilities

Borrowings and debt

Bank borrowings and debt instruments are initially measured at fair value of the consideration received, net of directly attributable transaction costs.

Subsequently, they are measured at amortized cost using the effective interest method. All costs related to the issuance of borrowings or debt instruments, and all differences between the issue proceeds net of transaction costs and the value on redemption, are recognized within ***Financial expenses*** in the income statement over the term of the debt using the effective interest method.

Liabilities related to business combinations and to non-controlling interests

Liabilities related to business combinations and to non-controlling interests are classified as applicable into a

current portion and a non-current portion. These line items are used to recognize contingent consideration payable in connection with business combinations (see Note B.3.1. for a description of the relevant accounting policy), and the fair value of put options granted to non-controlling interests.

Fair value adjustments to put options granted to non-controlling interests are recognized in equity.

Other non-derivative financial liabilities

Other non-derivative financial liabilities include trade accounts payable, which are measured at fair value (which in most cases equates to face value) on initial recognition, and subsequently at amortized cost.

B.8.6. Fair value of financial instruments

The disclosures required under IFRS 13 relating to the fair value of the principal financial assets and liabilities reported in the consolidated balance sheet and in the notes to the consolidated financial statements, and to the level of these instruments in the fair value hierarchy, are presented in Note D.16. The disclosures required under IFRS 13 relating to the sensitivity of level 3 fair value measurements are presented in Note D.18.

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The table below shows the disclosures required under IFRS 7 relating to the measurement principles applied to financial instruments.

			Method used to determine fair value			
					Market data	
Note	Type of financial instrument	Measurement principle	Valuation model	Exchange rate	Interest rate	Volatility
D.7.	Available-for-sale financial assets (quoted equity securities)	Fair value	Quoted market price		N/A	
D.7.	Available-for-sale financial assets (unquoted debt securities)	Fair value	Present value of future cash flows	N/A	Mid swap + z-spread for bonds of comparable risk and maturity	N/A
D.7.	Long-term loans and advances	Amortized cost	The amortized cost of long-term loans and advances at the end of the reporting period is not materially different from the fair value.			
D.7.	Financial assets recognized under the fair value option[1]	Fair value	Market value (net asset value)		N/A	
D.20.	Forward currency contracts	Fair value	Present value of future cash flows	ECB Fixing	< 1 year: Mid Money Market > 1 year: Mid Zero Coupon	N/A
D.20.	Currency options	Fair value	Options: Garman & Kohlhagen	ECB Fixing	< 1 year: Mid Money Market > 1 year: Mid Zero Coupon	Mid in-the-money
D.20.	Interest rate swaps	Fair value	Present value of future cash flows	N/A	< 1 year: Mid Money Market and LIFFE interest rate futures > 1 year: Mid Zero Coupon	N/A
D.20.	Cross-currency swaps	Fair value	Present value of future cash flows	ECB Fixing	< 1 year: Mid Money Market and LIFFE interest rate futures > 1 year: Mid Zero Coupon	N/A
D.13.	Investments in mutual funds	Fair value	Market value (net asset value)		N/A	
D.13.	Negotiable debt instruments, commercial paper, instant access deposits and term deposits	Amortized cost	Because these instruments have a maturity of less than 3 months, amortized cost is regarded as an acceptable approximation of fair value as disclosed in the notes to the consolidated financial statements. In the case of debt with a maturity of less than 3 months, amortized cost is regarded as an acceptable approximation of fair value as reported in the notes to the consolidated financial statements.			
D.17.	Debt	Amortized cost[2]	For debt with a maturity of more than 3 months, fair value as reported in the notes to the consolidated financial statements is determined either by reference to quoted market prices at the end of the reporting period (quoted instruments) or by discounting the future cash flows based on observable market data at the end of the reporting period (unquoted instruments).			
D.18.	Liabilities related to business combinations and to non-controlling interests (CVRs)	Fair value	Quoted market price		N/A	
D.18.	Liabilities related to business combinations and to non-controlling interests (other than	Fair value[3]	Under IAS 32, contingent consideration payable in a business combination is a financial liability. The fair value of such liabilities is determined by adjusting the contingent			

CVRs)	consideration at the end of the reporting period using the method described in Note D.18.

(1) These assets are held to fund a deferred compensation plan offered to certain employees.

(2) In the case of debt designated as a hedged item in a fair value hedging relationship, the carrying amount in the consolidated balance sheet includes changes in fair value attributable to the hedged risk(s).

(3) For business combinations completed prior to application of the revised IFRS 3, contingent consideration is recognized when payment becomes probable (see Note B.3.1.).

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The other financial assets and liabilities included in the consolidated balance sheet are:

- Non-derivative current financial assets and liabilities: because these items have a maturity close to the end of the reporting period, the Group regards their carrying amount (i.e. historical cost less any credit risk allowance) as a reasonable approximation of their fair value;

- Equity interests in companies not quoted in an active market and the fair value of which cannot be measured reliably, which are measured at amortized cost in accordance with IAS 39.

B.8.7. Derecognition of financial instruments

Sanofi derecognizes a financial asset when the contractual rights to cash flows from the asset have ended or have been transferred and when the Group has transferred substantially all risks and rewards of ownership of the asset. If the Group has neither transferred nor retained substantially all the risks and rewards of ownership of a financial asset, it is derecognized if the Group does not retain control of the asset.

A financial liability is derecognized when the Group s contractual obligations in respect of the liability are discharged, cancelled or extinguished.

B.8.8. Risks relating to financial instruments

Market risks in respect of non-current financial assets, cash equivalents, derivative instruments and debt are described in the risk factors presented in Item 3.D. and Item 11.

Credit risk is the risk that customers may fail to pay their debts. This risk also arises as a result of the concentration of the Group s sales with its largest customers, in particular certain wholesalers in the United States. Customer credit risk is described in the risk factors presented in Item 3.D.

B.9. INVENTORIES

Inventories are measured at the lower of cost or net realizable value. Cost is calculated using the weighted average cost method or the first-in, first-out method, depending on the nature of the inventory.

The cost of finished goods inventories includes costs of purchase, costs of conversion and other costs incurred in bringing the inventories to their present location and condition.

Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale.

B.10. CASH AND CASH EQUIVALENTS

Cash and cash equivalents as shown in the consolidated balance sheet and statement of cash flows comprise cash, plus liquid short-term investments that are readily convertible into cash and are subject to an insignificant risk of changes in value in the event of movements in interest rates.

B.11. TREASURY SHARES

In accordance with IAS 32, Sanofi treasury shares are deducted from equity, irrespective of the purpose for which they are held. No gain or loss is recognized in the income statement on the purchase, sale, impairment or cancellation of treasury shares.

B.12. PROVISIONS FOR RISKS

In accordance with IAS 37 (Provisions, Contingent Liabilities and Contingent Assets), Sanofi records a provision when there is a present obligation, whether legal or constructive, as a result of a past event; it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation; and a reliable estimate can be made of the amount of the outflow of resources.

If the obligation is expected to be settled more than twelve months after the end of the reporting period, or has no definite settlement date, the provision is recorded within ***Provisions and other non-current liabilities***.

Provisions relating to the insurance programs in which the Group s captive insurance company participates are based on risk exposure estimates calculated by management, with assistance from independent actuaries, using Incurred But Not Reported (IBNR) techniques. Those techniques use past claims experience, within the Group or in the market, to estimate future trends in the cost of claims.

Contingent liabilities are not recognized, but are disclosed in the notes to the financial statements unless the possibility of an outflow of economic resources is remote.

Provisions are estimated on the basis of events and circumstances related to present obligations at the end of the reporting period and of past experience, and to the best of management s knowledge at the date of preparation of the financial statements.

Reimbursements offsetting the probable outflow of resources are recognized as assets only if it is virtually certain that they will be received. Contingent assets are not recognized.

Restructuring provisions are recognized if the Group has a detailed, formal restructuring plan at the end of the reporting period and has announced its intention to implement this plan to those affected by it.

No provisions are recorded for future operating losses.

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Sanofi records non-current provisions for certain obligations, such as legal or constructive environmental obligations and litigation, where an outflow of resources is probable and the amount of the outflow can be reliably estimated. Where the effect of the time value of money is material, these provisions are measured at the present value of the expenditures expected to be required to settle the obligation, calculated using a discount rate that reflects an estimate of the time value of money and the risks specific to the obligation.

Increases in provisions to reflect the effects of the passage of time are recognized in ***Financial expenses***.

B.13. EMISSION RIGHTS

Under international agreements, the European Union has committed to reducing greenhouse gas emissions and instituted an emissions allowance trading scheme. Less than ten of the Group s European sites are directly affected by this scheme. If allocated allowances at Group level were to be insufficient to cover actual emissions, an expense would be recognized to reflect the additional allowances deliverable, measured at the market value of the allowances.

B.14. REVENUE RECOGNITION

Revenue arising from the sale of goods is presented in the income statement within ***Net sales***. Net sales comprise revenue from sales of pharmaceutical products, active ingredients, and vaccines, net of sales returns, customer incentives, discounts, and of certain sales-based payments paid or payable to the healthcare authorities.

Revenue is recognized when all of the following conditions have been met: the risks and rewards of ownership have been transferred to the customer; the Group no longer has effective control over the goods sold; the amount of revenue and costs associated with the transaction can be measured reliably; and it is probable that the economic benefits associated with the transaction will flow to the Group, in accordance with IAS 18 (Revenue). In particular, the contracts between Sanofi Pasteur and government agencies specify conditions for the supply and acceptance of batches of vaccines; revenue is recognized when those conditions are achieved.

The Group offers various types of price reductions on its products. In particular, products sold in the United States are covered by various governmental programs (such as Medicare and Medicaid) under which products are sold at a discount. In addition, rebates are granted to healthcare authorities, and under contractual arrangements with certain customers. Some wholesalers are entitled to chargeback incentives based on the selling price to the end customer, under specific contractual arrangements. Cash discounts may also be granted for prompt payment.

Returns, discounts, incentives and rebates, as described above, are recognized in the period in which the underlying sales are recognized as a reduction of sales revenue.

These amounts are calculated as follows:

- provisions for chargeback incentives are estimated on the basis of the relevant subsidiary s standard sales terms and conditions, and in certain cases on the basis of specific contractual arrangements with the customer. They represent management s best estimate of the ultimate amount of chargeback incentives that will eventually be claimed by the customer;

- provisions for rebates based on attainment of sales targets are estimated and accrued as each of the underlying sales transactions is recognized;

- provisions for price reductions under Government and State programs, largely in the United States, are estimated on the basis of the specific terms of the relevant regulations or agreements, and accrued as each of the underlying sales transactions is recognized; and

- provisions for sales returns are calculated on the basis of management s best estimate of the amount of product that will ultimately be returned by customers. In countries where product returns are possible, the Group operates a returns policy that allows the customer to return products within a certain period on either side of the expiry date (usually 6 months before and 12 months after the expiry date). The provision is estimated on the basis of past experience of sales returns.

The Group also takes into account factors such as levels of inventory in its various distribution channels, product expiry dates, information about potential discontinuation of products, the entry of competing generics into the market, and the launch of over-the-counter medicines.

In each case, the provisions are subject to continuous review and adjustment as appropriate based on the most recent data available to management.

The Group believes that it has the ability to measure each of the above provisions reliably, using the following factors in developing its estimates:

- the nature and patient profile of the underlying product;

- the applicable regulations or the specific terms and conditions of contracts with governmental authorities, wholesalers and other customers;

- historical data relating to similar contracts, in the case of qualitative and quantitative rebates and chargeback incentives;

- past experience and sales growth trends for the same or similar products;

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- actual inventory levels in distribution channels, monitored by the Group using internal sales data and externally provided data;
- the shelf life of the Group s products; and
- market trends including competition, pricing and demand.

Non-product revenues, mainly comprising royalty income from license arrangements that constitute continuing operations of the Group (see Note C.), are presented in ***Other revenues***.

B.15. COST OF SALES

Cost of sales consists primarily of the industrial cost of goods sold, payments made under licensing agreements, and distribution costs. The industrial cost of goods sold includes the cost of materials, depreciation of property, plant and equipment and software, personnel costs, and other expenses attributable to production.

B.16. RESEARCH AND DEVELOPMENT

Note B.4.1. Research and development not acquired in a business combination and Note B.4.3. Other intangible assets acquired in a business combination describe the principles applied to the recognition of separately acquired research and development.

Contributions or reimbursements received from alliance partners are recorded as a reduction of ***Research and development expenses***.

B.17. OTHER OPERATING INCOME AND EXPENSES

B.17.1. Other operating income

Other operating income includes the share of profits that the Group is entitled to receive from alliance partners in respect of product marketing agreements. It also includes revenues generated under certain complex agreements, which may include partnership and co-promotion arrangements.

Upfront payments received are deferred until the service obligation is met. Milestone payments are assessed on a case by case basis, and recognized in the income statement on delivery of the products and/or provision of the services in question. Revenue generated in connection with these services is recognized on the basis of delivery of the goods or provision of the services to the other contracting party.

This line item also includes realized and unrealized foreign exchange gains and losses on operating activities (see Note B.8.4.), and operating gains on disposals not regarded as major disposals (see Note B.20.).

B.17.2. Other operating expenses

Other operating expenses mainly comprise the share of profits that alliance partners are entitled to receive from the Group under product marketing agreements.

B.18. AMORTIZATION AND IMPAIRMENT OF INTANGIBLE ASSETS

B.18.1. Amortization of intangible assets

The expenses recorded in this line item comprise amortization of product rights (see Note D.4.), because the benefit of those rights to the Group s commercial, industrial and development functions cannot be separately identified.

Amortization of software, and of other rights of an industrial or operational nature, is recognized as an expense in the income statement, in the relevant line items of expense by function.

B.18.2. Impairment of intangible assets

This line item includes impairment losses (other than those associated with restructuring) recognized against intangible assets (including goodwill, but excluding software and other rights of an industrial or operational nature), and any reversals of such impairment losses.

B.19. FAIR VALUE REMEASUREMENT OF CONTINGENT CONSIDERATION LIABILITIES

Changes in the fair value of contingent consideration that was (i) already carried in the books of an acquired entity, or (ii) granted in connection with a business combination and initially recognized as a liability in accordance with the revised IFRS 3, are reported in profit or loss in accordance with the principles described in Note B.3.1. Such adjustments are reported separately in the income statement, in the line item ***Fair value remeasurement of contingent consideration liabilities***. This line item also includes the effect of the unwinding of discounting, and of exchange rate movements where the liability is expressed in a currency other than the functional currency of the reporting entity.

B.20. RESTRUCTURING COSTS AND OTHER GAINS AND LOSSES, AND LITIGATION

B.20.1. Restructuring costs

Restructuring costs include early retirement benefits, compensation for early termination of contracts, and rationalization costs relating to restructured sites. Asset impairment losses directly attributable to restructuring are also recorded on this line. Restructuring costs included on this line relate only to unusual and major restructuring plans.

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B.20.2. Other gains and losses, and litigation

This line item includes the impact of material transactions of an unusual nature or amount which the Group believes it is necessary to report separately in the income statement in order to improve the relevance of the financial statements.

The line item ***Other gains and losses, and litigation*** includes the following:

- gains and losses on major disposals of property, plant and equipment, of intangible assets, of assets (or groups of assets and liabilities) held for sale, or of a business within the meaning of the revised IFRS 3, other than those considered to be restructuring costs;
- impairment losses and reversals of impairment losses on assets (or groups of assets and liabilities) held for sale, other than those considered to be restructuring costs;
- gains on bargain purchases;
- costs and provisions relating to major litigation; and
- certain exceptional items, as described in Note D.35.

B.21. FINANCIAL EXPENSES AND INCOME

B.21.1. Financial expenses

Financial expenses mainly comprise interest charges on debt financing, negative changes in the fair value of financial instruments (where changes in fair value are recorded in profit or loss), realized and unrealized foreign exchange losses on financing and investing activities, impairment losses on financial instruments, and reversals of impairment losses on financial instruments.

Financial expenses also include expenses arising from the unwinding of discounts on long-term provisions, and the net interest cost related to employee benefits. This line item does not include commercial cash discounts, which are included in net sales.

B.21.2. Financial income

Financial income includes interest and dividend income, positive changes in the fair value of financial instruments (where changes in fair value are recorded in profit or loss), realized and unrealized foreign exchange gains on financing and investing activities, and gains or losses on disposals of financial assets.

B.22. INCOME TAX EXPENSE

Income tax expense includes all current and deferred taxes of consolidated companies.

Sanofi accounts for deferred taxes in accordance with IAS 12 (Income Taxes), using the methods described below:

- Deferred tax assets and liabilities are recognized on taxable and deductible temporary differences, and on tax loss carry-forwards. Temporary differences are differences between the carrying amount of an asset or liability in the balance sheet and its tax base.

- Reforms to French business taxes came into force on January 1, 2010, introducing a new tax known as the CET (*Contribution Economique Territoriale*). This tax has two components: the CFE (*Cotisation Foncière des Entreprises*) and the CVAE (*Cotisation sur la Valeur Ajoutée des Entreprises*). The second component is determined by applying a rate to the amount of value added generated by the business during the year. Given that (i) the CVAE component is calculated as the amount by which certain revenues exceed certain expenses and (ii) this tax will be borne primarily by companies that own intellectual property rights on income derived from those rights (royalties and margin on sales to third parties and to other Group companies), the Group regards the CVAE component as meeting the definition of income taxes specified in IAS 12, paragraph 2 (taxes which are based on taxable profits).

- Deferred tax assets and liabilities are calculated using the tax rate expected to apply in the period when the corresponding temporary differences are expected to reverse, based on tax rates enacted or substantively enacted at the end of the reporting period.

- Deferred tax assets are recognized in respect of deductible temporary differences, tax losses available for carry-forward and unused tax credits to the extent that future recovery is regarded as probable. The recoverability of deferred tax assets is assessed on a case-by-case basis, taking into account the profit forecasts contained in the Group s medium-term business plan, and the tax consequences of the strategic opportunities available to the Group.

- The Group recognizes a deferred tax liability for temporary differences relating to interests in subsidiaries, associates and joint ventures except when the Group is able to control the timing of the reversal of the temporary differences. This applies in particular when the Group is able to control dividend policy and it is probable that the temporary differences will not reverse in the foreseeable future.

- No deferred tax is recognized on eliminations of intragroup transfers of interests in subsidiaries, associates or joint ventures.

- Each tax entity calculates its own net deferred tax position. All net deferred tax asset and liability positions are then aggregated and shown in separate line items on the relevant side of the consolidated balance sheet. Deferred tax assets and liabilities are offset only if (i) the Group has a legally enforceable right to offset current tax assets and current tax liabilities, and (ii) the deferred tax

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assets and deferred tax liabilities relate to income taxes levied by the same taxation authority.

- Deferred taxes are not discounted, except implicitly in the case of deferred taxes on assets and liabilities which are already impacted by discounting.

- Withholding taxes on intragroup royalties and dividends, and on royalties and dividends collected from third parties, are accounted for as current income taxes.

In accounting for business combinations, the Group complies with the revised IFRS 3 in regards to the recognition of deferred tax assets after the initial accounting period. Consequently, any deferred tax assets recognized by the acquiree after the end of this period in respect of temporary differences or tax loss carry-forwards existing at the acquisition date are recognized by the Group in profit or loss.

The positions adopted by the Group on tax matters are based on our interpretation of tax laws and regulations. Some of those positions may be subject to uncertainty. In such cases, the Group assesses the amount of the tax liability on the basis of the following assumptions: that our position will be examined by one or more tax authorities on the basis of all relevant information; that a technical assessment is carried out with reference to legislation, case law, regulations, and established practice; and that each position is assessed individually, with no offset or aggregation between positions. Those assumptions are assessed on the basis of facts and circumstances existing at the end of the reporting period. When an uncertain tax position is considered probable, a tax liability is recognized (or a deferred tax asset is not recognized) measured using the Group s best estimate. The amount of the liability includes any penalties and late payment interest. The line item ***Income tax expense*** includes the effects of tax disputes, and any penalties and late payment interest arising from such disputes.

B.23. EMPLOYEE BENEFIT OBLIGATIONS

Sanofi offers retirement benefits to employees and retirees of the Group. Such benefits are accounted for in accordance with IAS 19 (Employee Benefits), the revised version of which was mandatorily applicable for the first time in 2013.

Benefits are provided in the form of either defined contribution plans or defined benefit plans. In the case of defined contribution plans, the cost is recognized immediately in the period in which it is incurred, and equates to the amount of the contributions paid by the Group. For defined benefit plans, the Group generally recognizes its obligations to pay pensions and similar benefits to employees as a liability, based on an actuarial estimate of the rights vested or currently vesting in employees and retirees, using the projected unit credit method. Estimates are performed at least once a year, and rely on financial

assumptions (such as discount rates) and demographic assumptions (such as life expectancy, retirement age, employee turnover, and the rate of salary increases).

Obligations relating to other post-employment benefits (healthcare and life insurance) offered by Group companies to employees are also recognized as a liability based on an actuarial estimate of the rights vested or currently vesting in employees and retirees at the end of the reporting period.

These liabilities are recognized net of the fair value of plan assets.

In the case of multi-employer defined benefit plans where plan assets cannot be allocated to each participating employer with sufficient reliability, the plan is accounted for as a defined contribution plan, in accordance with paragraph 34 of IAS 19.

The benefit cost for the period consists primarily of current service cost, past service cost, net interest cost, gains or losses arising from plan settlements not specified in the terms of the plan, and actuarial gains or losses arising from plan curtailments. Net interest cost for the period is determined by applying the discount rate specified in IAS 19 to the net liability (i.e. the amount of the obligation, net of plan assets) recognized in respect of defined benefit plans. Past service cost is recognized immediately in profit or loss in the period in which it is incurred, regardless of whether or not the rights have vested at the time of adoption (in the case of a new plan) or of amendment (in the case of an existing plan).

Actuarial gains and losses on defined benefit plans (pensions and other post-employment benefits), also referred to as Remeasurements of the net defined benefit liability (asset) , arise as a result of changes in financial and demographic assumptions, experience adjustments, and the difference between the actual return and interest cost on plan assets. The impacts of these remeasurements are recognized in ***Other comprehensive income***, net of deferred taxes; they are not subsequently reclassifiable to profit or loss.

B.24. SHARE-BASED PAYMENT

Share-based payment expense is recognized as a component of operating income, in the relevant classification of expense by function. In measuring the expense, the level of attainment of any performance conditions is taken into account.

B.24.1. Stock option plans

The Group has granted a number of equity-settled share-based payment plans (stock option plans) to some of its employees. The terms of those plans may make the award contingent on the attainment of performance criteria for some of the grantees.

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In accordance with IFRS 2 (Share-Based Payment), services received from employees as consideration for stock options are recognized as an expense in the income statement, with the opposite entry recognized in equity. The expense corresponds to the fair value of the stock option plans and is charged to income on a straight-line basis over the four-year vesting period of the plan.

The fair value of stock option plans is measured at the date of grant using the Black-Scholes valuation model, taking into account the expected life of the options. The resulting expense also takes into account the expected cancellation rate of the options. The expense is adjusted over the vesting period to reflect actual cancellation rates resulting from option holders leaving the Group.

B.24.2. Employee share ownership plans

The Group may offer its employees the opportunity to subscribe to reserved share issues at a discount to the reference market price. Shares allotted to employees under these plans fall within the scope of IFRS 2. Consequently, an expense is recognized at the subscription date, based on the value of the discount offered to employees.

B.24.3. Restricted share plans

The Group may award restricted share plans to certain of its employees. The terms of those plans may make the award contingent on the attainment of performance criteria for some of the grantees.

In accordance with IFRS 2, an expense equivalent to the fair value of such plans is recognized on a straight line basis over the vesting period of the plan, with the opposite entry recognized in equity. Depending on the country, the vesting period of such plans is either three or four years. Plans with a two-year or three-year vesting period are subject to a two-year lock-up period.

The fair value of stock option plans is based on the fair value of the equity instruments granted, representing the fair value of the services received during the vesting period. The fair value of an equity instrument granted under a plan is the market price of the share at the grant date, adjusted for expected dividends during the vesting period.

B.25. EARNINGS PER SHARE

Basic earnings per share is calculated using the weighted average number of shares outstanding during the reporting period, adjusted on a time-weighted basis from the acquisition date to reflect the number of Sanofi shares held by the Group. Diluted earnings per share is calculated on the basis of the weighted average number of ordinary shares, computed using the treasury stock method.

This method assumes that (a) all outstanding dilutive options and warrants are exercised and (b) the Group acquires its own shares at the quoted market price for an amount equivalent to the cash received as consideration for the exercise of the options or warrants plus the expense arising on unamortized stock options.

B.26. SEGMENT INFORMATION

In accordance with IFRS 8 (Operating Segments), the segment information reported by the Group is prepared on the basis of internal management data provided to the Chief Executive Officer, who is the Group s chief operating decision maker. The performance of those segments is monitored individually using internal reports and common indicators.

The segments reported by the Group correspond to its operating segments, with no aggregation. The Group consists of three operating segments: Pharmaceuticals, Human Vaccines (Vaccines) and Animal Health. All other activities are combined in a separate segment, Other. Those segments reflect the Group s internal organizational structure and are used internally for performance measurement and resource allocation.

Information on operating segments is provided in Note D.35.

B.27. MANAGEMENT OF CAPITAL

In order to maintain or adjust the capital structure, the Group can adjust the amount of dividends paid to shareholders, repurchase its own shares, issue new shares, or issue securities giving access to its capital.

The following objectives are defined under the terms of the Group s share repurchase programs:

- the implementation of any stock option plan giving entitlement to purchase shares in the Sanofi parent company;
- the allotment or sale of shares to employees under statutory profit sharing schemes and employee savings plans;
- the consideration-free allotment of shares (i.e. restricted share plans);
- the cancellation of some or all of the repurchased shares;
- market-making in the secondary market by an investment services provider under a liquidity contract in compliance with the ethical code recognized by the *Autorité des marchés financiers* (*AMF*);
- the delivery of shares on the exercise of rights attached to securities giving access to the capital by redemption, conversion, exchange, presentation of a warrant or any other means;
- the delivery of shares (in exchange, as payment, or otherwise) in connection with mergers and acquisitions;

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- the execution by an investment services provider of purchases, sales or transfers by any means, in particular via off-market trading; or

- any other purpose that is or may in the future be authorized under the applicable laws and regulations.

The Group is not subject to any constraints on equity capital imposed by third parties.

Total equity includes ***Equity attributable to equity holders of Sanofi*** and ***Equity attributable to non-controlling interests***, as shown on the consolidated balance sheet. We define Debt, net of cash and cash equivalents as (i) the sum of short-term debt, long-term debt and interest rate derivatives and currency derivatives used to hedge debt, minus (ii) the sum of cash and cash equivalents and interest rate derivatives and currency derivatives used to hedge cash and cash equivalents.

B.28. NEW PRONOUNCEMENTS ISSUED BY THE IASB AND APPLICABLE FROM 2016 ONWARDS

The note below describes standards, amendments and interpretations issued by the IASB that will have mandatory application in 2016 or subsequent years, and the Group s position regarding future application. None of those standards, amendments or interpretations has been early adopted by the Group.

B.28.1. Standards

At the end of May 2014 the IASB issued IFRS 15 (Revenue from Contracts with Customers). This standard relates to the recognition and measurement of revenue arising in the course of an entity s ordinary activities from contracts with customers (i.e. net sales). IFRS 15 is a converged standard common to both IFRS and U.S. generally accepted accounting principles (U.S. GAAP), and will replace IAS 18 (Revenue) and IAS 11 (Construction Contracts). First-time application of IFRS 15, which has not yet been accepted by the European Union, is scheduled for annual accounting periods beginning on or after January 1, 2018. IFRS 15 sets out five successive steps that must be applied in all cases, regardless of the nature of the transaction (sales of goods, sales of services, licensing, etc). These steps are:

- identify the contract(s);

- identify the performance obligations incumbent on the vendor under the contract;

- determine the transaction price;

- allocate the transaction price to the performance obligations in the contract;

- recognize the corresponding revenue.

Since the publication of IFRS 15 in June 2014, the Group has been actively involved in working sessions on this issue, such as the working group established by the ANC (the French accounting standard-setter) and at the international level, the Transition Resource Group (TRG) set up

by the IASB and the U.S. Financial Accounting Standards Board (FASB) to provide feedback on issues raised by preparers of financial statements and to help educate the markets about the new standard. An analysis of the impacts of IFRS 15 on the Group is currently in progress. Due to the organizational structure of the Group, the IFRS 15 implementation project will be split into three phases: a diagnostic phase in ten pilot countries, an implementation phase conducted within each business activity, and finally preparation of the financial statements for the year ended December 31, 2018.

In July 2014 the IASB issued IFRS 9 (Financial Instruments). This standard is intended to replace IAS 32 and IAS 39, the standards that currently apply to the presentation, recognition and measurement of financial instruments. IFRS 9 combines the three phases of the IASB s financial instruments project: classification and measurement, impairment, and hedge accounting. The changes introduced by IFRS 9 relate to:

- rules for the classification and measurement of financial assets, which reflect the business model for managing the assets and the contractual cash flows from the assets;
- rules for the recognition of impairment losses on trade receivables, which must now be based on an expected loss approach rather than actual losses;
- the treatment of hedge accounting.

First-time application of IFRS 9, which has not yet been endorsed by the European Union, is scheduled for annual accounting periods beginning on or after January 1, 2018. The impacts of IFRS 9 are currently under review.

The European Union endorsement process for IFRS 15 and IFRS 9 was ongoing as of the end of the reporting period.

In January 2016, the IASB issued IFRS 16 (Leases), which is effective for annual periods beginning on or after January 1, 2019. This new standard aligns the accounting treatment of operating leases with that already applied to finance leases (i.e. recognition in the balance sheet of future lease payments and the associated rights of use).

B.28.2. Amendments, annual improvements and interpretations

In May 2014, the IASB issued Clarification of Acceptable Methods of Depreciation and Amortization , an amendment to IAS 16 and IAS 38 applicable from 2016 onwards. This

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amendment clarifies the methods that may be applied in depreciating or amortizing certain assets on the basis of the economic benefits they generate, and will not affect the depreciation and amortization policies applied by the Group.

In May 2014, the IASB issued Accounting for Acquisitions of Interests in Joint Operations , an amendment to IFRS 11 applicable from 2016 onwards. This amendment applies in cases where an existing business is contributed to a joint operation, or where an entity acquires items constituting a joint operation that meets the definition of a business, and clarifies that in such cases the principles described in IFRS 3 (Business Combinations) must be applied in accounting for the transaction.

In September 2014, the IASB issued Annual Improvements to IFRSs2012-2014 Cycle . This standard lists various amendments applicable no earlier than 2016. The Group does not expect a material impact on the financial statements from those amendments, which apply mainly to the following standards:

- IFRS 7 (Financial Instruments: Disclosures): clarification on how to assess whether an entity has continuing involvement in a transferred asset as a result of a servicing contract, and on the level of disclosures required;

- IFRS 7 (Financial Instruments: Disclosures): clarification that it is not necessary to provide the additional disclosures required by the Offsetting amendment to IFRS 7 in interim financial statements; and

- IAS 19 (Employee Benefits): clarification that the depth of the market in High Quality Corporate Bonds (HQCB) used as the basis for determining the discount rate applied to post-employment benefits should be assessed at the level of each currency (and hence not necessarily at individual country level, for example in the eurozone).

All of the amendments and annual improvements described above have been endorsed by the European Union.

C/ Principal Alliances

C.1. ALLIANCE ARRANGEMENTS WITH REGENERON

Collaboration agreement on Zaltrap® (aflibercept)

The collaboration agreement signed by Sanofi and Regeneron Pharmaceuticals, Inc. in September 2003 on the development and commercialization of Zaltrap® (aflibercept) was amended and restated in February 2015. That amendment ended Regeneron s obligation to reimburse 50% of the development costs funded by Sanofi. As of December 31, 2014, the balance of outstanding development costs was 0.8 billion.

Collaboration agreement on the discovery, development and commercialization of human therapeutic antibodies

In November 2007, Sanofi and Regeneron signed new agreements (amended in November 2009 and further amended in 2015 in connection with the immuno-oncology agreements described below) for the discovery, development and commercialization of fully human therapeutic antibodies. Under the 2009 amended agreements Sanofi committed to funding the discovery and pre-clinical development of fully human therapeutic antibodies by up to $160 million per year through 2017. Sanofi has an option to develop and commercialize antibodies discovered by Regeneron pursuant to this collaboration. Following the signature in July 2015 of the immuno-oncology collaboration agreement described below, $75 million (spread over three years) was reallocated to that new agreement.

If the option is exercised, Sanofi co-develops the antibody with Regeneron and is responsible for funding. Sanofi and Regeneron share co-promotion rights and profits on sales of the co-developed antibodies. On receipt of the first positive Phase III trial results for any such antibody, the subsequent Phase III costs for that antibody are split 80% Sanofi, 20% Regeneron. Amounts received from Regeneron under those arrangements are recognized by Sanofi as a reduction in the line item Research and development expenses . Once a product begins to be commercialized, and provided that the share of quarterly results under the agreement represents a profit, Sanofi is entitled to an additional profit-share (capped at 10% of Regeneron s share of quarterly profits) until Regeneron has paid 50% of the cumulative development costs incurred by the parties in the collaboration. In addition, Sanofi may be required to make milestone payments based on cumulative sales of all antibodies. As of December 31, 2015, the aggregate development costs incurred by both parties was 3.9 billion (including 2.6 billion funded 100% by Sanofi and 1.3 billion funded 80% by Sanofi and 20% by Regeneron).

On the earlier of (i) 24 months before the launch date or (ii) the first positive Phase III trial result Sanofi and Regeneron will share the commercial expenses of the antibodies jointly developed under the license agreement. Sanofi recognizes all the sales of those antibodies. Profits and losses arising from commercial operations in the United States are split 50/50. Outside the United States, Sanofi is entitled to between 55% and 65% of profits depending on sales of the antibodies, and bears 55% of any losses. The share of profits and losses attributable to Regeneron under the agreement is recognized in the line items *Other operating income* or *Other operating expenses* , which are components of operating income. In addition, Regeneron is entitled to receive payments of up to $250 million contingent on the attainment of specified levels of sales outside the United States.

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If Sanofi opts not to exercise its license option for an antibody, Sanofi would receive a royalty from Regeneron on sales of that antibody.

Collaboration agreement on the discovery, development and commercialization of antibodies in the field of immuno-oncology

On July 28, 2015, Sanofi and Regeneron announced a new global collaboration to discover, develop and commercialize new antibody cancer treatments in the emerging field of immuno-oncology. As part of the agreement, the two companies will jointly develop a programmed cell death protein 1 (PD-1) inhibitor antibody currently in Phase I testing, and plan to initiate clinical trials in 2016 with new therapeutic candidates based on ongoing, innovative preclinical programs. Sanofi has made an upfront payment of $640 million to Regeneron. The companies will invest approximately $1 billion from discovery through proof of concept (POC) development (usually a Phase IIa study) of monotherapy and novel combinations of immuno-oncology antibody candidates to be funded 25% by Regeneron ($250 million) and 75% by Sanofi ($750 million). Under the terms of the discovery program, Sanofi is entitled to an additional profit-share (capped at 10% of Regeneron s share of quarterly profits) until the progressive payments from Regeneron reach 50% of clinical development costs initially funded by Sanofi.

Sanofi and Regeneron have also committed to equally fund no more than $650 million (or $325 million per company) for development of REGN2810, a PD-1 inhibitor antibody. In addition, Sanofi will make a one-time milestone payment of $375 million to Regeneron in the event that sales of a PD-1 product and any other collaboration antibody sold for use in combination with a PD-1 product were to exceed, in the aggregate, $2 billion in any consecutive 12-month period. Finally, the two companies agreed to reallocate $75 million (spread over three years) to immuno-oncology antibody research and development from Sanofi s $160 million annual contribution to their existing antibody collaboration, which otherwise continues as announced in November 2009. Beyond the committed funding, additional funding will be allocated as programs enter post-POC development.

C.2. ALLIANCE ARRANGEMENTS WITH BRISTOL-MYERS SQUIBB (BMS)

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

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

Under the terms of this new agreement, which took effect on January 1, 2013, BMS returned to Sanofi its rights to Plavix® and Avapro®/Avalide® in all markets worldwide with the exception of Plavix® in the United States and Puerto Rico, giving Sanofi sole control and freedom to operate commercially in respect of those products. In exchange, BMS will receive royalty payments on Sanofi s sales of branded and unbranded Plavix® and Avapro®/Avalide® worldwide (except for Plavix® in the United States and Puerto Rico) until 2018, and will also receive a payment of $200 million from Sanofi in December 2018, part of which will be used to buy out the non-controlling interests (see Note D.18.). Rights to Plavix® in the United States and Puerto Rico remain unchanged and continue to be governed by the terms of the original agreement until December 2019.

In all of the territories managed by Sanofi (including the United States and Puerto Rico for Avapro®/Avalide®) as defined in the new agreement, Sanofi recognizes in its consolidated financial statements the revenue and expenses generated by its own operations. The share of profits reverting to BMS subsidiaries is presented within ***Net income attributable to non-controlling interests*** in the income statement.

In the territory managed by BMS (United States and Puerto Rico for Plavix®), Sanofi recognizes its share of profits and losses within the line item ***Share of profit/(loss) of associates and joint ventures***.

D/ Presentation of the financial statements

D.1. IMPACT OF CHANGES IN THE SCOPE OF CONSOLIDATION DUE TO ACQUISITIONS

D.1.1. Regeneron Pharmaceuticals Inc. (Regeneron)

During 2015, Sanofi acquired further shares in the biopharmaceutical company Regeneron at a cost of 117 million. As of December 31, 2015, the Group s investment in Regeneron had a carrying amount of 2,245 million (see Note D.6.) and represented an equity interest of 22.1%.

During 2014, Sanofi acquired 7 million Regeneron shares, raising its equity interest in that company to 22.3% as of December 31, 2014, versus 15.9% as of December 31, 2013. With effect from the start of April 2014, this interest is accounted for by the equity method, following the nomination of a Sanofi designee to the Regeneron Board of Directors. Previously, the investment in Regeneron was reported in the balance sheet in the Available-for-sale financial assets category and measured at market value in accordance with IAS 39 (Financial Instruments: Recognition and Measurement). As of the date on which the equity method was first applied, the investment was measured at acquisition cost in accordance with IAS 28 (Investments in Associates and Joint Ventures). Under IAS 28, the cost of

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the investment is equivalent to the aggregate amount of the successive acquisition prices paid (including acquisition-related costs) for the interests in Regeneron (see Note B.1.). Consequently, the changes in the market value of the investment in Regeneron that had previously been recognized in ***Other comprehensive income*** were reversed out on first-time application of the equity method. Goodwill is

calculated on each successive acquisition of shares; it represents the excess of the acquisition price over the share of the identifiable net assets acquired, measured in accordance with IFRS 3 (Business Combinations).

The main effects of the change to the equity method in accounting for the Regeneron investment are set forth below:

(million)	December 31, 2013	Reclassification from available-for-sale financial assets[2]	Acquisitions during 2014[3]	Other movements[4]	December 31, 2014
Investments in associates and joint ventures	-	256	1,629	57	1,942
Available-for-sale financial assets	3,157	(3,157)	-	-	-
Shareholders equity[1]	2,607	(2,607)	-	57	57
Deferred tax liabilities	294	(294)	-	-	-
Historical cost of acquisition	**256**	**-**	**1,629**	**-**	**1,885**

(1) Amount net of taxes.

*(2) Reversal of changes in the value of the investment previously recognized in **Other comprehensive income**.*

(3) Acquisition price (including acquisition-related costs) of the 7 million shares acquired during 2014.

(4) Mainly comprises (126) million for Sanofi s share of net losses (including the effect of amortizing fair value remeasurements of the acquired share of the intangible assets and inventories of Regeneron) and a currency translation difference of 175 million.

D.1.2. Other changes in the scope of consolidation due to acquisitions

The impacts of acquisitions made during 2015 are not material to the Group.

In 2014, Sanofi took control of Globalpharma Co. LLC, a pharmaceutical company based in Dubai, with the intention of using it as a platform for the manufacture and marketing of the Group s generics portfolio in the Middle East, to include anti-infective, cardiovascular and gastro-intestinal products. The impacts of this acquisition are not material to the Group.

On March 20, 2013, Sanofi completed the acquisition of 100% of Genfar S.A., the leading manufacturer of pharmaceutical products in Colombia. Genfar S.A. is also the second-largest generics company in Colombia in terms of sales, generating annual revenue of approximately 100 million. The provisional purchase price allocation resulted in the recognition of goodwill amounting to 119 million (see Note D.4.). The provisional purchase price allocation also included the fair value of the other intangible assets identified in the acquisition, amounting to 59 million at the acquisition date. The impacts of this acquisition on the Group s business operating income and consolidated net income for the year ended December 31, 2013 are not material. The final purchase price allocation for this acquisition was completed in 2014, and was not materially different from the provisional allocation in 2013. The impacts

of the other acquisitions made during 2013 are not material to the Group.

D.2. IMPACT OF CHANGES IN SCOPE OF CONSOLIDATION DUE TO DIVESTMENTS

D.2.1. Exchange of the Animal Health Business

On December 15, 2015, Sanofi and Boehringer Ingelheim signed an exclusivity agreement with a view to exchanging Sanofi s Animal Health business (valued at 11.4 billion) for Boehringer Ingelheim s Consumer Health Care business (valued a6.7 billion). The transaction would also involve a gross cash payment from Boehringer Ingelheim to Sanofi of 4.7 billion. The two parties are aiming to close the transaction in the fourth quarter of 2016.

Completion of the transaction is regarded as highly probable. In accordance with the classification and presentation requirements of IFRS 5 (see Note B.7.), all assets of the Animal Health business included in the exchange and all liabilities directly related to those assets are classified in the line items ***Assets held for sale or exchange*** and ***Liabilities related to assets held for sale or exchange***, respectively, in the consolidated balance sheet as of December 31, 2015. Because the Animal Health business is an operating segment of the Group (see Note D.35., Segment Information), it qualifies as a discontinued operation under IFRS 5 (see Note B.7.). Consequently, the net income or loss from that business is presented separately in the

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consolidated income statement as ***Net income/(loss) of the held-for-exchange Animal Health business***. This presentation in a separate line item in the income statement applies to operations for the year ended December 31, 2015 and for the comparative periods presented.

Finally, the cash flows arising from operating, investing and financing activities of the Animal Health business are presented in separate line items in the consolidated statements of cash flows for the year ended December 31, 2015 and for the comparative periods presented.

For detailed information about the contribution of the Animal Health business to the consolidated financial statements refer to Note D.36., Held-for-exchange Animal Health Business .

D.2.2. Other divestments

No other disposals were made by the Group in 2015 that materially affected the scope of consolidation.

No disposals were made by the Group in 2014 or 2013 that materially affected the scope of consolidation.

D.3. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment (including assets held under finance leases) comprise:

(*million*)	Land	Buildings	Plant & equipment	Fixtures, fittings & other	Property, plant and equipment in process	Total
Gross value at January 1, 2013	**384**	**6,281**	**8,306**	**2,118**	**2,035**	**19,124**
Changes in scope of consolidation	3	12	11	-	-	26
Acquisitions and other increases	1	1	67	43	970	1,082
Disposals and other decreases	(6)	(19)	(15)	(128)	(9)	(177)
Currency translation differences	(20)	(215)	(187)	(46)	(40)	(508)
Transfers[(1)]	2	437	567	120	(1,112)	14
Gross value at December 31, 2013	**364**	**6,497**	**8,749**	**2,107**	**1,844**	**19,561**
Changes in scope of consolidation	-	(3)	2	-	3	2
Acquisitions and other increases	-	6	60	47	980	1,093
Disposals and other decreases	(9)	(16)	(30)	(116)	(17)	(188)
Currency translation differences	16	233	191	41	54	535
Transfers[(1)]	1	198	447	136	(905)	(123)
Gross value at December 31, 2014	**372**	**6,915**	**9,419**	**2,215**	**1,959**	**20,880**
Changes in scope of consolidation	(4)	1	(8)	1	(22)	(32)
Acquisitions and other increases	-	11	76	59	1,172	1,318
Disposals and other decreases	(3)	(4)	(17)	(126)	(23)	(173)

Currency translation differences	5	144	122	24	25	320
Transfers[1]	(1)	269	463	228	(1,083)	(124)
Reclassification of the Animal Health business[2]	(33)	(604)	(313)	(54)	(76)	(1,080)
Gross value at December 31, 2015	**336**	**6,732**	**9,742**	**2,347**	**1,952**	**21,109**
Accumulated depreciation & impairment at January 1, 2013	**(15)**	**(2,232)**	**(4,723)**	**(1,431)**	**(145)**	**(8,546)**

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(*million*)	Land	Buildings	Plant & equipment	Fixtures, fittings & other	Property, plant and equipment in process	Total
Changes in scope of consolidation	-	4	1	-	1	6
Depreciation expense	-	(356)	(600)	(184)	(1)	(1,141)
Impairment losses	(5)	(13)	2	-	(10)	(26)
Disposals	-	14	8	119	9	150
Currency translation differences	1	71	96	29	(1)	196
Transfers[1]	(1)	(77)	50	11	(1)	(18)
Accumulated depreciation & impairment at December 31, 2013	**(20)**	**(2,589)**	**(5,166)**	**(1,456)**	**(148)**	**(9,379)**
Changes in scope of consolidation	-	4	2	-	-	6
Depreciation expense	-	(356)	(577)	(192)	-	(1,125)
Impairment losses	(2)	(37)	(26)	(4)	(28)	(97)
Disposals	3	9	23	113	15	163
Currency translation differences	(1)	(64)	(78)	(24)	(2)	(169)
Transfers[1]	3	54	42	14	4	117
Accumulated depreciation & impairment at December 31, 2014	**(17)**	**(2,979)**	**(5,780)**	**(1,549)**	**(159)**	**(10,484)**
Changes in scope of consolidation	6	5	12	-	22	45
Depreciation expense	-	(376)	(607)	(208)	-	(1,191)
Impairment losses	-	(38)	(42)	(11)	(41)	(132)
Disposals	-	3	15	122	13	153
Currency translation differences	-	(33)	(49)	(17)	-	(99)
Transfers[1]	-	34	90	(4)	(1)	119
Reclassification of the Animal Health business[2]	-	252	145	26	-	423
Accumulated depreciation & impairment at December 31, 2015	**(11)**	**(3,132)**	**(6,216)**	**(1,641)**	**(166)**	**(11,166)**
Carrying amount at December 31, 2013	344	3,908	3,583	651	1,696	10,182
Carrying amount at December 31, 2014	355	3,936	3,639	666	1,800	10,396
Carrying amount at December 31, 2015	**325**	**3,600**	**3,526**	**706**	**1,786**	**9,943**

*(1) This line also includes the effect of the reclassification of assets to **Assets held for sale or exchange**.*

*(2) This line comprises the property, plant and equipment of the Animal Health business, reclassified to **Assets held for sale or exchange** as of December 31, 2015 in accordance with IFRS 5 (see Notes D.2.1. and D.36.)*

Acquisitions during 2015 amounted to 1,318 million. The Pharmaceuticals segment made acquisitions totaling 964 million, primarily investments in industrial facilities (594 million excluding Genzyme in 2015, compared with 452 million in 2014 and 444 million in 2013) and in constructing and equipping research sites (82 million in 2015, versus 55 million in 2014 and 88 million in 2013). Genzyme accounted for 80 million of Pharmaceuticals segment acquisitions in 2015 (versus 113 million in 2014 and 116 million in 2013). The Vaccines segment made 260 million of acquisitions in 2015 (versus 202 million in 2014 and 210 million in 2013). Acquisitions of property, plant and equipment during the year included 15 million of capitalized interest costs (versus 20 million in 2014 and 25 million in 2013).

Firm orders for property, plant and equipment stood at 436 million as of December 31, 2015 (348 million as of December 31, 2014 and 324 million as of December 31, 2013). Property, plant and equipment pledged as security for liabilities amounted to 249 million as of December 31, 2015 (versus 242 million as of December 31, 2014 and 196 million as of December 31, 2013).

Impairment tests of property, plant and equipment conducted using the method described in Note B.6. resulted in the recognition during 2015 of net impairment losses of 132 million. In 2014, net impairment losses totaled 97 million, primarily in the Pharmaceuticals segment. In 2013, net impairment losses were 26 million, primarily in the Vaccines segment.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The table below shows amounts for items of property, plant and equipment held under finance leases:

(million)	2015	2014	2013
Land	3	3	3
Buildings	101	99	85
Other property, plant and equipment	8	4	3
Total gross value	**112**	**106**	**91**
Accumulated depreciation and impairment	(69)	(55)	(41)
Carrying amount	**43**	**51**	**50**

Future minimum lease payments due under finance leases as of December 31, 2015 were 83 million (versus 74 million as of December 31, 2014 and 78 million as of

December 31, 2013), including 15 million of interest (versus 12 million as of December 31, 2014 and 15 million as of December 31, 2013).

The payment schedule is as follows:

December 31, 2015		Payments due by period			
(million)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Finance lease obligations					
· principal	67	18	30	4	15
· interest	16	5	5	3	3
Total	**83**	**23**	**35**	**7**	**18**

D.4. GOODWILL AND OTHER INTANGIBLE ASSETS

Movements in goodwill comprise:

(million)	Goodwill
Balance at January 1, 2013	**38,073**
Acquisitions during the period[1]	134
Currency translation differences	(1,073)
Balance at December 31, 2013	**37,134**
Acquisitions during the period	23
Currency translation differences	2,040

Balance at December 31, 2014	**39,197**
Reclassification of the Animal Health business[2]	(1,510)
Currency translation differences	1,870
Balance at December 31, 2015	**39,557**

(1) Mainly comprises 119 million arising on Genfar (see Note D.1.2.).

(2) The goodwill on the Animal Health business, now reclassified to ***Assets held for sale or exchange***.

Genzyme acquisition (2011)

The Genzyme final purchase price allocation resulted in the recognition of intangible assets (other than goodwill) totaling 10,059 million at the acquisition date. That figure included 7,727 million for marketed products in the fields of rare diseases (primarily Cerezyme®, Fabrazyme® and Myozyme®), renal endocrinology (primarily Renagel®), biosurgery (primarily Synvisc®) and oncology. Also included were intangible assets valued at 2,148 million at the acquisition date relating to Genzyme s in-process research and development projects, primarily Lemtrada® (alemtuzumab) and eliglustat. The Genzyme brand was attributed a fair value of 146 million.

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As of December 31, 2015, the carrying amount of marketed products and the Genzyme brand represented more than 99% of the intangible assets of Genzyme (other than goodwill), and in-process research and development represented less than 1%.

During 2015, some of the Genzyme acquired research and development (474 million) came into commercial use, and started being amortized from the date of marketing approval. The main product involved was Cerdelga® (eliglustat) outside the United States.

During 2014, some of the Genzyme acquired research and development (778 million) came into commercial use, and started being amortized from the date of marketing approval. The main products involved were Cerdelga® (eliglustat) and Lemtrada® (alemtuzumab) in the United States.

During 2013, some of the Genzyme acquired research and development (415 million) came into commercial use, and started being amortized from the date of marketing approval. The main such item was Lemtrada® (alemtuzumab) in Europe.

Aventis acquisition (2004)

On August 20, 2004, Sanofi acquired Aventis, a global pharmaceutical group created in 1999 by the merger between Rhône-Poulenc and Hoechst.

As part of the process of creating the new Group, the two former parent companies Sanofi-Synthélabo (renamed Sanofi) and Aventis were merged on December 31, 2004.

The total purchase price as measured under IFRS 3 (Business Combinations) was 52,908 million, of which 15,894 million was settled in cash.

Goodwill arising from the acquisition of Aventis amounted to 30,587 million as of December 31, 2015 (versus 29,143 million as of December 31, 2014 and 27,608 million as of December 31, 2013).

Rights to marketed products and goodwill arising on the Aventis acquisition were allocated on the basis of the split of the Group s operations into business and geographical segments, and valued in the currency of the relevant geographical segment (mainly euros and U.S. dollars) with assistance from an independent valuer.

During 2014, some of the Aventis acquired research and development (47 million) came into commercial use, and started being amortized from the date of marketing approval. The main product involved was Jevtana® in Japan.

During 2013, some of the acquired Aventis research and development (118 million) came into commercial use, and started being amortized from the date of marketing approval. The main products involved were the multiple sclerosis treatment Aubagio® (teriflunomide) in Europe and other countries outside the United States, and Zaltrap® (aflibercept) in Europe.

Movements in other intangible assets comprise:

(million)	**Acquired R&D**	**Products, trademarks and other rights**	**Software**	**Total other intangible assets**

Gross value at January 1, 2013	**5,896**	**49,303**	**1,028**	**56,227**
Changes in scope of consolidation	6	59	-	65
Acquisitions and other increases	90	118	102	310
Disposals and other decreases	(628)	(46)	(51)	(725)
Currency translation differences	(159)	(2,038)	(31)	(2,228)
Transfers[(1)]	(703)	707	4	8
Gross value at December 31, 2013	**4,502**	**48,103**	**1,052**	**53,657**
Changes in scope of consolidation	-	61	-	61
Acquisitions and other increases	164	281	138	583
Disposals and other decreases	(175)	(95)	(46)	(316)
Currency translation differences	230	3,541	42	3,813
Transfers[(1)]	(1,239)	1,239	54	54
Gross value at December 31, 2014	**3,482**	**53,130**	**1,240**	