Sanofi
Form 20-F
March 11, 2015

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 20-F

(Mark One)

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

or

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

For the fiscal year ended December 31, 2014
or

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

or

o **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, 2014 was:

Ordinary shares: 1,319,367,445

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

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 o NO ý.

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 ý No o

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 o No o

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" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ý	Accelerated filer o	Non-accelerated filer o

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

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

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 o Item 18 o

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 o No ý.

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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, 2014.

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

All references herein to "United States" or "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® a trademark of Oxford Biomedica; Spedra and Stendra trademarks of Vivus Inc.; Squarekids® a trademark of Kitasato Daiichi Sankyo Vaccine Co., Ltd.; Stargen a trademark of Oxford Biomedica; 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 Farmeceutici 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 and Miriopen® 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.); UshStat® a trademark of Oxford BioMedica; 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, for calendar year 2014, 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.

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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 vaccines business are based on internal estimates unless stated otherwise.

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

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

Risk factors which could affect 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 used in the Form 20-F

ADR/ADS	American Depositary Receipt/American Depositary Share
AFEP	*Association française des entreprises privées* (French association of large companies)
AMF	*Autorité des marchés financiers* (the French market regulator)
ANDA	Abbreviated New Drug Application
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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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, 2014, 2013 and 2012 are included in Item 18 of this annual report.

The consolidated financial statements of Sanofi for the years ended December 31, 2014, 2013 and 2012 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, 2014. 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, 2014.

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Sanofi reports its financial results in euros.

SELECTED CONDENSED FINANCIAL INFORMATION

	As of and for the year ended December 31,				
(€ million, except per share data)	**2014**	**2013(a)**	**2012(a)**	**2011**	**2010**
IFRS Income statement data [b]:					
Net sales	33,770	32,951	34,947	33,389	32,367
Gross profit	23,080	22,315	24,859	24,193	24,638
Operating income	6,143	5,105	6,430	5,861	6,535
Net income attributable to equity holders of Sanofi	4,390	3,716	4,888	5,646	5,467
Basic earnings per share (€)[b)/(c)]:					
Net income attributable to equity holders of Sanofi	3.34	2.81	3.70	4.27	4.19
Diluted earnings per share (€)[b)/(d)]:					
Net income attributable to equity holders of Sanofi	3.30	2.77	3.68	4.26	4.18
IFRS Balance sheet data:					
Goodwill and other intangible assets	53,740	52,529	58,265	62,221	44,411
Total assets	97,392	96,055	100,399	100,672	85,264
Outstanding share capital	2,620	2,641	2,646	2,647	2,610
Equity attributable to equity holders of Sanofi	56,120	56,904	57,352	56,193	53,097
Long term debt	13,276	10,414	10,719	12,499	6,695
Cash dividend paid per share (€)[e]	2.85&zwsp;[f]	2.80	2.77	2.65	2.50
Cash dividend paid per share ($) [e)/(g)]	3.46&zwsp;[f]	3.86	3.65	3.43	3.34

(a)

Includes the impacts of applying IFRIC 21 (see Note A.2.2. to our consolidated financial statements included at Item 18 of this annual report).

(b)

The results of operations of Merial, for 2010, previously reported as held-for-exchange, have been reclassified and included in net income of continuing operations in accordance with IFRS 5.36., following the announcement that Merial and Intervet/Schering-Plough are to be maintained as two separate businesses operating independently.

(c)

Based on the weighted average number of shares outstanding in each period used to compute basic earnings per share, equal to 1,315.8 million shares in 2014, 1,323.1 million shares in 2013, 1,319.5 million shares in 2012, 1,321.7 million shares in 2011, and 1,305.3 million shares in 2010.

(d)

Based on the weighted average in each period of the number of shares outstanding plus stock options and restricted shares with a potentially dilutive effect; i.e., 1,331.1 million shares in 2014, 1,339.1 million shares in 2013, 1,329.6 million shares in 2012, 1,326.7 million shares in 2011, and 1,308.2 million shares in 2010.

(e)

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

(f)

Dividends for 2014 will be proposed for approval at the annual general meeting scheduled for May 4, 2015.

(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 2010 through March 2015 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."

	Period-end Rate	Average Rate (1)	High	Low
		(U.S. dollar per euro)		
2010	1.33	1.32	1.45	1.20
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
Last 6 months				
2014				
September	1.26	1.29	1.31	1.26
October	1.25	1.27	1.28	1.25
November	1.24	1.25	1.26	1.24
December	1.21	1.23	1.25	1.21
2015				
January	1.13	1.16	1.20	1.13
February	1.13	1.12	1.15	1.12
March [2]	1.07	1.10	1.12	1.07

(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 March 6, 2015, we have used European Central Bank Rates for the period from March 9, 2015 through March 10, 2015.

(2)

In each case, measured through March 10, 2015.

On March 10, 2015 the European Central Bank Rate was 1.0738 per euro.

B. Capitalization and Indebtedness

N/A

C. Reasons for Offer and Use of Proceeds

N/A

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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. 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 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.

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 coverage before the patents expire, and manufacturers of biosimilars or interchangeable versions of the products are seeking to have their version of the product approved before the exclusivity period ends. Furthermore, in an infringement suit against a third party, we may not prevail and the decision rendered may not 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 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. If we fail to obtain a required license for a country where the valid third-party intellectual property right 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 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 (see "Item 8. Financial Information A. Consolidated Financial Statements and Other Financial Information Information on Legal or Arbitration Proceedings" for additional information including on litigation related to Lantus® one of the Group's flagship products) of our small molecule and biological pharmaceutical products. 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.

Further, 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. To the extent that governments could adopt more permissive approval frameworks (for instance regarding the duration of data exclusivity that could be shortened, or the scope of new products receiving data exclusivity that could be narrowed) and competitors could be able to obtain broader marketing approval for biosimilars including as a substitutable product, our products would become subject to increased competition (see also "Changes in the laws or regulations that apply to us could affect the Group's

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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 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.

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

Product liability is a significant business risk for any pharmaceutical company, and the Group's diversification could increase our product liability exposure as liability claims relating to our new 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 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. As a result market authorization suspension or withdrawal may take place. Following a recall or a withdrawal, pharmaceutical companies can face significant product liability claims.

Furthermore, we commercialize several devices (notably those using new technologies) which, in case of malfunction, could cause unexpected damages and lead to product liability claims (see " We are increasingly dependent on information technologies and networks.").

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. This is true particularly in the United States, and especially for genericized products where Sanofi is the innovator, as innovators have been held liable in some U.S. jurisdictions for damages caused by a product commercialized by generic manufacturers. 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 case of self-insurance, the legal costs that we would bear for handling such claims and potential indemnifications to be paid to claimants could affect our financial condition.

Due to insurance conditions, even when the Group has insurance coverage, recoveries from insurers may not be totally successful. Moreover, the insolvency of a carrier could negatively affect our ability to achieve the practical recovery of the coverage 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 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 approvals.

Obtaining marketing authorization is a long and regulated process requiring extensive documentation and data to be provided to the regulatory authorities. Regulatory processes differ from one authority to another. Either at the

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time of the filing of the application for a marketing authorization or later during its review, each regulatory authority may impose its own requirements, 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. These requirements have increased the costs associated with maintaining regulatory approvals and achieving reimbursement for our products. Post-regulatory approval reviews and data analyses can lead to the issuance of recommendations by government agencies, health professional and patient or other specialized organizations regarding the use of products; for example, a recommendation to limit the patient 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. For example, further to the Warning Letter received from the FDA in July 2012 and following inspections conducted at manufacturing facilities in Canada and France, Sanofi Pasteur has submitted a remediation plan to the FDA. In 2014 the issues raised in the 2012 Warning Letter were waived by the FDA. If we were to receive another Warning Letter following the inspection of one of our facilities and if we fail to adequately respond to that or any other warning letter identifying a deficiency further to a control, or otherwise fail to comply with applicable regulatory requirements, under the applicable pharmaceutical regulation, we could be subject to enforcement, remedial and/or punitive actions by the FDA, the EMA or other regulatory authorities.

In addition, 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 are diminished. Approximately 70% 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 technical constraints and 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, as well as 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 have also set up policies and procedures which are 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 and/or our officers 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 partners' 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

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remedies, potentially leading to the imposition of additional regulatory controls or exclusion from government reimbursement programs or market 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. We have entered into such agreements in the past and for example we expect to enter into such an agreement and be subject to the terms and conditions of the agreement for a period of five years as part of a settlement 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 subject to extensive legislation and regulation. Changes in applicable laws 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, 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 prosecution of patents 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 instance, 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 2014, we spent €4,824 million on research and development, amounting to 14.3% of our net sales.

Our industry is driven by the imperative need for constant innovation, but we may not be investing in the right technology platforms, therapeutic areas, and products classes in order to build a robust pipeline and fulfill unmet medical needs. Fields of discovery and especially 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.

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The research and development process typically takes from 10 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 compounds will be proven safe or effective. See "Item 4. Information on the Company B. Business Overview B.5. Global Research & Development B.5.2. Pharmaceuticals". 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 effectiveness 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.

In November 2014, we announced our intent to launch up to 18 new medicines and vaccines between 2014-2020, but there can be no assurance that our research and development strategy will deliver the expected result in the targeted timeframe or at all, which could affect our profitability in the future.

Following each product marketing approval, the medical need served by the product and the corresponding reimbursement rate are evaluated by other governmental agencies, requiring in some cases additional 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, investigators whether independently or with our authorization, may conduct studies or analysis beyond our control that may ultimately report results negatively affecting our sales either permanently or temporarily. It may take time for Sanofi to address the reported findings. For instance following a third party analysis of data alleging a link between insulin glargine and cancer, Sanofi initiated a large scale epidemiological program in 2009 to generate more information on whether there was any association between cancer and insulin use and to assess whether there was any difference in risk between insulin glargine and other insulins. Results of Sanofi's studies were available only three years later and concluded there was no increased risk of cancer in people with diabetes treated with Lantus®.

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, 2014 compared with year ended December 31, 2013 Net Sales by Product Pharmaceuticals segment"). Lantus® is particularly important; it was the Group's leading product with revenues of €6,344 million in 2014, representing 18.8% of the Group's consolidated revenues for the year. Lantus® is a flagship product of the Diabetes division, one of the Group's main divisions. However, in November 2014, we announced that we expect our global Diabetes sales to be flat to slightly growing at constant exchange rates between 2015 and 2018 (assuming no entry of a substitutable insulin glargine biosimilar on the U.S. market before 2019). Nevertheless our actual sales may differ from these expectations given the numerous underlying assumptions such as the dynamics of the basal insulin market in the U.S., the conversion of patients from Lantus® to Toujeo®, the continued growth of our diabetes products in Emerging Markets, or the U.S. launches of Afrezza®, Lyxumia® and LixiLan. Furthermore, the launch of new medicines and vaccines in other therapeutic areas and the sustained performance of our other growth platforms may not allow us 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 generic competitors, often leading to a rapid and severe decline in revenues on those products. For example, Plavix® lost its market exclusivity in the United States in May 2012 and as a result, its U.S. sales dropped by 90% within the two months following the loss of market exclusivity (for information on the expected impact of biosimilar entry see " We may lose market share to competing remedies, biosimilar or generic brands.")

Furthermore, in general, if our flagship products were to encounter problems such as material product liability litigation, unexpected side effects, 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

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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.

We may lose market share to competing remedies, biosimilar or generic brands.

We are faced with intense competition from generic products, biosimilars and brand-name drugs including from retail chains and distributors. For example in 2015 in Japan, we expect generic competition on Plavix® starting from mid year.

Doctors or patients may choose these products over ours 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 a product also depends on our ability to educate patients 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 both an adverse price and volume effects for our genericized products. For example, Plavix® lost its market exclusivity in the United States in May 2012 and as a result, its U.S. sales dropped by 90% within the two months following the loss of market exclusivity. Substitution is often permitted for generics 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 Europe, in many countries, automatic substitution of biologics is officially prohibited or not recommended. Nevertheless competition from even 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 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 implicate more of our products, including those with relatively modest sales.

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

Many of our products are manufactured using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. Third parties supply us with a 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 meeting 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, Praluent®, currently under development, will be administered with an auto-injector manufactured by a third party. The success of this product, once launched, will depend partially on the performance of this device.

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We must also be able to produce sufficient quantities of the products to satisfy demand. We may have difficulties scaling-up production of our products which are under development once they are approved. In 2014 we entered into an agreement with Boehringer Ingelheim for the manufacture of therapeutic monoclonal antibodies to reinforce our manufacturing capacity to support upcoming product launches, however, there is no certainty that this agreement will deliver the expected benefits in terms of manufacturing capabilities.

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 unavailability of adequate amounts of raw materials meeting our standards (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, starting from 2012 Sanofi Pasteur encountered production issues which caused delays in the supply of Pentacel® vaccine in the U.S. While these problems have either been remediated or are in the process of being remediated, Sanofi Pasteur continues to face a strong demand for its vaccines that requires it in certain cases to manage the supply allocation. Sanofi Pasteur is working to increase its 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.

The complexity of these processes, as well as strict internal and health authorities standards for the manufacture of our products, subject us to risks as the investigation and remediation of any identified or suspected problems can cause production delays, substantial expense, product recalls, lost sales and inventories, and delay the launch of new products, which could adversely affect our operating results and financial condition, 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 biological products. In the event of manufacturing disruptions, it is also difficult to use back-up facilities or set up new facilities because biological products 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 a second or third facility 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 are subject to even greater criticism when they occur with respect to life saving medicines with limited or no viable therapeutic alternatives. Independently of the level of revenues lost as a result of the shortage of a particular product, such shortages can have a negative impact on the patients, customers and professional healthcare providers' confidence 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.

Furthermore, we are sometimes required to use animals to test our products in the development phase and our vaccines before distributing them. Testing on animals is vital for the development of a product and many times, it is the only way to study the effects of a product under development in a living body before tests are made on humans. Studies performed on animals also provide significant information on the causes and progress of diseases. Some countries require additional tests to be made on animals, even if the product is already approved. 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.

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

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

- price controls imposed by governments in many countries;
- removal of a number of drugs from government reimbursement schemes (for instance 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; and
- the tendency of governments and private health care providers to favor generic pharmaceuticals.

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 or otherwise discouraging physician prescriptions of our products; policies requiring the automatic substitution of generics or biosimilars could also be put in place. For example, in the United States, the federal health care reform law is increasing the government's role with respect to price, reimbursement and the 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. Implementation of health care reform has affected and will continue to affect our revenues and/or margins. For instance, in 2014, we had to increase the level of rebates for Lantus® required to maintain favorable formulary positions with key payers in the U.S. Some U.S. states are also considering legislation that would influence the marketing and prices of and access to drugs and 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.

Governmental and private third-party payers and purchasers of pharmaceutical products may also claim damages related to a preliminary injunction alleging they have over-reimbursed a drug if we do not ultimately prevail in the patent litigation. For example in Australia our patent on clopidogrel was ultimately held invalidated. Since 2013, the Australian Government has been seeking damages for its alleged over-reimbursement of clopidogrel drugs due to the preliminary injunction we had obtained against GenRX (a subsidiary of Apotex) during the course of the litigation.

Furthermore there is a growing number of mergers of retail chains and distributors, this consolidation of distribution channels increases 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. The negotiation on the price in a country may also be incompatible with the global positioning of our product, which may lead us to not launch the product in that country.

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 on low cost markets for resale on higher cost markets.

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 the reliance on third parties for key aspects of our business will continue to characterize our activities.

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. We also have collaborative arrangements with Merck & Co., Inc. for the

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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). 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, we are subject to the risk that certain decisions, such as the establishment of budgets, development and promotion strategies and specific tasks, are under the control of our collaboration partners, and that, 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 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 the current worldwide financial slowdown. The United States poses particular client credit risk issues, because of the concentrated distribution system in which approximately 65% of our consolidated U.S. pharmaceutical sales are accounted for by just three wholesalers. We are also exposed to large wholesalers in other markets, particularly in Europe. Worldwide, the Group's three main customers represent 23.0% of our gross total revenues. An inability of one or more of these wholesalers to honor their debts to us could adversely affect our financial condition (see Note D.34. to our consolidated financial statements included at Item 18 of this annual report).

In some countries, some customers are public or subsidized health systems. The economic and credit conditions in these countries may lead to longer payment terms. 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.").

The 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 heightened pressure on drug prices, increased substitution of generic drugs, and the exclusion of certain products from formularies.

Further, we believe 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 system 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. Moreover, current economic conditions in the United States have resulted in 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 goes into effect in the U.S. in 2015 and 2016, some

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(1) 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 and by Notes D.10. and D.34. to our consolidated financial statements included at Item 18 of this annual report.

(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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employers may seek to reduce costs by reducing or eliminating employer group healthcare plans or transferring a greater portion of healthcare costs to their employees.

Our CHC and animal health business 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 case 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 affected. See also "We are subject to the risk of non-payment by our customers".

Moreover, 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, resulting in a material and adverse effect on 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 a Group product were to be the subject of counterfeits, the Group could incur substantial reputational and financial harm. See "Item 4. Information on the Company B. Business Overview B.6. Markets B.6.2. Competition."

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 project, patent litigation and the launch of competing products), with adverse effects on our financial condition and the value of our assets.

Furthermore, if any of our strategic equity investments decline in value and remain below cost for an extended duration, we may be required to write down our investment. We also own a significant stake in Regeneron Pharmaceuticals Inc. (22.3% of share capital as of December 31, 2014), 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.

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 certain European countries, Russia and Venezuela could also negatively affect the value of our assets (see " The 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 from time to time 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.

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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).

We are increasingly dependent on information technologies and networks.

Our business increasingly depends on the use of information technologies, which means that certain key areas such as research and development, production and sales are to a large extent dependent on our information systems or those of third party providers, notably for storing and transferring confidential or sensitive information. Moreover, we commercialize a number of devices using new technologies which, in case of malfunctions could lead to a risk of harm to patients (see " Product liability claims could adversely affect our business, results of operations and financial condition") or the unavailability of our products. While we and our third-party service providers have secure information technology systems for the protection of data, 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 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 security breach, which could have a material adverse effect on our operating results and financial condition.

The expansion of social media platforms and mobile technologies presents new risks and challenges.

New technologies are increasingly used 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 instance, 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 posts or comments about Sanofi, our business, directors or officers on any social networking web site could seriously damage our reputation. In addition, our employees and partners may use the social media tools and mobile technologies inappropriately which may give rise to liability for the Company, or which could lead to the exposure of sensitive information. In either case, such uses of social media and mobile technologies could have a material adverse effect on our business, financial condition and results of operations.

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.

As a complement to our portfolio of products, we pursue a strategy of selective acquisitions, in-licensing and collaborations in order to develop growth opportunities. The implementation of this strategy depends on our ability to identify business development opportunities and execute them at a reasonable cost and under acceptable conditions of financing. Moreover, entering into in-licensing or partnership agreements generally requires the payment of significant "milestones" well before the relevant products are placed on 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").

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 newly acquired activities or businesses;
- integration takes longer than expected;
- the loss of key employees occurs; or

we have higher than anticipated integration costs.

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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.

Moreover, we may miscalculate the risks associated with newly acquired activities or businesses at the time they are acquired or not have the means or access to 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 is completed due to lack of historical data. As a result, risk management and the coverage of such risks, particularly through insurance policies, may prove to be insufficient or ill-adapted.

The globalization of the Group's business exposes us to increased risks in specific areas.

Emerging Markets are among the pillars of our overall strategy. Difficulties in adapting to 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.

The significant expansion of our activities in Emerging Markets further 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 regulatory frameworks, difficulties in recruiting qualified personnel or maintaining required 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 as well as other legal matters, could adversely affect our business, results of operations and financial condition").

Also as a global healthcare leader, we are exposed to a number of risks inherent in sectors in which, in the past, we have been less active such as the generic and consumer healthcare sectors whose business models and trade channels are different from the traditional pharmaceutical activity in particular regarding promotional efforts and trade terms.

Our strategic objectives may not be fully realized.

Our strategy is focused on four key priorities in order to deliver sustainable long-term growth and maximize shareholder returns: grow a global healthcare leader with synergistic businesses, bring innovative products to market, seize value-enhancing growth opportunities, and adapt our structure for future opportunities and challenges.

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.

The Group concentrates its efforts around identified businesses to meet significant growth objectives. There is no guarantee that we will meet these objectives or that these businesses, such as Emerging Markets or innovative products, will grow in line with anticipated growth rates. A failure to continue to expand our business in these areas could affect our results of operations or financial condition.

The successful launch of a new pharmaceutical product involves substantial investment in sales and marketing activities. In November 2014, we announced our intent to launch up to 18 new medicines and vaccines between 2014-2020; however there can be no assurance that these product candidates will be approved, with the requested indications, or if at all, and if approved, will achieve commercial success. The success of a product also depends on our ability to successfully produce and launch it. The strategy of launch that we may develop (notably in terms of timing, pricing, market access, marketing efforts and dedicated sales forces) may not deliver the benefits that we expect. The relevant competitive environment may also have evolved at the time of the actual launch, modifying our initial expectations. The need to prioritize the allocation of financial resources and sales forces may cause delays in the expected launch of some of our products.

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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; and
- 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 or criminal penalties and 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.

Furthermore, we are or may become involved in claims, lawsuits and administrative proceedings relating to environmental matters. Some current and former Sanofi's 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, or our subsidiaries that we demerged,

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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 aiming 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 (in North Africa, Middle East, Asia, Pacific, Europe, Central and Latin Americas), floods (in Africa, Asia Pacific and Europe) 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 2014, 34% of our net sales were realized in the United States, 34% in Emerging Markets (including countries that are or may in future be 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 upon the sale of assets, merger, tender offer or similar transactions 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

(3)

Information in this section is complementary 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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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.

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

As of December 31, 2014, L'Oréal held approximately 8.96% of our issued share capital, accounting for approximately 16.28% 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 announced that it 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 aggregate 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 and there can be no assurance that the product sales milestone #1 or the other product sales milestones will be achieved. The 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

Introduction

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

In 2014, our net sales were €33,770 million. We are the fourth largest pharmaceutical group in the world and the second largest in Europe in terms of sales (IMS data).

Sanofi is the parent company of a consolidated group of companies. A list of our principal subsidiaries can be found in Note F to our consolidated financial statements included at Item 18 of this annual report.

The Group is organized around three principal activities: Pharmaceuticals, Human Vaccines via Sanofi Pasteur, and Animal Health via Merial. These activities are operating segments within the meaning of the IFRS 8 accounting standard (see Note D.35. to the consolidated financial statements).

We invest in the following activities (see "B. Business Overview B.1. Strategy" below): Emerging Markets[1], Diabetes Solutions, Vaccines, Consumer Health Care, Animal Health, Genzyme, and Other Innovative Products[2]. Unlike the Vaccines and Animal Health activities, which are also operating segments within the meaning of IFRS 8, the Diabetes Solutions, Consumer Health Care, Genzyme, and Other Innovative Products activities are units whose performance is monitored primarily on the basis of net sales, and the products they sell are included in our Pharmaceuticals operating segment. The Emerging Markets platform includes products from all three of our principal activities (Pharmaceuticals, Human Vaccines and Animal Health), and its performance is monitored primarily on the basis of net sales.

Net sales of these activities for the year ended 2014 are presented in "Item 5 Results of Operations Year Ended December 31, 2014 Compared with Year Ended December 31, 2013" below.

Within our Pharmaceuticals activity, which generated net sales of €27,720 million in 2014, we specialize in the following therapeutic areas:

Diabetes Solutions: our products in this area include Lantus®, a long-acting human insulin analog which is the world-leading brand in the insulin market; 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; Afrezza®, a rapid-acting inhaled insulin and Toujeo®, a new formulation of insulin glargine.

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 I (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.

Rare Diseases and Multiple Sclerosis are the therapeutic areas of our "Genzyme" activity.

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

Other 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 cardiovascular medicines include Multaq®, an anti-arrhythmic drug, and two hypertension treatments: Aprovel®/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

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(1) *World excluding the United States, Canada, Western Europe (France, Germany, UK, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Sweden, Portugal, the Netherlands, Austria, Switzerland, Ireland, Finland, Norway, Iceland and Denmark), Japan, Australia and New Zealand.*

(2) *The "Other Innovative Products" activity covers new product launches since 2009 which do not belong to the other activities listed: Multaq®, Jevtana®, Auvi-Q®, Mozobil® and Zaltrap®*

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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.

Our pharmaceutical portfolio also includes a wide range of other products: Consumer Health Care products, a category in which we have become the third largest global player (source: Nicholas Hall) and for which we have created a dedicated division, and other prescription drugs including generics.

Our Human Vaccines (Vaccines) activity is operated through Sanofi Pasteur. Net sales from vaccines amounted to €3,974 million in 2014, 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. Its net sales reached €2,076 million in 2014 with a wide range of products to improve the health, well-being and performance of a large variety of animals (both production and companion).

We obtained regulatory approval for three new products during the last six months of 2014: Cerdelga®, Lemtrada® and Fluzone® ID Quadrivalent.

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.

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 for 2014 from IMS Health MIDAS (retail and hospital) and Nicholas Hall for Consumer Health Care.

For the 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.

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.

The Group is present in around 100 countries over five continents, and employed 113,496 people at the end of 2014.

History

The Group has more than a century of service in the pharmaceutical industry. Sanofi-Synthélabo (formed in 1999 by the merger of Sanofi, founded in 1973, and Synthélabo, founded in 1970) and Aventis (formed in 1999 by the combination of Rhône-Poulenc, formed in 1928, and Hoechst, founded in 1863) were combined in 2004 and are the principal legacy companies of our continuously expanding Group.

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In recent years, we have undertaken a series of acquisitions to become a diversified healthcare company and to create new activities or strengthen existing ones, including Consumer Health Care, Generics, Rare Diseases and Animal Health.

Main changes since 2009

In 2009, we acquired Zentiva a Prague-based branded generics group, and Medley, one of the leading generics companies in Brazil.

On February 9, 2010 we successfully completed our tender offer for all outstanding shares of common stock of Chattem, Inc. (Chattem), a leading U.S. consumer healthcare company.

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 Merck's interest in Merial.

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

B. Business overview

B.1. Strategy

Sanofi is a global healthcare leader offering therapeutic solutions focused on patients' needs. Like other pharmaceutical groups, we are facing competition from generics for many of our major products, in an environment subject to strong cost containment pressures from both third party payers and healthcare authorities. We responded to these major challenges by implementing a strategy with the aim of repositioning Sanofi for more stable and sustainable revenue and earnings growth. In recent years, we have transformed the Group by decreasing our reliance on existing "blockbuster" medicines (medicines with over $1 billion in global annual sales), optimizing our approach to Research and Development (R&D) and increasing our diversification.

Growing a global healthcare leader with synergistic platforms

Our ambition is to offer an integrated set of businesses in the healthcare field, with opportunities to create synergies across our activities, both upstream at the R&D level and downstream in the marketplace. To achieve this objective, Sanofi has been investing in the following activities: Emerging Markets, Diabetes Solutions, Vaccines, Consumer Health Care, Animal Health, Genzyme, and Other Innovative Products. We regularly review our strategy and its implementation, and are continuing to apply this strategy with a focus on four key priorities.

Bringing innovative products to market

We regularly review our R&D portfolio to improve the allocation of our resources. Our decision-making processes ensure that commercial potential and the scope for value creation are factored into our development choices. The result is an ongoing rationalization and optimization of our portfolio, allowing us to focus on high added value projects and, where appropriate, to reallocate some of our internal resources to partnerships and collaborations. We have redesigned our R&D footprint. Our R&D is based on an organizational structure focused on meeting patient needs and encouraging entrepreneurship. This network-based organization, open to external opportunities, enables our R&D portfolio to capitalize more effectively on innovation from a wide range of different sources.

In line with this policy, we entered into new alliance and licensing agreements during 2014 to give us access to new technologies and/or to broaden or strengthen our existing areas of research. We have also made progress towards our objective of offering more products with added value for patients, with two new pharmaceutical products (Cerdelga® and Lemtrada® in the U.S.) and one new vaccine (Fluzone® ID Quadrivalent in the U.S.) approved in 2014. We currently have nine pharmaceutical projects and six vaccines in late-stage development or in registration. Over the period 2014-2020, up to 18 products are expected to be launched: 12 pharmaceutical products (Cerdelga®, Lemtrada®, Toujeo®, Afrezza®, Praluent®, Lyxumia®, Lixilan, sarilumab, dupilumab, insulin Lispro, patisiran and Anti-CD38 mAB), five vaccines (Shan5 , Dengue Vaccine, PR5i, a rotavirus vaccine and a Cdiff vaccine) and one animal health product (NexGard®).

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Seizing value-enhancing growth opportunities

Business development remains a key part of our overall strategy, targeting acquisitions and alliances that create and/or strengthen platforms for long-term growth and create value for our shareholders. We invested around €2.3 billion in external growth in 2014 in line with this targeted policy, announcing several new transactions (acquisitions of assets, equity investments, partnerships) including with Alnylam Pharmaceuticals, Inc. and Bayer (Germany/equine products). We also entered into a number of collaborations during 2014, including with Alnylam Pharmaceuticals, Inc. in rare genetic diseases; with Eli Lilly on Cialis® over the counter; and with Mannkind on Afrezza®.

We increased our equity interest in the biopharmaceutical company Regeneron Pharmaceuticals Inc. to 22.3% as of December 31, 2014, compared with 15.9% as of December 31, 2013. Since the beginning of April 2014, our investment in Regeneron has been accounted for by the equity method (see Note D.1. to the consolidated financial statements).

In the years to come, we expect to continue our external growth strategy, to access external innovation and further strengthen our operations. We will remain financially disciplined in line with our business development policy, so that we can execute strategically important transactions and partnerships capable of delivering a return on investment in excess of our cost of capital.

Adapting our structure for future opportunities and challenges

We have adapted our operating model, previously focused on best-selling prescription drugs in our traditional markets, to a broader set of products and services that better reflect the diversity and geographical reach of our activities. In particular, we have tailored our strategy, structure and product offering to the needs of each region, so as to deliver the most appropriate solution to each patient. This has led to a dramatic shift in our product mix, and the shift in focus from blockbuster products to growth platforms. In 2008, 61% of our sales came from our 15 top-selling products, while 76.4% of our 2014 sales were generated by our growth platforms. In addition, 33.6% of our 2014 sales were in Emerging Markets, where we have expanded our offerings in high-growth areas such as Generics and Consumer Health Care.

We have also realigned our industrial capacity so as to reflect our production forecasts and our analyses of growth opportunities. Together with the streamlining of our R&D structures and tight control over our selling, general and administrative expenses, this has helped us successfully navigate of this period during which several of our leading medicines lost patent exclusivity, in a tougher economic climate with new healthcare cost containment measures in many markets.

We have also invested in the biotechnology sector, demonstrating our belief in biotechnology and innovation. In addition to the collaboration and partnership agreements described in this report, we also use our investment fund Sanofi Genzyme BioVentures (SGBV) to invest in promising companies in the biotechnology field, such as Unum Therapeutics and Lysosomal Therapeutics Inc.

B.2. Main Pharmaceutical Products

Within the Pharmaceuticals business, our most important products can be grouped into the key fields of diabetes solutions, rare diseases, multiple sclerosis, oncology, thrombosis and cardiovascular disease prevention, nephrology and biosurgery. 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 " 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.

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The table below shows the net sales of the main pharmaceutical products for the year ended December 31, 2014.

Therapeutic Area / Product Name	2014 Net Sales (€ million)	Drug Category / Main Areas of Use
Diabetes Solutions		
Lantus® (insulin glargine)	6,344	Long-acting analog of human insulin Type 1 and 2 diabetes mellitus
Amaryl® (glimepiride)	360	Sulfonylurea Type 2 diabetes mellitus
Apidra® (insulin glulisine)	336	Rapid-acting analog of human insulin Type 1 and 2 diabetes mellitus
Insuman® (insulin)	137	Human insulin (rapid and intermediate acting) Type 1 and 2 diabetes mellitus
Lyxumia® (lixisenatide)	27	GLP-1 receptor agonist Type 2 diabetes mellitus
Rare Diseases		
Cerezyme® (imiglucerase for injection)	715	Enzyme replacement therapy Gaucher disease
Myozyme®/Lumizyme® (alglucosidase alpha)	542	Enzyme replacement therapy Pompe disease
Fabrazyme® (agalsidase beta)	460	Enzyme replacement therapy Fabry disease
Aldurazyme® (laronidase)	172	Enzyme replacement therapy Mucopolysaccharidosis Type I
Multiple Sclerosis		
Aubagio® (teriflunomide)	433	Oral immunomodulating agent MS
Lemtrada® (alemtuzumab)	34	Humanized monoclonal antibody targeting CD52 antigen MS
Oncology		
Jevtana® (cabazitaxel)	273	Cytotoxic agent Prostate cancer
Taxotere® (docetaxel)	266	Cytotoxic agent Breast cancer Non small cell lung cancer Prostate cancer Gastric cancer Head and neck cancer
Thymoglobulin® (anti-thymocyte globulin)	217	Polyclonal anti-human thymocyte antibody preparation Acute rejection in organ transplantation Aplastic anemia Graft-versus-Host Disease
Eloxatin® (oxaliplatin)	210	Cytotoxic agent Colorectal cancer
Mozobil® (plerixafor)	111	Hematopoietic stem cell mobilizer Hematologic maligancies
Zaltrap® (aflibercept)	69	Recombinant fusion protein Oxaliplatin resistant metastatic colorectal cancer

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Therapeutic Area / Product Name	2014 Net Sales (€ million)	Drug Category / Main Areas of Use
Other Prescription Drugs		
Plavix® (clopidogrel bisulfate)	1,862	Platelet adenosine disphosphate receptor antagonist Atherothrombosis Acute coronary syndrome with and without ST segment elevation
Lovenox® (enoxaparin sodium)	1,699	Low molecular weight heparin Treatment and prevention of deep vein thrombosis Treatment of acute coronary syndromes
Aprovel® (irbesartan) / CoAprovel® (irbesartan & hydrochlorothiazide)	727	Angiotensin II receptor antagonist Hypertension
Renagel® (sevelamer hydrochloride) / Renvela® (sevelamer carbonate)	684	Oral phosphate binders High phosphorus levels in patients with chronic kidney disease (CKD) on dialysis
Depakine® (sodium valproate)	395	Anti-epileptic Epilepsy
Synvisc® / Synvisc-One® (hylan G-F 20)	352	Viscosupplements Pain associated with osteoarthritis of the knee
Stilnox® / Ambien® / Myslee® (zolpidem tartrate)	306	Hypnotic Sleep disorders
Multaq® (dronedarone)	290	Anti-arrhythmic drug Atrial Fibrillation (AF)
Allegra® (fexofenadine hydrochloride)	192&zwsp;[(1)]	Anti-histamine Allergic rhinitis Urticaria
Actonel® (risedronate sodium)	82	Biphosphonate Osteoporosis Paget's disease
Auvi-Q® / Allerject	72	Epinephrine auto-injector Emergency treatment of severe allergic reactions
Consumer Health Care		
Total	3,337	
Generics		
Total	1,805	

(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®, a long acting analog of human insulin; Amaryl®, a sulfonylurea; Apidra®, a rapid acting analog of human insulin; and Insuman®, a human insulin. In February 2013, the European Commission granted marketing authorization in Europe for Lyxumia®, a once daily prandial GLP-1 receptor agonist.

Two new products are being launched in 2015: Toujeo® (U300) and Afrezza®.

Afrezza®

Afrezza® is a rapid acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes. The product was launched in the United States at the beginning of February 2015. Afrezza® is in-licensed from MannKind.

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Toujeo® (Insulin glargine 300 U/mL):

In Phase I studies, Toujeo®, a new formulation of insulin glargine, demonstrated improved pharmacodynamics with an even flatter and more prolonged action profile than Lantus®, which in clinical trials translated into good glycemic outcomes with less hypoglycemia.

The Phase III program, completed with 12 months data, includes four global studies (EDITION I, II, III and IV) and two studies in Japanese patients (EDITION JPI and JPII). The Phase III program assessed the efficacy and safety of Toujeo® compared with Lantus® in various patient populations with type 1 diabetes and type 2 diabetes.

In all three studies in type 2 diabetes (EDITION I-III), a similar level of glycemic control (HbA1c) between Toujeo® and Lantus® was demonstrated over the 6-month period, while a lower risk of hypoglycemia was found in the Toujeo® group. Extension of the studies to 12 months demonstrated maintenance of glycemic control and did not identify any new safety signals. In the EDITION IV study in type 1 diabetes, similar glycemic control and safety profiles were achieved regardless of whether the injection was in the morning or the evening. The 12-month results of the EDITION JPI (type 1 diabetes) and EDITION JPII (type 2 diabetes) studies confirmed these findings with comparable glycemic control and a reduced risk of hypoglycemia in the Toujeo® group.

On February 25, 2015, the U.S. Food and Drug Administration (FDA) approved Toujeo® (insulin glargine [rDNA origin] injection, 300 U/mL), a once-daily long-acting basal insulin, to improve glycemic control in adults living with type 1 and type 2 diabetes. Toujeo® is expected to be available in the U.S. at the beginning of the second quarter of 2015.

On February 26, 2015, Toujeo® received a positive opinion from the CHMP for use in adults with type 1 and type 2 diabetes. A decision from the EMA is expected in May 2015.

Toujeo® will be 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® is currently pending marketing authorization with other health authorities around the world.

Lantus®

Lantus® (insulin glargine) is a long acting analog of human insulin, offering an improved pharmacokinetic and pharmacodynamic profile. Lantus® is indicated for once daily subcutaneous administration in the treatment of adult patients with type 2 diabetes mellitus 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 mellitus.

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, and the only disposable pen that combines a low injection force of up to 80 units per injection with ease of use;
- ClikSTAR®, a reusable insulin pen first approved in 2009 in the European Union and Canada and now available in more than 30 countries worldwide; and
- 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 India; going forward, Sanofi intends to make AllSTAR accessible to other emerging markets.

In their 2012 updates, the American Diabetes Association and European Association for the Study of Diabetes (EASD) maintained their 2008 treatment recommendations for type 2 diabetes. This consensus statement further established basal insulins such as Lantus®, or a sulfonylurea such as Amaryl®, as two preferred second line treatment options for people with diabetes who are unable to achieve glycemic control targets with lifestyle intervention and metformin (which reduces hepatic glucose production and decreases insulin resistance) alone.

These treatment recommendations reinforce the timely use of basal insulin as a core therapy for type 2 diabetes.

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Lantus® is the world number one 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 2014 were the United States, France, China, and Germany.

In the United States, Sanofi's pediatric regulatory exclusivity for the Lantus compound expired in February 2015. The Lantus® compound patent expired in August 2014 in the US, 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 will expire in major European countries in May 2015. Sanofi also has patents protecting the Lantus® formulation and devices which deliver Lantus® that are currently in litigation and which expire on varying dates between 2023 and 2028 (including pediatric regulatory exclusivity).

Amaryl® / Amarel® / Solosa®

Amaryl® (glimepiride) is an orally administered once daily sulfonylurea (a glucose lowering agent), available either in simple form or in combination with metformin, indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes. Amaryl® reduces the body's blood sugar level in two ways: by helping the body to produce more insulin both at mealtimes and between meals, and by decreasing insulin resistance.

Amaryl® is subject to generic competition in the United States and Japan.

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 and the ClikSTAR® reusable 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 where treatment with insulin is required. Human insulin is produced by recombinant DNA technology in Escherichia coli strains. Insuman® is supplied in vials, cartridges, pre filled disposable pens (OptiSet® and SoloSTAR®), or reusable pens (ClickSTAR®). 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.

Lyxumia®

Lyxumia® (lixisenatide) is a once daily prandial GLP-1 receptor agonist and is indicated for the treatment of adults with type 2 diabetes mellitus 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 European Union 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 50 countries and launched in over 20 countries around the world.

The FDA application was withdrawn in September 2013, to avoid the potential risk that public disclosure of interim data might compromise the ongoing ELIXA CV outcomes trial. Sanofi intends to resubmit the application in 2015 once the ELIXA CV trial results are known.

Additional Phase IIIb studies are ongoing.

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BGStar® / iBGStar® / MyStar Extra®

Sanofi and its partner AgaMatrix are co-developing intelligent solutions in diabetes care that demonstrate their commitment to simplifying and innovating the diabetes management experience for people with diabetes and healthcare providers. These blood glucose monitoring solutions are exclusive to Sanofi and are designed to be synergistic with the rest of our diabetes treatment portfolio. BGStar®, iBGStar® and MyStar Extra® are modern and intelligent blood glucose monitoring solutions which are easy to use, accurate, reliable and fit the lifestyle of people with diabetes today:

MyStar Extra® provides unique parameters which are critical for insulin titration such as three day fasting blood glucose average, fasting blood glucose trend over the last 10 days, and estimation of the A1C trend. MyStar Extra® launched in October 2013 is available in most European countries including Italy, Spain, France, Germany and the United Kingdom. BGStar® and iBGStar® are available in most European Countries (including France, Germany, Spain, Italy and the United Kingdom), in Canada and in some other countries including Brazil.

These monitoring devices are an important step towards our vision of remaining a global leader in diabetes care by integrating intelligent monitoring technology, therapeutic innovations, personalized services and support solutions.

b) Rare Diseases

The acquisition of Genzyme in 2011 brought to the Group specialized expertise in rare diseases, a sector where there remain many unmet medical needs, and expanded our presence in the biotechnology sector.

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 there are approximately 10,000 Gaucher patients worldwide.

Cerezyme® is the only therapy with a 19 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 United States, 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 patients who switch from enzyme replacement therapy (ERT), as well as in untreated patients. 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 United States. It received European Medicines Agency (EMA) approval in January 2015.

Myozyme® / Lumizyme®

Myozyme® / Lumizyme® (alglucosidase alpha) are enzyme replacement therapies used to treat Pompe disease, an inherited, progressive and often fatal LSD. We estimate that there are approximately 10,000 Pompe patients worldwide.

Myozyme® has been marketed since 2006 in the United States and the European Union and is currently available in 48 markets worldwide. Outside the United States, Myozyme® is marketed for patients with both infantile and late onset disease. Lumizyme® has been marketed since June 2010 in the United States. Initially designed

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specifically to treat patients with late onset Pompe disease and patients over eight years of age without evidence of cardiac hypertrophy, since August 1, 2014 it has also been approved for infantile onset Pompe Disease.

Myozyme® and Lumizyme® are administered by intravenous infusion. Both products are a recombinant form 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 is estimated to be diagnosed in over 10,000 people worldwide.

Fabrazyme® is administered by intravenous infusion.

Fabrazyme® is available in over 40 countries around the world.

Aldurazyme®

Aldurazyme® (laronidase) is an enzyme replacement therapy used to treat Mucopolysaccaridosis Type I (MPS I). MPS I occurs in approximately one in 100,000 newborns worldwide, but incidence and the prevalence of phenotypic groups varies from region to region.

The principal markets for Aldurazyme® are the United States, Europe and Latin America.

c) 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 2 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® (teriflunomide), 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). In 2014, the U.S. labeling was updated to incorporate the results of TOWER, and the U.S. and E.U. labeling were updated to include the results of TOPIC.

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 United States in August 2013 and is now approved in more than 50 countries around the world, including the European Union and Brazil, with additional marketing applications under review by regulatory authorities globally. Including clinical trials and commercial use, approximately 30,000 patients have been treated with Aubagio® to date.

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Lemtrada® (alemtuzumab) is a humanized monoclonal antibody targeting CD52 antigen. Alemtuzumab was developed to treat patients with relapsing forms of MS. In September 2014, interim results from the second year of the extension of the CARE MS studies were presented at the European Committee for Research and Treatment in Multiple Sclerosis (ECTRIMS) meeting. In this analysis of patients who received 2 courses of Lemtrada® in CARE MS I and II (at start of study and 12 months later) and then completed their fourth year of follow-up (second year of the extension study), relapse rates and sustained accumulation of disability remained low. In approximately 70 percent of patients, disability scores improved or remained stable for an additional two years beyond the two-year pivotal multiple sclerosis studies, and approximately 70 percent of patients who received Lemtrada® in the pivotal studies did not receive further treatment with Lemtrada® through the second year of the extension study. No new safety signals were identified.

In September 2013, Lemtrada® was granted marketing authorization in the European Union 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 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 40 countries Additional marketing applications for Lemtrada® are under review by regulatory agencies around the world.

d) 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 European Union.

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 United States in 2010. In the United States, Jevtana® therapy is now covered by CMS (Centers for Medicare and Medicaid Services), 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 (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 2014 were the United States, France, Germany, Italy and the UK.

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). Taxotere® is indicated for early stage and metastatic breast cancer, first-line and second-line metastatic Non-Small Cell Lung Cancer

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(NSCLC), androgen-independent (hormone-refractory) metastatic prostate cancer, advanced gastric adenocarcinoma (including adenocarcinoma of the gastroesophageal junction), and the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck. The top four countries contributing to sales of Taxotere® in 2014 were Japan, China, Taiwan and South Korea. Generics of docetaxel were launched in Europe, in the United States, and in Japan (see " 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 United States 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, except in Canada where Eloxatin® still has exclusivity until December 2015.

The main three countries contributing to sales of Eloxatin® in 2014 were Canada, China and the United States.

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 2014 were the United States, China, France and Japan.

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 2014 were the United States, Germany, the UK 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), VEGF-B and placental growth factor (PlGF), 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 United States, 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 United States since August 2012.

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

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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 2014 were the United States, Germany, France and the United Kingdom.

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

e) Other Prescription 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 the treatment of acute coronary syndrome (ACS) with and without ST segment elevation in combination with acetylsalicylic acid (ASA). Plavix® is also available in a 300 mg tablet that reinforces early use by simplifying its approved loading dose administration in patients with ACS.

Plavix® is also indicated in combination with 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 United States and other markets.

Generics are expected to launch in 2015 in Japan.

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

The main countries contributing to sales of Plavix® / Iscover® in 2014 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. In the United States, three enoxaparin generics have been approved as well as Sanofi's own Lovenox® generic. No biosimilar of Lovenox has been authorized in the European Union yet. In 2014, 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 very good safety profile.

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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 BP or who are likely to need multiple drugs to achieve their blood pressure goals.

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 2014 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 United States, 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 European Union and 65,000 in Brazil. In the European Union, Renvela® is also approved to treat CKD patients not on dialysis.

Renagel® and Renvela® are marketed in more than 80 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 December 15, 2014, there have been no approvals of generics in the United States. However, as part of an amendment to the ANDA settlement, Sanofi granted Impax a license to sell a specific allotment of bottles of an authorized generic version of Renvela® tablets on April 16, 2014. This amendment did not change Sanofi's prior settlement agreement with Impax to sell generic versions of two other sevelamer products, Renvela® for oral suspension and Renagel®, which must obtain FDA ANDA approval in order to launch.

The main countries contributing to sales of Renagel® and Renvela® in 2014 were the United States, France, Italy, Brazil and the United Kingdom.

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

In the United States, 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 " f) 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").

The main country contributing to Allegra® / Telfast® sales in 2014 was Japan.

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Depakine®

Depakine® (sodium valproate) is a broad-spectrum anti-epileptic drug that has been prescribed for more than 40 years. Numerous clinical trials as well as many years of experience have demonstrated its efficacy for most forms of epilepsy and it is generally well-tolerated. Consequently, Depakine® remains the reference treatment for epilepsy throughout the world.

Depakine® is also a mood stabilizer, registered in many countries in the treatment of manic episodes within the scope of bipolar disorder and in the prevention of mood relapses and recurrences.

Sanofi produces a wide range of Depakine® formulations, meeting the specific requirements of the various types of patients: syrup, oral solution, injection, enteric tablet, Depakine® Chrono (a sustained release tablet) and Depakine® Chronosphere (a granule formulation packaged in sachets, a form particularly suitable for children, the elderly and adults with difficulties swallowing).

Depakine® is registered in 130 countries and marketed in 124 countries. Sodium valproate generics are available in most markets.

The main countries contributing to net sales of Depakine® in 2014 were China, the United Kingdom and Italy.

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 generally well tolerated, allowing the patient to awaken with a reduced risk of impaired attention, decreased alertness or memory lapses throughout the day.

Stilnox® is marketed in over 100 countries. It is available under the brand name Ambien® / Ambien®CR in the United States 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 United States and Europe. In Japan, generics of Myslee® entered the market in 2012.

In 2014, the main countries contributing to Stilnox® / Ambien® / Myslee® sales were Japan and the United States.

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 United States. Synvisc-One® is approved for use in patients with OA of the knee in United States 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 osteoarthritis synovial fluid.

In 2014, the main countries contributing to Synvisc® and Synvisc One® sales were the United States, Mexico, France, Canada, Germany and Brazil.

Multaq®

Multaq® (dronedarone) is the most extensively studied anti arrhythmic drug in atrial fibrillation (AF) and has demonstrated a unique cardiovascular (CV) outcome benefit in the ATHENA study in addition to effective rhythm control in the EURIDIS and ADONIS studies which was confirmed in real-world investigations.

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Multaq® is a multichannel blocker with both rhythm (prevention of AF recurrences) and rate (decrease of ventricular rate) controlling properties and additional effects (anti-hypertensive, vasodilatory). It is the first and only anti arrhythmic drug to have shown a significant reduction in CV hospitalization and death in patients with paroxysmal and persistent AF.

The main countries contributing to Multaq® sales in 2014 were the United States, Germany and Italy.

Actonel®

Actonel® (risedronate sodium) is a biphosphonate used for the treatment of osteoporosis and Paget's disease. For additional information on the commercialization of this product, see "Item 5 Financial presentation of Alliances Alliance Arrangements with Warner Chilcott".

Auvi-Q®

Auvi-Q® (epinephrine injection, USP), is the first-and-only epinephrine auto-injector with audio and visual cues that talk you through the injection process. Auvi-Q® is for the emergency treatment of life-threatening allergic reactions in people who are at risk for or have a history of anaphylaxis. Up to six million Americans may be at risk of anaphylaxis, although the precise incidence is unknown and likely underreported.

Sanofi licensed the North American commercialization rights to Auvi-Q® from Kaleo Pharma. Auvi-Q® is marketed as Allerject® in Canada.

f) Consumer Health Care (CHC)

Consumer Health Care is one of the key platforms in Sanofi's global growth strategy. In 2014, our Consumer Health Care sales reached €3.337 million, an increase of 11.1% (or 16.5% at constant exchange rates); nearly 53% of these sales were generated in Emerging Markets, 20% in Western Europe and 21% in the United States.

Our 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, focusing on meeting consumer needs in terms of health and well-being 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 products previously available only on prescription;
- our international dedicated sites integrated into the industrial network, manufacturing products to the highest pharmaceutical quality standards.

We are the third largest player in the global consumer healthcare market, and the fastest growing company 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 on prescription only.** In 2014, Sanofi signed a license agreement with Eli Lilly giving Sanofi exclusive rights to apply for approval of Cialis® OTC in the United States, Europe, Canada and Australia. We also hold exclusive rights to market Cialis® OTC following receipt of all necessary regulatory approvals, and have launched Allegra® and Nasacort 24H® without prescription in the United States.

Pursuing the external growth strategy via the targeted acquisition of products or companies enabling us to strengthen our consumer offering, such as the acquisition of Chattem in the United States in 2010.

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Highlights of our numerous product launches throughout the world in 2014 include the following brands:

In the United States:

- Nasacort® Allergy 24H, a nasal spray suspension indicated in the treatment of seasonal and perennial upper respiratory tract allergies (allergic rhinitis) in adults and children aged 2 and over.

- IcyHot SmartRelief®, an innovative drug-free pain relief device, based on TENS (Transcutaneous Electrical Nerve Stimulation technology, blocking pain signals and stimulating the production of endorphins, the body's naturally produced pain-relievers). Since Fall 2014, IcyHot SmartRelief® has been available across the United States.

In France: Doliprane® Etat grippal, indicated for adults and children over 15 in the treatment of colds, rhinitis, nasopharyngitis and flu symptoms, clear runny nose and watery eyes, sneezing, headaches and/or fever.

In Italy: Enterogermina® 6 milliardi, a probiotic indicated for the prevention and restoration of gut flora in the treatment of acute or chronic intestinal disorders.

Growth during 2014 was also supported by a range of Consumer Health Care products that gives us a historical presence in analgesics and digestive health.

Doliprane® offers a range of paracetamol-based products for pain and fever. Because of a wide range of dosage options (from suspensions containing 2.4% paracetamol to 1 g formulations) and pharmaceutical forms (suspensions, tablets, powders, suppositories), Doliprane® covers the needs of patients of all ages. Doliprane® is sold mainly in France and various African countries.

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 it is growing 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 prevention and restoration of gut flora in the treatment of acute or chronic intestinal disorders (in babies and adults). Enterogermina® is sold in Europe and is enjoying 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. Maalox® is available in various forms: tablets, oral suspension, sachet, thus offering consumers a range of suitable solutions. Maalox® is now available in 55 countries in Europe, Latin America and Asia.

Magne B6® is a food supplement containing magnesium and vitamin B6. Magne B6® has a wide range of therapeutic indications: irritability, anxiety, sleep disorders and women's health issues (premenstrual syndrome and menopausal

problems). Magne B6® is mainly available 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, which has been augmented by several new products, continues to grow.

These historical products are supplemented by:

The main products from Chattem in the United States (in addition to Allegra® OTC and Nasacort 24H), which are ACT®, Gold Bond®, Icy Hot®, Rolaids®, Cortizone-10®, Selsun Blue® and Unisom®.

In China, BMP Sunstone markets Haowawa®, a leading brand of children's cough and cold remedies. Minsheng Pharmaceuticals Co. Ltd markets 21 Super Vita®, one of the leading vitamin and mineral supplements.

Through Universal Medicare in India, the Group markets neutraceuticals and other products including vitamins, antioxidants, mineral supplements and anti-arthritis products such as Seacod®, CoQ®10, Collaflex and Multivit®.

We are also continuing to expand in the VMS (Vitamins, Minerals and Supplements) market with the Omnivit® range in various emerging market countries and with the Cenovis® and Nature's Own® brands on the Australian market.

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g) Generics

To reinforce our generics business, we created a global Generics division in 2013.

In 2014, sales of the Generics division reached €1,805 million, an increase of 11.1% (or 16.2% at constant exchange rates) compared with 2013.

In Europe, sales fell by 4% under the impact of price cuts: while volumes increased overall by 4.5%, prices fell by 9%. Sanofi Generics lost market share in France and the Czech Republic against a backdrop of strong competition, but gained in England and Italy. Net sales grew in the United Kingdom, Italy, Spain and Greece but fell in France, Germany and the Czech Republic. Latin America is up by 6% overall at constant exchange rates in 2014 (excluding Brazil), led by Colombia and Venezuela. In Brazil, market share has stabilized since the beginning of the year. The level of trade discounts has lowered, as have inventory levels held by wholesalers; operational indicators such as stockouts and returns have improved.

In the Middle East, we acquired a significant stake in Globalpharma Company LLC through a partnership agreement with Dubai Investment. Globalpharma is a company based in Dubai with net sales of €31 million in 2013 and with activities in several countries of the region.

Overall, emerging markets have contributed significantly to growth in our generics sales, especially in Africa (+10%) and Asia (6%, excluding Japan). Sales in Russia remained stable, with the fourth quarter impacted by the monetary crisis which led to a reduction in inventories held by wholesalers.

Sales in the United States fell by 31%, reflecting a decline in sales of authorized generics of Lovenox® and Taxotere®.

B.3. Vaccine Products

Sanofi Pasteur, the vaccines division of Sanofi, offers a broad range of vaccines. In 2014, 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 €3,974 million. Sales were favorably impacted by record sales of influenza vaccines and recovery of Pentacel® sales in the United States after 2013 supply issues.

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 2014, Sanofi Pasteur MSD net sales amounted to €848 million.

Sanofi Pasteur keeps expanding 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.

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The table below lists net vaccine sales by product range:

(€ million)	**2014 Net Sales**
Polio/Pertussis/Hib Vaccines	1,154
Influenza Vaccines	1,178
Meningitis/Pneumonia Vaccines	455
Adult Booster Vaccines	398
Travel and Other Endemic Vaccines	377
Other Vaccines	412
Total Vaccines	**3,974**

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 preferences.

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 200 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 20 countries have already included 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 (IPV) vaccines 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. Supply issues that affected Pentacel® in 2013 have been resolved and delivery of this vaccine progressively improved throughout 2014.

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® is already available in Canada and Australia. A marketing authorization application for Quadracel® was submitted to the FDA in March 2014.

Shan5 , developped 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.

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 was submitted to the FDA in the US in August 2014 and to the EMA in Europe in January 2015. PR5i should be the first hexavalent vaccine in the U.S. market.

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

Sanofi Pasteur is one of the world's leading developers and manufacturers of polio vaccines, with both oral polio vaccines (OPV) and injectable inactivated polio vaccines (IPV) 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 Alliance support paves the way for the implementation of the recommendation made by the WHO expert group on immunization (SAGE) that all countries introduce at least one dose of IPV in their routine immunization schedule before the end of 2015. The end of February 2014 marked an important milestone in the global fight against polio with UNICEF's decision to award Sanofi Pasteur unprecedent 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 began with IPV introduction in the Philippines in October 2014. 2015 is expected to be a turning point for the Polio End Game strategy with more than one hundred countries introducing IPV, including three countries where polio remains endemic: Afghanistan, Nigeria and Pakistan.

b) Influenza Vaccines

Sanofi Pasteur is a world leader in the production and marketing of influenza vaccines with over 220 million doses delivered in 2014. 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 remains focused on meeting the increasing demand for seasonal influenza vaccines through the launch of innovative vaccines. The differentiated product strategy is strengthening Sanofi Pasteur's leadership 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 2014, 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 6 months, adolescents and adults. Fluzone® Quadrivalent/ FluQuadri vaccine was launched in 2014 in several 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 US 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 December 2014 Fluzone® ID Quadrivalent was approved by the FDA for commercialization in the U.S.

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 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., more than 100 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 by breaking the cycle of transmission to infants who are immunized or only partially vaccinated. Adacel® is now registered in more than 60 countries.

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Repevax® (also marketed under the trademark Adacel-Polio®) is a combination vaccine that provides the same benefits as Adacel® along with offering 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 as 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, Saudi Arabia and numerous countries in Latin America, the Middle East and Asia Pacific regions.

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.

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 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) Other Products

Growth in other products is mainly driven by VaxServe, a leading specialty distributor in the U.S. market. 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 be closer to our customers and better serve their needs.

B.4 Animal Health: Merial

Our Animal Health activity is carried out by Merial, one of the world's leading animal healthcare companies. This company is dedicated to the research, development, manufacture and marketing of innovative pharmaceutical products and vaccines used by veterinarians, farmers and pet owners. Merial offers a full range of products to enhance the health, well-being and performance of a wide range of animals, both production and companion. Merial became Sanofi's dedicated Animal Health division following the joint announcement by Merck & Co. Inc. and Sanofi in 2011 of the end of their agreement to create a new animal health joint venture by combining their respective animal health activities (see Note D.2 to the consolidated financial statements).

The range of veterinary products covers four main segments: 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 anti-parasitic flea and tick brand for dogs and cats, the highest selling veterinary product in the world; Heartgard®, a parasiticide for control of heartworm in companion animals; Nexgard®, an oral anti-parasitic for the treatment and prevention of fleas and ticks in dogs; Ivomec®, a parasiticide 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 production animals; and Circovac®, a PCV2 (porcine circovirus type 2) vaccine. Merial plays an important role in veterinary public health activities of governments around the world. Merial is the world leader in vaccines for Foot-and-Mouth disease, rabies and bluetongue.

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Merial's net sales amounted to €2,076 million in 2014. The performance in 2014 was boosted by the successful launch of Nexgard® which, in the first year of launch, has become one of the 15 top-selling animal health products in the world, as well as the launch of Broadline® in Europe. Another major factor for the Companion Animal franchise is the performance of the Frontline® brand both in the United States and Europe, supported by additional targeted investment and a favorable season.

Growth for Merial's Production Animal franchise is in line with that of the market. Despite the avian flu pandemic in Asia and increased competition, the Avian franchise is growing. The Ruminants Franchise meanwhile experienced solid growth, boosted by emerging market countries and the success of LongRange (eprinomectin injectable anti-parasitic against internal and external parasites in cattle) in the United States.

In 2014, Merial's range of anti-parasitic products for companion animals was extended with:

- the approval in September 2013 in the United States by the FDA and in February 2014 in Europe by the EMA, of NexGard® (afoxolaner) tablets administered once a month for the prevention and treatment of flea and tick infestations in adult dogs and puppies. The product was launched in the United States in January 2014 and in Europe in March 2014;

- the approval in December 2013 by the EMA in Europe of Broadline®, a broad spectrum internal and external anti-parasitic treatment and prevention for cats valid throughout the European Union. 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 EU member states in May 2014, followed by the approval of marketing authorizations from June 2014 of 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.

On January 19, 2015, the European Commission approved NexGard® Spectra (afoxolaner and milbemycin oxime). This product further strengthens Merial's companion animal anti-parasitic arsenal and is available only on prescription. This new chewable tablet, built 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 Companion Animal segment, Merial has secured the supply of Heartgard® by acquiring the Barceloneta site in Puerto Rico from Merck & Co. Inc. and will make use of the site's expertise in chewables manufacturing technology. In the Production Animal segment, Merial has acquired Bayer's equine portfolio, consisting of Legend®/Hyonate (hyaluronate sodium) and Marquis® (ponazuril). Legend®/Hyonate® is an injectable solution that treats noninfectious 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.

Merial's principal markets are the United States, France, Brazil, Italy, United Kingdom, Germany, China, Australia, Japan, Spain and Canada. Mature markets represent 71% of Merial's total net sales with growth of more than 7%.

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 from drug discovery to medical affairs across three 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 medical value differential to patients and payers and to reduce healthcare costs for society.

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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 2014 included three major Units (Diabetes, Oncology, and Genzyme) driving projects from target identification to commercialization, a launch unit built around our PCSK9 (alirocumab) project, an immuno-inflammation franchise focused on driving immune-inflammation development projects, and Therapeutic Strategic Units (TSUs) driving projects from target identification to proof of concept. 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;

- 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 4 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 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) built jointly by R&D and Commercial Operations. The IDC includes senior representatives from R&D, Commercial Operations 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

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

The clinical portfolio as of the date of filing of this annual report 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 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.

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The clinical portfolio for new products can be summarized as follows (as of February 5, 2015)

	Phase I	Phase II	Phase III / registration
Diabetes Solutions	SAR425899		Lyxumia® (lixisenatide) Lixilan® (lixisenatide / insulin glargine) Toujeo® (glargine U300) SAR342434 (insulin lispro)
Oncology	SAR125844 SAR245408 SAR405838 SAR408701 SAR566658	SAR245409 SAR3419 SAR650984	
Cardiovascular diseases		fresolumimab	Praluent® (alirocumab)
Immune Mediated diseases (including Multiple Sclerosis)	GZ402668 SAR113244 SAR252067	SAR156597 vatelizumab	sarilumab dupilumab
Age Related Degenerative Diseases	SAR228810	SAR391786	
Infectious diseases		ferroquine (combo OZ439)	
Rare diseases	GZ402665 GZ402666	GZ402671	patisiran (SAR438027) revusiran (SAR438714)
Ophthalmology	StarGen UhsStat GZ402663	sarilumab (uveitis)	

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

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.)

Main compounds currently in Phase III and in the registration Phase

Toujeo (Glargine U300):

A new formulation of insulin glargine has demonstrated in Phase I studies an improved pharmacodynamic profile with an even flatter and more prolonged action profile than Lantus®, with the potential to translate into good glycemic outcomes with less hypoglycemia.

The Phase III program, completed with 12 months data, includes four EU/US studies (EDITION I, II, III and IV) and two studies in Japanese patients (EDITION JPI and JPII). The Phase III program assessed the efficacy and safety of Toujeo® compared with Lantus® in various patient populations (type 1 and type 2 Diabetes Mellitus/T1DM and T2DM).

In all three studies in T2DM (EDITION I, II &III), a similar level of glycemic control (HbA1c) in Toujeo® and Lantus® was demonstrated over the 6-month period, while a lower risk of hypoglycemia was found in the Toujeo® group. The extension of the studies to 12 months demonstrated maintenance of glycemic control and did not identify any safety signals. In the EDITION IV study in T1DM, similar glycemic control and safety profile were achieved

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regardless of whether the injection was in the morning or in the evening. The 12-month results of the EDITION JPI (T1DM) and EDITION JPII (T2DM) studies confirmed the aforementioned findings of comparable glycemic control as well as reduced hypoglycemia reporting in the Toujeo® group.

On February 25, 2015, the U.S. Food and Drug Administration (FDA) approved Toujeo® to improve glycemic control in adults living with type 1 and type 2 diabetes. Toujeo® is expected to be available in the U.S. at the beginning of the second quarter of 2015. On February 26, 2015, Toujeo® received CHMP (Committee for Medicinal Products for Human Use) positive opinion for use in adults with type 1 and type 2 diabetes. Further Marketing Applications were submitted in Japan (July 2014), Australia (May 2014), Switzerland (May 2014) and Canada (June 2014).

Lixilan® Fixed-Ratio: Lixilan® Fixed-Ratio, a combination of insulin glargine and lixisenatide, is under clinical development; a proof-of-concept study to examine the glycemic control of Lixilan® versus insulin glargine alone over 24 weeks was completed in 2014. The Lixilan® Phase III program is ongoing with two clinical studies. All patients were enrolled during 2014:

LixiLan-O study in patients insufficiently controlled on oral antidiabetic drugs, and

LixiLan-L study in patients not at goal on basal insulin.

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

Finally, a **new dual glucagon agonist (SAR425899)** entered Phase I in July 2014 for the treatment of patients with type 2 Diabetes Mellitus.

Sanofi Diabetes maintains a significant network of R&D collaborations with world leading academic institutions, including collaborations with the Joslin Diabetes Center (an affiliate of Harvard Medical School), the Charite in Berlin and the Helmholtz Zentrum in Munich. We also have collaborations with Gentofte Hospital (Copenhagen), and Gubra (a Danish biotech company specialized in gut hormone R&D). Sanofi and JDRF (Juvenile Diabetes Research Foundation) continue to jointly fund selected innovation projects in the field of type 1 diabetes research.

Sanofi and Medtronic have mutually agreed not to pursue the negotiations for a business partnership for which a non-binding memorandum of understanding had been signed in June 2014. 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.

b) Oncology

Main products in Phase II

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 or planned studies in multiple myeloma. Two studies are ongoing, one as a single agent and the other one in combination with lenalidomide/dexamethasone. Enrollment of patients into the three planned studies is due to begin in 2015. These studies are investigating **SAR650984** in combinations with: (i) carfilzomib; (ii) pomalidomide, and (iii) bortezomib/dexamethasone.

SAR245409 (XL765) was in-licensed from Exelixis, Inc. and is being developed by Sanofi. This oral agent is dual inhibitor of both (i) phosphoinositide-3-kinase (PI3K), and (ii) the mammalian target of rapamycin (mTOR). A Phase II trial of monotherapy in mantle cell lymphoma, follicular lymphoma, chronic lymphocytic leukemia and diffuse large B cell lymphoma, and a Phase II trial in combination with pimasertib (MEK inhibitor from Merck Serono) in Low Grade Serious

Ovarian, are ongoing.

Coltuximab ravtansine (SAR3419) is an Antibody Drug Conjugate (ADC) maytansin-loaded anti-CD19 mAb that has been in-licensed from Immunogen Inc and is being developed in Phase II in B-cell malignancies.

Main products in early stage

SAR125844 is a potent and selective MET-tyrosine-kinase inhibitor. Development of this compound is being conducted by Sanofi using two Clinical Phase I single agent studies in Europe, the United States and Asia

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Pacific, with **SAR125844** administered intravenously every week. Both studies include a dose escalation part followed by an expansion cohort focused on MET driven solid tumors. Promising efficacy and safety data have been reported from Phase I, with long tumor responses in patients with MET amplified Non-small cell lung cancer (ASCO, 2014). The start of the Phase II program is planned in 2015.

SAR245408 (XL147) was in-licensed from Exelixis, Inc. and is being developed by Sanofi. This oral phosphoinositide-3-kinase (PI3K) inhibitor is currently under evaluation in a Phase I study of the new formulation (Polymorphic Form E Tablet).

SAR405838 is a potent inhibitor of the HDM2/P53 interaction. The inactivation of the p53 function is an almost universal feature of human cancer cells. P53 is the most frequently mutated gene in cancer, with ~50% of tumors disabling p53 via the acquisition of somatic mutations. In ~50% of the tumors that retain the p53 wild-type status, the p53 function is frequently disabled by HDM2; **SAR405838** is aimed at intervening in this situation. The program is in Phase I with two ongoing studies.

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.

Projects discontinued in 2014

SAR153192 is a monoclonal antibody, directed against the Delta-Like-Ligand-4 from our alliance with Regeneron. This program has been discontinued in Phase I and the rights returned to Regeneron.

SAR260301 targets PI3K (Phosphoinositide 3 Kinase) pathway inhibition through selective inhibition of the PI3K beta-isoform. The program, which was in Phase I, has been terminated because of the poor pharmacokinetic properties observed.

SAR256212 (MM-121) under an exclusive global collaboration and licensing agreement, Merrimack Pharmaceuticals, Inc. and Sanofi were co-developing SAR256212, a fully human monoclonal antibody targeting ErbB3, in Breast, Lung and Ovarian Cancer. In June 2014, Sanofi returned the worldwide rights of **SAR256212** to Merrimack.

SAR307746 is a fully human IgG1 monoclonal antibody targets angiopoietin 2 (Ang2), issued from our alliance with Regeneron. This program (Phase I) has been discontinued and the rights returned to Regeneron.

c) Cardiovascular diseases

Praluent® alirocumab (SAR236553), developed in collaboration with Regeneron: positive results from Phase III studies with alirocumab, an investigational monoclonal antibody targeting PCSK9 (proprotein convertase subtilisin/kexin type 9), were obtained in 2014.

All nine Phase III trials of alirocumab in people with hypercholesterolemia met their primary efficacy endpoint of a greater percent reduction from baseline in low-density lipoprotein cholesterol (LDL-C) at 24 weeks compared to placebo or active comparator. The mean percent reduction in LDL-C from baseline at 24 weeks in alirocumab-treated patients was consistent with results seen in previous alirocumab

trials. The nine trials were ODYSSEY LONG TERM, FH I, FH II, HIGH FH, COMBO I, COMBO II, OPTIONS I, OPTIONS II and ALTERNATIVE. All patients received alirocumab in addition to standard-of-care lipid-lowering therapy, with the exception of some patients in ODYSSEY ALTERNATIVE.

The 2,341-patient ongoing ODYSSEY LONG TERM trial evaluated the long-term safety and efficacy of alirocumab compared to placebo. Both treatment groups received statins and some patients also received additional lipid-lowering therapies. The trial met its primary efficacy endpoint at 24 weeks. A pre-specified interim safety analysis was performed when all patients reached one year and approximately 25 percent of patients reached 18 months of treatment. A lower rate of adjudicated major cardiovascular events (cardiac death, myocardial infarction, stroke, and unstable angina requiring hospitalization) was observed in the alirocumab arm compared to placebo in a post-hoc analysis (p-value of less than 0.05). The potential of alirocumab to demonstrate cardiovascular benefit is being prospectively assessed in an ongoing 18,000-patient ODYSSEY OUTCOMES trial.

Alirocumab was generally well tolerated in the nine ODYSSEY trials. The most common adverse events were nasopharyngitis and upper respiratory tract infections, which were generally balanced between treatment groups.

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Injection site reactions occurred more often in the alirocumab group compared to placebo. Serious adverse events and deaths were generally balanced between treatment groups as were other key adverse events including musculoskeletal, neurocognitive and liver-related events.

The nine ODYSSEY trials, along with the previously announced MONO trial, encompass over 5,000 patients studied in double-blind trials for 24-104 weeks and will be used to support registration of alirocumab in major markets.

In January 2015, the FDA accepted the Praluent® Biologics License application (BLA) for priority review and the EMA accepted the Praluent® Marketing Authorization Application for review in the European Union.

The ODYSSEY clinical trial program remains ongoing. This includes three additional studies, CHOICE I, CHOICE II (both evaluating monthly doses of alirocumab) and OUTCOMES, which are expected to report primary endpoints in 2015 and beyond.

Fresolimumab (GZ402669) TGF-ß antagonist in Phase II for the treatment of Focal Segmental Glomerulosclerosis (FSGS).

d) Immune Mediated diseases and Multiple Sclerosis

Main products in Phase III

Sarilumab (SAR153191), a monoclonal antibody against the Interleukin-6 Receptor (anti IL-6R mAb) derived from our alliance with Regeneron, is in Phase III in adult patients with moderate to severe rheumatoid arthritis (RA). The SARIL-RA Phase III program evaluating two doses of sarilumab is underway with one completed (SARIL-RA-MOBILITY) and six ongoing clinical studies:

The SARIL-RA-TARGET study is investigating the effects of Sarilumab when added to DMARD (Disease-Modifying Anti-Rheumatic Drug) therapy in patients with active RA who are inadequate responders or intolerant to tumor necrosis factor alpha (TNF-α) antagonists on reduction of signs and symptoms at week 24 and improvement of physical function over 24 weeks in patients;

The SARIL-RA-ASCERTAIN study is a safety calibrator study evaluating sarilumab and tocilizumab in combination with DMARD therapy in patients with RA who are inadequate responders to, or intolerant of, TNF-alpha inhibitors over 24 weeks;

The SARIL-RA-EXTEND study, which enrolled patients from MOBILITY and is enrolling participants by invitation from the TARGET and ASCERTAIN studies, aims to evaluate in this uncontrolled extension the long term safety and efficacy of Sarilumab on top of DMARDs in patients with active RA;

The SARIL-RA-MONARCH is evaluating sarilumab vs adalimumab, both given as monotherapy in patients with RA. The primary endpoint is at week 24;

The SARIL-RA-ONE is an open label trial of sarilumab monotherapy. The primary endpoint is the incidence of anti-drug antibodies at week 24;

The SARIL-RA-EASY is a usability study comparing two devices: the auto-injector and the pre-filled syringe. Initial treatment is 12 weeks for the purpose of the primary endpoint.

Dupilumab (SAR231893) is a monoclonal antibody against the Interleukin-4 alpha Receptor (anti IL-4R alpha) derived from our alliance with Regeneron. Dupilumab modulates signaling of both IL 4 and IL 13 pathways. It is currently being

developed in several indications: atopic dermatitis in Phase III, asthma with a Phase III start planned in 2015, nasal polyposis (Positive Phase IIa proof of concept study) and eosinophilic eosophagitis 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).

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 atopic dermatitis

An open-label extension study of dupilumab in patients with atopic dermatitis. This is a multicenter study to assess the long-term safety and efficacy of repeat doses of dupilumab in adults with moderate-to-severe atopic dermatitis who have previously participated in controlled studies of dupilumab.

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Asthma: A randomized, double-blind, placebo-controlled, dose-ranging study to evaluate dupilumab in patients with moderate to severe uncontrolled asthma is currently ongoing and anticipated to complete in May 2015.

Nasal Polyposis: an evaluation of dupilumab in patients with bilateral nasal polyposis and chronic symptoms of sinusitis randomized, bouble-blind, Phase II, placebo controlled, 2 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) randomized, double-blind, parallel, placebo-controlled study to assess the efficacy, safety and tolerability of dupilumab in this population, is to be initiated.

Main products in Phase II

Vatelizumab (SAR339658), a humanized monoclonal antibody directed at the VLA-2 (Very Late Antigen 2) integrin receptor, was in-licensed from Glenmark Pharmaceuticals in May 2011. The primary target indication is relapsing form of MS (RMS). A seamless Phase IIA/B study in remitting relapsing MS patients to assess proof of concept and dose response started in 2014; enrolment is ongoing. Its long term safety extension study is planned to start in January 2015. A Phase IIA study in patients with ulcerative colitis was initiated in 2012. However this Phase IIA study and its companion long term safety study were discontinued in 2014 due to difficult enrollment challenges. There were no safety concerns that contributed to this decision.

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

Main products in early stage

GZ402668 (GLD52), an IgG1 monoclonal antibody binding to CD52 a cell surface antigen present at high level on T ab B lymphocytes, entered Phase I.

SAR113244 (anti-CXCR5), a first-in-class humanized monoclonal antibody in Phase I for the treatment of Systemic lupus Erythematosus. A Phase 1B multiple ascending dose study in SLE patients was initiated in December 2014.

SAR252067, a fully human antibody targeted against TNFSF14 (LIGHT) in Phase I in Crohn's disease.

Projects discontinued in 2014

SAR100842 (LPA1 receptor antagonist) a Phase IIA study in the treatment of systemic sclerosis was completed in 2013. Based on the clinical data the decision was taken to terminate the program.

e) Age Related Degenerative Diseases

SAR228810 (anti-protofibrillar AB mAb for the treatment of patients with mild cognitive impairment due to Alzheimer's Disease (AD) is in Phase I, in mild to moderate AD patients with confirmed amyloid pathology, in order to assess safety and PK (single and multiple IV and SC doses).

SAR391786, a monoclonal antibody against GDF8 (also known as myostatin), derived from our alliance with Regeneron, is in Phase II clinical development for the treatment of elderly patients with sarcopenia.

f) Infectious Diseases

Ferroquine (OZ439), a 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.

Final results of the Phase I combination study in healthy male adult subjects were made available in February 2014.

A Phase IIB clinical study of the combination of the two products, conducted in adults and children with P. falciparum malaria is to start in the first quarter of 2015 in Africa and Asia.

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Projects discontinued in 2014

SAR279356, Sanofi and Alopexx have agreed to let Alopexx take primary responsibility for the development of **SAR279356** (an anti-PNAG monoclonal antibody). As a consequence both parties have agreed to terminate their agreement relating to the development of this product.

SAR438584 (REGN2222) is a novel, fully human IgG1 mAb targeting a unique RSV-F epitope. Respiratory Syncytial Virus (RSV) is a leading cause of respiratory morbidity in infants. The program has been discontinued in Phase I and the rights returned to Regeneron.

g) 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.

patisiran (SAR438027) (mRNA inhibition Alnylam ALN-TTR02). The Phase III clinical trial is ongoing in the treatment of Familial Amyloid Neuropathy. 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 Alnylam ALN-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 Transthyretin (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

GZ402671 (CGS inhibitor) in Phase II for the treatment of Fabry disease. The Phase II trial in type 3 Gaucher disease is planned by the end of 2015.

Main products in early stage

GZ402665 (rhASM) olipudase alfa an enzyme replacement therapy targeting the treatment of the treatment of non-neurological manifestations of acid sphingomyelinase deficiency (ASMD), Niemann-Pick B disease. A Phase Ib study was completed in January 2014. All five patients in the Phase 1B study are fully enrolled in the long term trial and will continue to be treated with rhASM.

GZ402666 (Neo GAA) is a second generation enzyme replacement therapy targeting the treatment of Pompe disease. The program is currently in Phase I with the end of the clinical part (end of treatment for last patient) anticipated in February 2015.

h) 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.

Main products in early stage

GZ402663 (sFlt01 Phase I): a gene therapy to deliver an anti-angiogenic gene (anti-sFlt01) to stop the progression of neovascularization and edema related to wet Age-related Macular Degeneration (AMD) and to improve patients' vision.

UshStat® (**SAR421869** Phase I): a gene therapy to deliver a functional MY07A gene to the photoreceptor in Usher type 1B disease, an orphan inherited condition that results in progressive visual field constriction and vision loss.

StarGen (**SAR422459** Phase I): a gene therapy to treat (by replacing the missing ABCR gene) Stargardt disease, an orphan inherited condition that leads to progressive sight loss from age seven.

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Projects discontinued in 2014

RetinoStat® (SAR421868 Phase I): a gene therapy to treat wet Age-related Macular Degeneration (AMD); in March 2014, the DWG recommended that the license option for this product (developed by Oxford Biomedica) should not be exercised.

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 11 vaccines currently in advanced development as shown in the table below. The portfolio is well balanced, with five vaccine/antibody products for novel targets and six vaccines which are enhancements of existing vaccine products.

Phase I	**Phase II**	**Phase III**	**Submitted**
Streptococcus pneumonia* Pneumonia and meningitis vaccine	**Meningitis A,C,Y,W conj. 2nd generation** Meningococcal conjugate vaccine	**C. difficile toxoid vaccine*** Toxoid vaccine against *clostridium difficile*	**Dengue*** Mild-to-severe dengue fever vaccine
Herpes Simplex virus Type 2* HSV-2 vaccine	**Rabies VRVg** Purified vero rabies vaccine	**Rotavirus** Live attenuated tetravalent oral rotavirus vaccine	**PR5i, DTP-HepB-Polio-Hib(1)** Pediatric hexavalent vaccine (U.S., EU)
	Tuberculosis* Recombinant subunit vaccine	**Vaxigrip® QIV IM** Quadrivalent inactivated influenza vaccine	**Quadracel®** DTP(1) IPV vaccine 4-6 years (U.S.)

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

* *New targets*

Project highlights

This section focuses on vaccines candidates excluding PR5i and Quadracel® which are already described in the "B.3. Vaccine Products" section above.

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.

Rotavirus Vaccine

Rotavirus is the world's leading cause of severe, dehydrating diarrhea in children under age five. Shantha has a non-exclusive license for rotavirus strains from the NIH and is developing a live-attenuated human-bovine reassortant vaccine. The license excludes Europe, Canada, the U.S., China and Brazil. The Shantha rotavirus vaccine candidate completed Phase II in 2013.

Phase III study was initiated in India in October 2014. Results from the Phase I/II dose ranging study demonstrated the safety and immunogenicity of the vaccine candidate, and one dose has been selected for Phase III studies.

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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 second-generation meningococcal 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 rabies vaccines to be replaced by a single vaccine. The results of a Phase II clinical trial, carried out in 2009, 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. The clinical development plan for marketing authorization in the U.S. is currently ongoing.

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.

Sanofi Pasteur is also focused on the development of a multi-protein-based pneumococcal vaccine. This approach should result in a vaccine with superior serotype coverage, compared to current polysaccharide or conjugate based vaccines, and should not induce nor be sensitive to serotype replacement. A Phase I clinical trial in Bangladesh of a vaccine with three protein-based antigens ended in 2013; the results demonstrated the formulation to be safe and immunogenic in the target population.

New Vaccine Targets

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. The first objective is to have an evaluation of the real burden of the disease by 2015. The second 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 2 16 years living in highly endemic countries. The results show 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).

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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 can have in countries where dengue is endemic.

In January 2015, the rolling submission for Dengue vaccine was initiated in several endemic countries in Asia.

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's 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 comunicated in May 2014 showing the C.diff vaccine candidate to be generally well tolerated and immunogenic in the target population.

HIV A follow-up study to the phase III clinical trial in Thailand provided new clues, in 2011, about the types of immune responses that may have played a role in the protection seen in 2009 with our ALVAC®-HIV vaccine. In 2011, Sanofi Pasteur entered into a public-private partnership to substantiate and extend the vector prime/protein subunit boost regimen used in Thailand. This collaboration is expected to further the field of HIV vaccine development by sharing resources and by providing the manufacturing component of a partnership of funding agencies, research organizations, governments, and experts in the field of HIV vaccine development. Sanofi Pasteur is also looking at its NYVAC-HIV vaccine replicating vectors and a flavivirus-based viral vector, by participating in an international consortium under the Collaboration for AIDS Vaccine Discovery (CAVD).

Tuberculosis Statens Serum Institute of Denmark (SSI) 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 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.

Pseudomonas aeruginosa Sanofi Pasteur and KaloBios have entered into a negotiated agreement terminating their license and collaboration agreement for development of KB001-A. As a result of the transaction, KaloBios regained full global rights to the product in all indications.

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

Expenditures on research and development amounted to €4,824 million in 2014, comprising €4,174 million in the Pharmaceuticals segment, €493 million in Human Vaccines and €157 million in Animal Health. Research and development expenditures were the equivalent of about 14.3% of net sales in 2014, compared to about 14.5% in 2013 and 14.0% in 2012. 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 €986 million in 2014 compared to €951 million in 2013 and €1,037 million in 2012. Of the remaining €3,188 million relating to clinical development in the Pharmaceuticals segment (€3,136 million in 2013 and €3,181 million in 2012), 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 2014) compounds in the Pharmaceuticals segment, we set out below the date at which this compound entered into Phase III development, information concerning any compound

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patent in the principal markets for innovative pharmaceutical products (the United States, European Union 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® (lixisenatide)[3][4] (AVE0010)	May 2008[5]	2020	2020	2020	Dossier approved in Europe in February 2013; dossier submitted and withdrawn in the U.S. in December 2013. Complementary Phase III study to be added to the U.S. dossier before re-submission (expected in 2015)
Lixilan®	January 2014	2020	2020	2020	Phase III program ongoing. Submission in T2DM expected in the last quarter of 2015
Toujeo® Glargine U300	December 2011	2014 Protection extended to February 2015, by pediatric extension.	2014 Protection extended to May 2015, by pediatric extension, in most western European countries	2014	Submitted in April 2014. Regulatory approval granted on February 25, 2015 (U.S.) CHMP positive opinion on February 26, 2015 in Europe
SAR342434 Insulin Lispro	November 2014	NA	NA	NA	Phase III program ongoing in Type 1 & 2 Diabetes
Praluent® alirocumab (SAR236553)	July 2012	2029	2029	2029	Submitted in EU & US in the last quarter of 2014 for LDL-C reduction. Priority review granted by FDA. Phase III program ongoing in CV events reduction
sarilumab (SAR153191)	August 2011	2028	2027	2027	Phase III program in the treatment of Rheumatoid Arthritis ongoing; Submission expected in the last quarter of 2015 for US and 2016 for EU
dupilumab (SAR231893)	October 2014	2027	2029	2029	Phase III program in the treatment of Atopic Dermatitis ongoing
patisiran (SAR438027)	November 2013	2029	2029	2029	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 " 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 United States, the European Union, 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 " 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 (e.g., alirocumab). In the European Union 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 2014, 2013, and 2012 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 (Moving Annual Total) for the third quarter of 2014, 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 net sales are, respectively:

Emerging Markets (see definition in "Item 4. Information on the Company Introduction" above) represent 33.6% of our 2014 net sales. We are the leading healthcare company in emerging markets. In 2014, our sales in emerging markets grew by 9.3% at constant exchange rates. Latin America recorded double-digit sales growth in 2014. Sales in BRIC (Brazil, Russia, India and China) countries account for 36% of Emerging Markets sales. Sales in China and Russia were up 8.2% and 7.1% respectively (at constant exchange rates). In 2014, sales in Africa and the Middle East each exceeded €1 billion.

The United States represents 33.6% of our net sales; we rank twelfth with a market share of 3.5% (3.3% in 2013). Sales in the U.S. were up 8.7% at constant exchange rates in 2014.

Western Europe represents 23.3% of our net sales; we are the leading pharmaceutical company in France where our market share is 8.3% (8.7% in 2013), and we rank fourth in Germany with a 4.5% market share. In 2014, sales in Western Europe were stable at constant exchange rates.

Other countries represent 9.5% of our net sales; our market share in Japan is 3.2% (3.3% in 2013). Full-year 2014 net sales in Japan were down 8.6% at constant exchange rates.

A breakdown of our sales by geographical region is presented in "Item 5. Operating and Financial Review and Prospects Results of Operations Year Ended December 31, 2014 Compared with Year Ended December 31, 2103."

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, renal, and biosurgery products are also sold directly to physicians. With the exception of CHC products, these drugs are ordinarily dispensed to patients by pharmacies upon

presentation of a doctor's prescription.

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We use a selection of channels 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 mature products, as they provide the foundation for satisfying major therapeutic needs. 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 we sometimes use new media channels (such as the internet) to market our products. National education and prevention campaigns can be used to improve patients' knowledge of conditions.

Our sales representatives, who work closely with healthcare professionals, use their expertise to promote and provide information on our drugs. They represent our values on a day-to-day basis and are required to adhere to a code of ethics and to internal policies in which they receive training. As of December 31, 2014, we had a global sales force of 34,118 representatives: 8,191 in Europe (including 3,664 in Eastern Europe), 4,406 in the United States, and 21,521 in the rest of the world (including 6,152 in China).

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 either 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. Innovative drugs, a broad product range, and a presence in all geographical markets are key factors in maintaining a strong competitive position.

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

- competition between pharmaceutical companies to research and develop new patented products or new therapeutic indications;
- 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 at 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 and Merck in diabetes; Eli Lilly in diabetes and oncology; Bristol-Myers Squibb in oncology; GlaxoSmithKline in thrombosis and oncology; Novartis in diabetes, multiple sclerosis, thrombosis and oncology; Shire in rare diseases and renal; Pfizer in rare diseases and oncology; Biogen Idec, Teva and Merck Serono in multiple sclerosis; Bayer in multiple sclerosis and thrombosis prevention; Roche in oncology; Johnson & Johnson in oncology and thrombosis prevention; AstraZeneca in cardiovascular diseases and oncology; Boehringer-Ingelheim in diabetes and thrombosis; and Fresenius Medical Care in renal diseases.

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Based on 2014 sales Sanofi was the third-largest player in the global OTC market and competes with multinational corporations such as Johnson & Johnson, Bayer, Pfizer, Novartis, and GlaxoSmithKline as well as local players, especially in emerging markets.

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

In our Human Vaccines business, we compete primarily with multinational players backed by large healthcare groups, especially Merck (outside Europe) and GlaxoSmithKline. In specific market segments, Sanofi Pasteur competes with mid-size international players (such as CSL of Australia in the influenza market for the Southern Hemisphere). Sanofi Pasteur also competes with an increasing number of manufacturers entrenched in densely populated and economically emerging regions that are leveraging their cost/volume advantage and raising their level of technical capability and quality standards to compete with more sophisticated antigens in their domestic markets and increasingly in international donor markets. Multinational players are increasingly seeking alliances with manufacturers from emerging economies to secure positions in their markets of origin. Finally, there are emerging vaccine manufacturers in middle income countries, where privately owned companies in various industry sectors are investing in me-too vaccine production. Overall, there is increasingly intense competition for existing vaccines across the middle to low income segments.

In the Animal Health field, Sanofi is in competition mainly with major international groups such as Zoetis, Merck and Elanco/Novartis in both the production animal and companion animal segments; with Boehringer Ingelheim for production animals and for vaccines; with Elanco/Novartis and Bayer for companion animals and in particular for parasiticides; and with Virbac, Ceva and Vetoquinol, French companies with a global presence, for pharmaceutical products and vaccines.

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 " 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.

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 European Union, 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

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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 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 recent years, efforts have been made by members of the ICH (International Conference on Harmonization) on harmonization of product development and regulatory submission requirements. The ICH consists of the regulatory agencies of the three founding members (the European Union, Japan, and the United States), plus Health Canada and Swissmedic as observers/steering committee members. An example of these efforts is the Common Technical Document (CTD), which is a format used for product applications in ICH, with local or regional adaptation.

In 2014, the ICH Steering Committee continued its discussions on its reform on increased engagement and implementation of guidelines globally, increased transparency, and reviewed future ICH topics. Organizational reform measures are planned to foster international cooperation and a new funding model is currently being developed.

In June 2014, the ICH Steering Committee realized the first step of its ongoing structural reform by decision with immediate effect to include Swissmedic, the Swiss Agency for Therapeutic Products and the Canadian Health Authority, Health Canada as ICH members in recognition of their years of collaboration.

Emerging markets countries are starting to participate in ICH standardization discussions, and will be more involved in the near future. ICH has expanded beyond its initial members and observers with the 1999 formation of the Global Cooperation Group (GCG), which was formed as a subcommittee of the ICH Steering Committee in response to a growing interest in ICH Guidelines beyond the three ICH regions. Recognizing the need to engage actively with other harmonization initiatives, representatives from five Regional Harmonization Initiatives (RHIs) were invited to participate in GCG discussions: APEC, ASEAN, EAC, GCC, PANDRH and SADC. A further expansion of the GCG was agreed in 2007 and regulators were invited from countries with a history of ICH Guideline implementation and/or where major production and clinical research are carried out (Australia, Brazil, China, Chinese Taipei, India, Republic of Korea, Russia and Singapore).

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 United States and the European Union.

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 requirement of many countries, including Japan and several member states of the European Union, 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 European Union have been largely centralized with the EMA, pricing and reimbursement remain a matter of national competence.

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In the European Union, 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., works in the same way 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 European Union 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 2014, the EMA recommended 82 medicines for human use, virtually the same as in 2013 (81). Among them, 17 (18%) are intended for the treatment of rare diseases, (versus 11 in 2013), providing therapies for patients who often have only few or no treatment options. These include Cerdelga® (by Genzyme), a first line oral therapy for certain adults living with type 1 Gaucher disease. Seven positive opinions were granted after an accelerated assessment in 2014, versus one in 2013. This mechanism aims to speed up the assessment of medicines that are expected to be of major benefit for public health.

EMA provided more scientific support in the early stages of medicine development. Almost seven out of ten applicants received scientific advice from EMA's CHMP (only half of applicants in 2013).

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 benefit to risk 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 2010, new legislation aimed at improving patient protection by strengthening the E.U. system for the safety monitoring of medicines was approved. 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.

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This committee is also responsible for the design and evaluation of post-authorization safety studies (PASS) and pharmacovigilance audits.

In Europe, the PRAC has performed reviews of marketed products (by class or on *ad hoc* basis) through various procedures. 98 Sanofi products underwent PRAC review through signal and referral procedures from July 2012 to December 2014, generating 44 labeling variations (up to December 2014; 4 additional variations are ongoing). In only 2 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 October 2012 by Regulation (EU) No 1027/2012 (applicable since June 5, 2013 to centrally authorized medicines) and Directive 2012/26/EU (applicable since October 28, 2013 to nationally authorized medicines). 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 post-authorization safety studies (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 RMP (Risk Management Plan) or following a Health Authority request.

The Pharmacovigilance legislation also introduced a periodic safety report to be prepared by the 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.

Various information systems are in place to enhance pharmacovigilance, particularly to support the collection, management and analysis of data, information and knowledge. 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.

In March 2014, the EMA published the first summary for the public of the risk-management plan (RMP) of a newly authorized medicine, describing what is known and not known about the medicine's safety and states what measures will be taken to prevent or minimize its risks.

The database of medicinal products (Article 57) aims to deliver structured and quality assured information on medicinal products authorized in the EU. By December 31, 2014, MAHs (Marketing Authorization Holders) are required to complete previously submitted product data with additional information and from January 2015 onwards, industry is required to keep the structured information on medicines up-to-date and notify the EMA of any variation to the terms of the Marketing Authorization.

On October 6, 2014, the expansion of the public website maintained by the EMA allows the European citizens to obtain information on suspected side effects of an additional 1,700 active substances contained in medicines approved in the EU. This website launched in 2012 previously only contained information on suspected side effects reported with the centrally authorized medicines.

The PAES delegated regulation ((EU) 357/2014) was adopted in February 2014, and came into force in May 2014; it is intended to specify the situations in which PAES may be required.

The Regulation ((EU) 658/2014) of the European Parliament and of the Council of May 15, 2014 on fees payable to the EMA for the conduct of pharmacovigilance activities in respect of medicinal products for human use was published in the Official Journal of the EU on June 27, 2014. It is applicable only for companies involved in PSURs, PASSs and pharmacovigilance-related referral procedures (procedure-based fee) from August 26, 2014, and from July 2015 for annual fees applicable to nationally authorized products only.

In the United States, 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

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commercialize a product in the U.S., a New Drug Application (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 length of time and cost required for development of generics can be considerably less than for the originator's drug. With effect from October 1, 2012, under the Food and Drug Administration Safety and Innovation Act (FDASIA) and the Generic Drug User Fee Amendments (GDUFA), an application for a generic drug product requires a user fee payment. The ANDA pathway in the United States can only be used for generics of drugs approved under the FD&C Act.

FDA's Center for Drug Evaluation and Research approved 41 new molecular entities / therapeutic biologics in 2014 (versus 27 in 2013 and 39 in 2012). In 2014, nine new Breakthrough Therapy designated products were approved. In November 2014, Sanofi/Regeneron's investigative product dupilumab was granted breakthrough therapy designation by the FDA for the treatment of adults with moderate-to-severe atopic dermatitis who are not adequately controlled with topical prescription therapy and/or for whom these treatments are not appropriate. The designation is based on positive results from Phase I and II clinical trials.

In Japan, regulatory authorities can require local development studies, though they also accept multi-national studies. They can also request bridging studies 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 European Union and the United States. In order to solve this drug-lag problem, the MHLW (Ministry of Health, Labor and Welfare) introduced the new NHI (National Health Insurance) 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 with off-label indications for high medical needs. The pharmaceutical companies concerned are required to conduct submission based on available documentation within six months or file a clinical trial notification for registration within one year after the official development request of 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.

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 revised Pharmaceutical Affairs Law was enacted on November 27, 2013. 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).

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Consequently, the PMDA can accelerate the review of innovative medical devices. The third objective is accelerated commercialization of regenerative medicinal products.

The term "Regenerative Medicinal Products" used in the law includes cellular and tissue-based products and gene therapies. This concept is similar to "Advanced Therapy Medicinal Products (ATMPs)" in the 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 European Union, 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 low molecular weight heparins (LMWH). Starting in 2011 and continuing in 2014, the CHMP initiated a revision of the majority of the existing biosimilar guidelines (general over-arching guidelines, quality, non-clinical and clinical product specific guidelines).

At the end of October 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 in vivo non-clinical studies. This new concept is expected to facilitate the global development of biosimilars and to avoid unnecessary repetition of clinical trials. This revised guideline will come into force as of April 30, 2015. However, applicants can apply some or all provisions of this guideline with immediate effect.

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.

As of January 15, 2015, four 351k applications have been publicly disclosed.

To date, the FDA has published for consultation six draft guidance documents concerned with biosimilar development and approval. All six of these guidance documents remain in draft format. Guidance on naming 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 CMC (Chemistry, Manufacturing

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and Control) 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 decreased (sixteen in 2013, eight in 2014). Most of the generics applications for chemical entities use mutual recognition and decentralized procedures, with about 8% of the procedures relating to non-prescription products. Pricing systems for generics remain at national level in the E.U.

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 user fee program (GDUFA) 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 United Kingdom

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 by 2.0% in the first NHI price revision, by 1.75% if the substitution rate is 20% or higher but less than 40%, and by 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, while a 50% rule will be applied to oral first generics once more than ten with the same ingredients have obtained listing.

In addition, a 10% "precursor premium" will be introduced for new drugs with new mechanisms of action that obtain approval in Japan ahead of the rest of the world if they receive either the premium for innovativeness or the premium for usefulness.

B.6.3.4 Medical Devices

E.U.

Currently in the European Union, 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.

On September 26, 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 position of the European Parliament Committee on the Environment, Public Health and Food Safety (ENVI) was ratified by the full European Parliament on October 22, 2013. With these votes, members of the European Parliament endorsed 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

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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 recycling of single use medical devices is still under discussion.

The new 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.

U.S.

FDA's 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 European Union, one product has had a prescription-to-OTC switch approved through the centralized procedure since May, 2009.

In the U.S., FDA approved two prescription-to-OTC switches in 2014.

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 post-marketing 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.

B.6.3.6 Transparency and public access to documents

Transparency regarding clinical trials

Over the last two to three 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.

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European Union 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.

At the start of October 2014, the EMA adopted the policy 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 submitted after that date. Data will only start to become accessible once the final decision on a given procedure has been reached by the European Commission (timeframe of about 18 months).

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.

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.

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, non-prescription 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

E.U.

Regarding transparency for Health Care Professionals (HCP), there is no common harmonized approach in the E.U. 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 United Kingdom, Denmark, France, or Portugal).

The 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.

U.S.

The Physician Payments Sunshine Act, or "Sunshine Act", 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. The Sunshine Act requires manufacturers of pharmaceutical drugs and devices, as well as group purchasing organizations, to report payments or transfers of value (such as meals, honoraria, or travel reimbursements) made to U.S. physicians and teaching hospitals. 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.

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Manufacturers 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.

B.6.3.7 Other new legislation proposed or pending implementation

Clinical trials regulation in Europe

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 EU on May 28, 2014.

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

The legislation 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 do checks. 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.

Application of the regulation is subject to the E.U. portal and E.U. database, currenlty under development by the EMA, achieving full functionality. In any event, the Regulation will apply no earlier than May 28 2016.

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.

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 Licensing (AL) / Adaptive pathways Europe pilot project

The name of this concept has been changed from "adaptive licensing" to "adaptive pathways" to reflect the fact that this approach does not refer to a new procedure for the authorization of medicines but to the use of existing pathways to bring new medicines to patients.

AL is a new approach to licensing medicines in the form of a "soft" regulatory pathway. Starting in March 2014, AL 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.

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AL 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).

Falsified medicines

The European Union 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 good manufacturing practice (GMP) standards or standards at least equivalent to GMP. The manufacturing standards in the E.U. for active substances are those of the "International Conference for Harmonization" 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.

In 2014, several implementing measures for the Falsified Medicines Directive were adopted: the establishment of a common EU logo for online pharmacies was adopted in June 2014; the principles and guidelines for good manufacturing practice (GMP) for active substances were published in the Official Journal of the E.U. in November 2014 and will apply from May 15, 2015; the detailed rules for a unique identifier had to be adopted by end 2014 at the earliest.

No shortages of medicines from innovator or generic companies associated with the Falsified Medicines Directive have been identified, largely due to measures taken by companies to avoid importation problems.

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 10th Conference of the Parties of the Convention on Biological Diversity (CBD) on October 29, 2010 and subsequently signed by 92 countries. 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

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 on June 9, 2014 and has been applicable since the Nagoya Protocol itself came into force for the European Union, on October 12, 2014.

Currently, the Commission services are in the process of developing and implementing legislation further to Regulation ((EU) No 511/2014). It will relate to the register of collections, best practices as well as monitoring of user compliance (Articles 5, 7 and 8 of the EU ABS Regulation). This implementing act is expected to come into force in 2015.

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.

NDA electronic clinical trial data submission

In Japan, the PMDA intends to require pharmaceutical companies to submit clinical trial data for their NDAs in electronic formats, beginning 2016 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 would run through 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.

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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 makers will be required to file nonclinical toxicity study data in one of the SEND (Standard for the Exchange on Non-clinical Data) formats in due course.

In the European Union, 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, followed by the eSubmission web client, launched in January 2013. From March 2014, the use of the eSubmission Gateway or web client became mandatory for all eCTD submissions through the centralized procedure, order to improve efficiency and decrease costs for applicants.

Ebola FDA priority review U.S.

Adding Ebola to the FDA Priority Review Voucher Program Act was signed in to law December 16, 2014. It amends the FD&C Act to add filoviruses, a family of viruses that includes the Ebola virus, to the list of tropical diseases under the priority review voucher program, which awards vouchers to sponsors of human drug applications that are approved to prevent or treat tropical diseases. The law also allows priority review vouchers to be transferred between sponsors of human drug applications any number of times and reduces from 365 days to 90 days the advance notice required before submitting a human drug

Sanofi and its member companies are developing products, such as Dengue Vaccine, that would qualify for the tropical disease priority review voucher program. These vouchers would allow us to request priority review for other products in our pipeline that might otherwise receive a standard review, thus saving four months of review time by the FDA.

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

Significant recent events and trends:

In the United States, mandatory health insurance has begun (January 1, 2014). The positive effects of this on the size of the market should begin to appear over the coming years. Enrolment for 2015 is expected to be encouraged by the increase in the fee for not having healthcare coverage to 2% of household income (or $325 per person, whichever is higher, with exemptions).

In Europe, the financial crisis of recent years seems to have stabilised. 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 industrialisation programmes, is a prevalent theme in many emerging markets, notable examples being Russia and Brazil.

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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 United States (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 affords 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 2014, an EPO patent application may cover the 38 European Patent Convention member states, including all 28 member states of the European Union. 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

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13 Member States including France, Germany, and the United Kingdom. As of the date of this document only 6 countries including France have ratified.

The Unitary Patent will provide a unitary protection within the participating states of the European Union (when ratified by the member states with the exception of Italy and 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 brands". 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 (e.g. Lantus®) 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 European Union and the United States, 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 United States, 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 United States, 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 European Union, regulatory exclusivity is available in two forms: data exclusivity and marketing exclusivity. Generic drug applications will not be accepted for review until eight years after the first marketing authorization (data exclusivity). This eight-year period is followed by a two-year period during which generics cannot be marketed (marketing exclusivity). The marketing exclusivity period can be extended to three years if, during the first eight-year period, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which are deemed to provide a significant clinical benefit over existing therapies. This is known as the "8+2+1" rule.

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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 the Group's business exposes us to increased risks in specific areas".

Pediatric Extension

In the United States and Europe, 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 United States, 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 8 to 10 years.

Orphan Drug Exclusivity

Orphan drug exclusivity may be granted in the United States 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 European Union 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

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focus on active ingredient patents (compound patents) and 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. 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 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 (*e.g.*, patents claiming industrial processes). In each case below, we specify whether the active ingredient is claimed by an unexpired patent. Where patent terms have been extended to compensate for 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 to the FDA's Orange Book dates for Lantus®. 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 European Union. Specific situations may vary by country, most notably with respect to older patents and to countries having only recently joined the European Union.

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

Afrezza® (human insulin)

U.S.	**E.U.**	**Japan**
Compound: N/A Later filed patents: coverage ranging through 2031 Regulatory exclusivity: June 2017	Compound: N/A Later filed patent: 2030 (still pending) Regulatory exclusivity: Not yet approved in E.U.	Compound: N/A Later filed patent: 2030 (still pending) Regulatory exclusivity: Not yet approved in Japan

Aldurazyme® (laronidase)

U.S.	**E.U.**	**Japan**
Compound: November 2019 Later filed patents: June 2020 Regulatory Exclusivity: April 2015	Compound: November 2020 in some EU countries only	Compound: November 2020 Orphan Regulatory exclusivity: October 2016

Allegra® (fexofenadine hydrochloride)

U.S.	**E.U.**	**Japan[(1)]**
Compound: expired Generics on the market Converted to Over-the-Counter	Compound: expired Generics on the market	Compound: expired Generics on the market Converted to over-the counter

(1)

See "Item 8 A. Consolidated Financial Statements and Other Financial Information Information on Legal or Arbitration Proceedings Patents Allegra® Patent Litigation" of this annual report for further information.

Amaryl® (glimepiride)

U.S.	**E.U.**	**Japan**
Compound: expired	Compound: expired	Compound: expired

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Apidra® (insulin glulisine)

U.S.	**E.U.**	**Japan**
Compound: June 2018	Compound: September 2019 in most of the EU	Compound: May 2022
Later filed patents: ranging through January 2023	Later filed patent: March 2022	Later filed patent: July 2022
	Regulatory exclusivity: September 2014	Regulatory exclusivity: April 2017

Aprovel® (irbesartan)

U.S.	**E.U.**	**Japan**
Compound: expired	Compound: expired	Compound: March 2016
Generics on the market	Generics on the market	Regulatory exclusivity: April 2016

Aubagio® (teriflunomide)

U.S.	**E.U.**	**Japan**
Compound: expired	Compound: expired	Compound: expired
Later filed patents: coverage ranging through September 2030	Later filed patent: coverage ranging through September 2030	Later filed patent: coverage ranging through March 2024
Regulatory Exclusivity: September 2017	Regulatory exclusivity: August 2023	

Cerezyme® (imiglucerase)

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

Depakine® (sodium valproate)

U.S.	**E.U.**	**Japan**
Compound: N/A[(1)]	Compound: N/A[(1)]	Compound: N/A[(1)]
	Later filed patent: Depakine® Chronosphere formulation (October 2017)	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.	**E.U.**	**Japan**
Compound: N/A	Compound: N/A	Compound: N/A
Later filed patents: coverage ranging through September 2015		Later filed patents: expired
Biologics Regulatory Exclusivity: April 2015		Orphan regulatory exclusivity: expired

Insuman® (human insulin)

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

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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 EU countries	Later filed patents: coverage ranging through October 2030
Regulatory exclusivity: June 2015	Regulatory exclusivity: March 2021	Regulatory exclusivity: July 2022

Lantus® (insulin glargine)

U.S.	E.U.	Japan
Compound: expired[(1)]	Compound: original expiry date of SPCs in November 2014 in most of Western Europe extended until May 2015 by Pediatric Extensions	Compound: expired

(1) *Patent infringement suits were filed by Sanofi against Eli Lilly in the United States. 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.*

Lemtrada® (alemtuzumab)

U.S.	E.U.	Japan
Compound: December 2015	Compound: expired	Compound: expired
Regulatory Exclusivity: N/A		
Later filed patents: coverage ranging through September 2027 (pending)	Later filed patent: September 2027 (pending)	Later filed patent: September 2027 (pending)

Lovenox® (enoxaparin sodium)

U.S.	E.U.	Japan
Compound: none	Compound: expired	Compound: expired
Generics on the market		Regulatory exclusivity: January 2016

Lumizyme® / Myozyme® (alglucosidase alpha)

U.S.	E.U.	Japan
Compound: N/A	Compound: N/A	Compound: N/A
Later filed patents: coverage ranging through February 2023	Later filed patents: coverage ranging from March 2021 to May 2023	Later filed patents: July 2021
Orphan Drug Exclusivity: expired	Orphan Regulatory Exclusivity: March 2016	Orphan Regulatory Exclusivity: April 2017
Biologics Regulatory Exclusivity: April 2018	Biologics Regulatory Exclusivity: March 2016	

Lyxumia® (lixisenatide)

U.S.	E.U.	Japan
Compound: July 2020	Compound: July 2020	Compound: July 2020
	SPC coverage to July 2025 in most of Western Europe	PTE coverage to July 2024
	Regulatory Exclusivity: February 2023	Regulatory Exclusivity: June 2021

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Mozobil® (plerixafor)

U.S.	E.U.	Japan
Compound: N/A Later filed patents: coverage ranging through July 2023 Orphan Drug Exclusivity: December 2015	Compound: N/A Later filed patents: July 2022, with SPC coverage through July 2024, granted in some EU countries. Orphan Drug Exclusivity: August 2019	Compound: N/A Later filed patents: July 2022

Multaq® (dronedarone hydrochloride)

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

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

Renagel® (sevelamer hydrochloride)

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

Renvela® (sevelamer carbonate)

U.S.	E.U.	Japan
Compound: N/A Later filed patent: October 2025	Compound: N/A Later filed patent October 2025	Compound: N/A Later filed patent: October 2026

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

Synvisc-One® (hyaline G-F 20)

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

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Toujeo® (insulin glargine)

U.S.	**E.U.**	**Japan**
Compound: expired	Compound: May 2015 with SPC and Pediatric Extensions	Compound: expired
Later filed patents: coverage ranging through April 2034 (applications pending)	Later filed patents: coverage ranging through April 2034 (applications pending)	Later filed patents: coverage ranging through April 2034 (applications pending)
Regulatory exclusivity: February 2018		

Zaltrap® (aflibercept)

U.S.	**E.U.**	**Japan**
Compound: May 2020 (July 2022 if PTE is granted)	Compound: May 2020 (May 2025 if SPC granted)	Compound: May 2020
Biologics Regulatory Exclusivity: November 2023	Regulatory Exclusivity: November 2022	

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 United States (prior to the product being switched to over-the-counter status) and Plavix® in Europe.

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 United States, 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.

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

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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 United States

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 European Union, 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 trademark

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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 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 active pharmaceutical 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 minimize 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 are 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 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, Valeant 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, Sanofi's dedicated animal health division.

Merial markets pharmaceutical products Frontline®, Heartgard®, NexGard® and Previcox® (pets), Ivomec®, Eprinex® (large animals) and Gastrogard® (equine) and a broad range of vaccines Vaxxitek® (avian), FMD vaccine (large animals), Circovac® (swine) and Purevax® (pets). Some pharmaceutical products are subcontracted (in particular Eprinex®) but almost all veterinary vaccines are manufactured at Merial's own plants. Merial's dedicated animal health industrial operations cover all activities, from the purchase of raw materials through to the delivery of the finished product, meeting customer needs through a reliable and flexible offering that meets quality expectations. There are 18 production sites spread across nine countries.

All of our pharmaceutical and vaccine facilities are good manufacturing practice (GMP) compliant, in line with international guidelines. Our principal sites are approved by the FDA.

This applies to our pharmaceutical facilities in France (Ambarès, Tours, Le Trait, Maisons Alfort, Compiègne and Lyon); in the United Kingdom (Haverhill and Holmes Chapel); in Ireland (Waterford); in Germany (Frankfurt); in Hungary (Veresegyhaz); in Italy (Anagni); and in the United States (Saint Louis and Chattanooga). The Genzyme

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facilities in the United States (Allston, Framingham, Ridgefield, Northpointe-Lynnwood, Woburn and Northborough) and in Europe (Geel, Belgium) are all FDA approved.

Our Vaccines sites with FDA approval are Marcy l'Étoile and Le Trait (Fluzone® ID USA) in France; Swiftwater, Canton and Rockville in the United States; and Toronto in Canada.

Our Animal Health facilities in Athens, Worthington, Gainesville, Raleigh and Barceloneta (acquired in December 2014) in the United States 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 any 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. A modification to the remediation workplan was accepted by the FDA in March 2012. The workplan is expected to be completed in 2016. It includes a timetable of specified milestones. If the milestones are not met in accordance with the timetable, the FDA can require us to pay $15,000 per day, per affected drug, until these compliance milestones are met. Upon satisfying all compliance requirements in accordance with the terms of the consent decree, 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.

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. In 2014, Genzyme proposed a second modification to the workplan, which would alter the sequence in which some actions are performed without affecting the final completion date of the actions specified in the workplan as a whole. The FDA is reviewing that proposed modification. Genzyme has informed the FDA that the remaining actions specified in the workplan are progressing in line with the revised re-sequencing as proposed. If the FDA rejects Genzyme's proposal, Genzyme could be subject to liquidated damages, as described above, for failure to meet the deadlines specified in the version of the workplan that was accepted by the FDA.

In April 2014, the FDA withdrew the warning letter relating to the Sanofi Pasteur sites at Toronto (Canada) and Marcy l'Étoile (France) received in July 2012. Sanofi Pasteur is implementing an ongoing program designed to strengthen its production processes and tools, its systems and its quality culture, as well as its performance. Following the supply chain issues experienced in 2013, Sanofi Pasteur saw a gradual improvement in supplies of Pentacel® and Adacel® in the United States throughout 2014.

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 Ltd (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.

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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 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 and totaled approximately €86 million in 2014.

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The applicable environmental laws and regulations may require Sanofi to eradicate or reduce the effects of chemical substance usage and release at its 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. Under some of these laws and regulations, a current or previous owner or operator of a property may be held liable for the costs of removal or remediation of hazardous substances on, under or in its property, or transported from its property to third party sites, 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.

Moreover, as is the case for a number of companies involved in the pharmaceutical, chemical and 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 the Group'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, the Group 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; Frankfurt in Germany; Beaucaire, Valernes, Limay, Rousset, Romainville, Neuville, Vitry, Tours and Toulouse in France; Dagenham in the United Kingdom; Brindisi and Garessio in Italy; Ujpest in Hungary; Prague in the Czech Republic; 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.

Provisions have been established for the sites already identified and to cover contractual guarantees for environmental liabilities for sites that have been divested. For example, the Group is currently participating in an assessment process for natural resource damage liability (NRD) and in the allocation process for future remediation costs that are related to the past operations of a former Rhone-Poulenc site in Portland, Oregon. The Group retains the ultimate liability for these costs under contractual environmental guarantees granted at the time of Bayer's acquisition of the CropScience business. Potential environmental contingencies arising from certain business divestitures are described in Note D.22.e) to the consolidated financial statements included at Item 18 of this annual report. In 2014, Sanofi spent €58 million on rehabilitating sites previously contaminated by soil or groundwater pollution. In 2013, a comprehensive review was carried out relating to the legacy of environmental pollution. In light of data collected during this review, the Group adjusted the provisions to approximately €696 million as at December 31, 2014, versus €698 million as at December 31, 2013).

Due to changes in environmental regulations governing site remediation, the Group's provisions for remediation obligations may not be adequate given 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 of Aventis arising from its past involvement 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".

To our knowledge, the Group did not incur any liability in 2014 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. However, the Ocoyoacac Site was subject to an appeal by the Mexican authorities in 2014, leading to a ten-day production interruption for failure to comply with a required update of an environmental license.

Regular HSE audits (54 in 2014) 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, 14 specialized audits covering contractors (9) or biosafety (5) and 147 loss prevention technical visits were carried out by our teams in 2014.

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.

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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 classifies all chemical and pharmaceutical products handled within the Group and establishes workplace exposure limits for each of them. 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.

In addition, a committee has been set up to prepare and support the implementation of the new European Union REACH regulation on Registration, Evaluation, Authorization and Restriction of Chemicals. To fully comply with the new European regulation on the labeling of chemicals (Classification Labeling Packaging), 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 II (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

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annual implementation of HSE progress plans. In addition, 55 sites are currently ISO 14001 certified and 15 buildings are LEED certified either in U.S. and Europe. We believe that this strategy clearly expresses the commitment of both management and individuals to health, safety and the environment. In 2014, eight 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. In 2014, we reduced carbon dioxide emissions caused by our sales representation car fleet by 2.6% versus 2013 due to the policy of using energy efficient cars as well as a reduction in the number of cars. 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 13.5% 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.

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, 2014. 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 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 "Item 4A. History and Development of the Company"), 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 relating to Zaltrap® and human therapeutic

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antibodies (with Regeneron); Plavix® and Aprovel® (with BMS); and Actonel® (with Warner Chilcott, since acquired by Actavis). 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, Human Vaccines (Vaccines) and Animal Health.

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.

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 (United States);

Vaccines: Sanofi Pasteur (France) and Sanofi Pasteur, Inc. (United States);

Animal Health: Merial, Inc. (United States) and Merial S.A.S. (France).

For a description of our principal items of property, plant and equipment, see "Item 4.D. Property, Plant and Equipment". Our property, plant and equipment is held mainly by the following companies:

In France: Sanofi Pasteur S.A., Sanofi Chimie, Sanofi Winthrop Industrie, Sanofi, and Sanofi-Aventis Recherche & Développement;

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

In Germany: Sanofi-Aventis Deutschland GmbH;

In Belgium: Genzyme Flanders BVBA Holding Co.

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 87% of the Group's external financing and 81% of its surplus cash as of December 31, 2014.

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. Breakdowns are based on surface area. All surface area figures are unaudited.

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Breakdown of sites by use*

Industrial	60%
Research	13%
Offices	12%
Logistics	10%
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	31%
Owned	69%

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

The profound transformation of Sanofi and the increased importance of our growth platforms are driving ongoing change in our Industrial Affairs department in support of our new business model; since June 2013, the 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 biologics and injectables.

We carry out our industrial production at 107 sites in 40 countries (including 37 sites in emerging markets):

- 77 sites for our Pharmaceuticals activity, including Genzyme;
- 12 sites for the industrial operations of Sanofi Pasteur in vaccines; and
- 18 sites for the Animal Health activities of Merial.

In 2014, we produced the following quantities:

Pharmaceuticals:

Units manufactured and packaged: 3,503 million

Bulk products in unit equivalents: 413 million

Total: 3,916 million

Vaccines: 468 million filled containers (including outsourced production)

Animal Health: 571 million doses of vaccines for all species other than avian, 88 billion doses of avian vaccines, and 76 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 standards 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 "B.8 Production and Raw Materials."

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).

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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 (ClickSTAR® and SoloSTAR®));

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 6 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®, Myozyme®, Thyrogen®), Framingham Biosurgery (Seprafilm®, hyaluronic acid), Ridgefield (Synvisc®, Hectorol®, Mozobil®, Jonexa®, Kynamro®), Woburn (LeGoo®), and Lynnwood, Washington (Leukine®).

Industrial Sites: Vaccines (Sanofi Pasteur)

The headquarters of our Vaccines division, Sanofi Pasteur, is located in Lyon, France. Sanofi Pasteur has production and/or R&D sites at Swiftwater, Cambridge, Rockville, Canton and Orlando (United States); Toronto, (Canada); Marcy l'Étoile, Neuville and Val de Reuil (France); Shenzhen (China); Pilar (Argentina); Chachoengsao (Thailand); Hyderabad (India); and Ocoyoacac (Mexico).

In May 2009, we began construction of a new vaccine manufacturing center at our Neuville-sur-Saône site in France. This €300 million investment over the 2009-2011 period, the largest ever made by Sanofi, was intended to gradually replace the chemicals activity on the site (which was discontinued at the end of 2013) by vaccine production from 2014 onwards. In 2014, Neuville was approved by ANSM (the French national agency for the safety of medicines and healthcare products) for the production of dengue vaccine.

Also in 2014, the new influenza vaccine production facility at Shenzhen (China) successfully completed its first influenza campaign, while the facility at Ocoyoacac (Mexico) also dedicated to the manufacturing of influenza vaccine doubled its production capacity. Finally, the Shantha site at Hyderabad (India) started commercial production in 2014 of the Shan5 pediatric combination vaccine, having obtained prequalification from the World Health Organization (WHO) and approval from the Indian regulatory authorities.

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

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Industrial Sites: Animal Health (Merial)

Merial has 18 industrial sites in nine different countries and numerous administrative offices including its headquarters at Lyon, France.

Merial 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®;

China: Nanchang (live avian vaccines) and Nanjing (inactivated avian vaccines);

France: Toulouse (Frontline® and clostridial vaccines), Saint-Priest LPA (vaccines), Lyon Gerland, Saint-Herblon (Coophavet), Lentilly (packaging);

Italy: Noventa (inactivated avian vaccines);

Netherlands: Lelystad (antigen against foot-and-mouth disease);

Uruguay: Montevideo (primarily anti-clostridium antigens);

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 bovine and swine vaccines at Worthington (Minnesota), and a dedicated site at Barceloneta (Puerto Rico) for production and packaging of Heartgard® and Heartgard® plus; and

New Zealand: Ancare facility, Auckland (pharmaceutical products, mainly for the bovine market).

Research & Development sites

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

6 operational sites in France: Chilly/Longjumeau, Montpellier, Paris, Strasbourg, Toulouse and Vitry/Alfortville;

2 sites in the rest of Europe (Germany and the Netherlands), the larger of which is in Frankfurt (Germany);

5 sites in the United States, the largest being the Bridgewater, Cambridge and Framingham sites; and

2 sites in Asia (1 clinical research unit in Beijing, China and 1 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, Barceloneta 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, 2014 was €10,396 million. During 2014, we invested €1,093 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 capital expenditures and divestitures in 2012, 2013 and 2014 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, 2014, our firm commitments in respect of future capital expenditures amounted to €369 million. The principal locations involved were: for the Pharmaceuticals segment, the industrial facilities at Frankfurt (Germany), Framingham and Allston (United States), Mumbai (India); 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 €1.3 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.

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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 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 Sanofi **Diabetes** industrial network has a solid base in emerging markets, both in Russia with the Orel site (which is 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 Frankfurt site has begun transferring a number of technologies for manufacturing Insuman® insulin to the Indian site so that it can handle filling and packaging, initially for the local market and later for other emerging markets.

Our industrial pharmaceutical operations for the **Consumer Health Care** (CHC) platform are based on a network of 10 facilities. Of these, the facilities in Lisieux (France), and the factories producing Doliprane® at Hangzhou and Tangshan (China) and Virginia (Australia), serve local markets. Regional markets are served by our facilities at Suzano (Brazil) and Rzeszow (Poland), and by the Chattem facility in Tennessee (United States), while global markets are served by our facilities at Origgio (Italy), Cologne (Germany) and Veresegyház (Hungary). In addition to a new site under development in Vietnam and the strategy of developing a specialized CHC industrial network, we have recently incurred expenditures to support major projects such as the migration of a number of CHC products from other plants to the CHC network, the transfer of some few liquid and effervescent forms to our Cologne site, and the transformation of the Origgio site into a facility dedicated to a single product family.

In the **Other Innovative Products** platform, our industrial teams are pooling their expertise to develop ever more sophisticated processes. Three dedicated biotech hubs are being developed in Europe at Frankfurt (Germany); Vitry-sur-Seine (France), our biggest integrated cell culture facility, which in 2013 completed a production campaign of aflibercept (the active ingredient of Zaltrap®) as well as launching production of a new product; and Lyon Gerland (France), a new world center dedicated to production of Thymoglobulin® for the prevention and treatment of transplant rejection.

In March 2014, a platform dedicated to biological products was launched to develop synergies between our Pharmaceuticals activities, Sanofi Pasteur, Genzyme and our Biotherapeutics activities. This platform will enable us to build our presence in biotechnologies by adopting a cross-disciplinary approach to a range of issues such as production capacity utilization, development, biotechnologies of the future, and skills management.

The development of our **Emerging Markets** platform is built on a network of over 35 regional and local industrial sites in 20 countries, supporting growth in those markets.

In the Middle East, we inaugurated our new facility in King Abdullah Economic City (KAEC) in December 2014, with locally-manufactured products due to reach the market from 2015. At Sidi Abdellah in Algeria we are building what 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 will be integrated into our industrial network. The main products manufactured there are anti-infective, cardiovascular and gastro-intestinal drugs.

In Vietnam, we completed construction of our new facility in Ho Chi Minh City, which from 2015 will manufacture specialty pharmaceuticals and CHC products and will help support the launch of Lactacyd® in Japan.

Our Industrial Affairs department is constantly adapting the network of industrial sites to market needs, as a result of which a number of sites have been or are in the process of being sold or closed, such as Quetigny (France) and Fawdon (United Kingdom) in 2015, and Kansas City (United States) in 2016.

The industrial network of the **Genzyme** growth platform 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, approved by the FDA in January 2012. In addition, the Framingham Biologics site is building a new factory to increase purification capacity for production of Fabrazyme® representing an investment of $83 million.

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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. In September 2014, Sanofi Pasteur celebrated 40 years at the Val-de-Reuil industrial site in France, and inaugurated a new yellow fever vaccine production facility. This facility, representing an investment of €25 million, will double production capacity for the vaccine, helping to meet the needs of endemic regions.

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 $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. 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 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 2014, Sanofi highlighted industrial innovation in industrial sites by organizing its sixth 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.

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 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 on completion of phase 1, and three by 2015). All of these sites will meet environmental certification standards, and offer cost-effective space solutions.

In this context, the new "Campus Sanofi Val de Bièvre" (CSVB) was built on the old site (Gentilly Val De Bièvre) and completed in early March 2015.

Group support functions and operational divisions were brought together under one roof at the new world headquarters in the business district of Paris (54 rue La Boétie, 8th arrondissement) in February 2012. The headquarters, in which new work spaces have been developed, symbolizes the transformation of the Sanofi Group.

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 is due to be delivered at the end of March 2015 by its owner, Plastic Omnium. A second lease was signed in June 2014 on premises that from 2017 will house the corporate functions of Merial and Sanofi Pasteur; 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. This 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 work space consistent with the new Corporate Charter.

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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. Integrating the U.S. operations of Genzyme will provide opportunities for rationalizing office space use in the city.

Elsewhere in the world, a number of site optimization plans were completed in 2014, including the relocation to new premises of the regional office in Shanghai (China) at the start of the year, new Sanofi offices in Buenos Aires (Argentina), and the sale of freehold office premises at Mumbai (India) and land at Rueil Malmaison (France). Other projects are ongoing, such as construction of a new building to house our offices in Mumbai (India) and new office premises in Singapore.

Item 4.A. Unresolved Staff Comments

N/A

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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, 2014.

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 change figures in this item are given on a reported basis.

2014 Overview

During 2014, we continued to follow the strategic direction we set out in 2008, and to pursue our four key objectives: continuing to build a global healthcare leader with synergistic platforms, bringing innovative products to market, exploring value enhancing external growth opportunities, and adapting our structures to meet the opportunities and challenges of the future.

Having returned to growth in September 2013, our net sales were boosted by our growth platforms during 2014, despite more aggressive price competition in the U.S. diabetes market from the third quarter.

Our full-year net sales reached €33,770 million, 2.5% higher than in 2013 (4.9% at constant exchange rates, see definition at " Presentation of Net Sales" below), driven mainly by the performance of our Diabetes and Genzyme businesses and growth in Emerging Markets[(1)]. At the same time, the effects of generic competition eroded our net sales by €600 million (see " Impacts from generic competition" below). Products derived from our research efforts and launched during 2014 included Cerdelga® (Gaucher disease) and Lemtrada® (multiple sclerosis) in the United States for the Pharmaceuticals business and the Nexgard® anti-parasite treatment in the United States and Europe for the Animal Health business.

Business net income was €6,847 million, up 2.4% from 2013, while business earnings per share were 3.0% higher than in 2013 at €5.20. Net income attributable to equity holders of Sanofi reached €4,390 million, up 18.1% year-on-year, while earnings per share rose by 18.9% to €3.34. 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.

During 2014, we continued our policy of targeted acquisitions and of alliances in research and development. As a result of amendments made in January 2014 to the 2007 Investor Agreement between Sanofi and Regeneron Pharmaceuticals, Inc. (Regeneron), we increased our equity interest in Regeneron, which has been accounted for by the equity method since April 2014. As of December 31, 2014 we had an equity interest of 22.3% in Regeneron (see " Financial Presentation of Alliances Alliance arrangements with Regeneron Investor agreement" below). In genetic diseases, Genzyme and Alnylam Pharmaceuticals (Alnylam) extended their collaboration that began in 2012, with Genzyme becoming a major shareholder in Alnylam in 2014 with an equity interest of approximately 12%. We also entered into a worldwide collaboration agreement with MyoKardia, Inc. focusing on genetic cardiac diseases. In diabetes, we signed an exclusive global licensing agreement with MannKind Corporation for the development and commercialization of Afrezza®, a new fast-acting insulin inhaler for adults with type 1 and type 2 diabetes that was approved by the FDA in June 2014. In Consumer Health Care, we signed an agreement with Eli Lilly and Company with a view to securing regulatory approval in certain countries for over-the-counter Cialis® (tadalafil) for the treatment of male erectile dysfunction.

On October 29, 2014, our Board of Directors decided unanimously to remove Christopher A. Viehbacher from office as Chief Executive Officer of Sanofi. Serge Weinberg has since October 29, 2014, held the office of Chairman and Chief Executive Officer of Sanofi. On February 19, 2015, Sanofi announced that the Board of Directors had unanimously appointed Olivier Brandicourt as Chief Executive Officer of Sanofi as from April 2, 2015.

(1)

World excluding United States, Canada, Western Europe, Japan, Australia and New Zealand.

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As of December 31, 2014 our debt, net of cash and cash equivalents had risen to €7.2 billion, compared with €6.0 billion a year earlier. A dividend of €2.85 per share for the 2014 financial year, representing a payout of 54.8% of our business net income, will be submitted for approval by our shareholders at the Annual General Meeting on May 4, 2015.

Our operations generate significant cash flow. We recorded €7,690 million of net cash provided by operating activities in 2014 compared to €6,954 million in 2013. During 2014, we paid out €3,676 million in dividends. With respect to our financial position, we ended 2014 with our debt, net of cash and cash equivalents (see definition at " Liquidity and Capital Resources" below) at €7,171 million (2013: € 6,043 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 12.7% at the end of 2014 compared to 10.6% at the end of 2013. See " Liquidity and Capital Resources" below.

Impacts from generic competition

Some of our flagship products continued to experience sales erosion in 2014 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 for each product.

A comparison of our consolidated net sales for the years ended December 31, 2014 and 2013 (see " Results of Operations Year Ended December 31, 2014 Compared with Year Ended December 31, 2013") shows that in 2014, generic competition led to a loss of € 600 million of net sales on a reported basis. The table below sets forth the impact by product.

(€ million) **Product**	**2014 Reported**	**2013 Reported**	**Change on a reported basis**	**Change on a reported basis (%)**
Plavix® Western Europe	217	257	(40)	-15.6%
Aprovel® Western Europe	190	338	(148)	-43.8%
Renagel®/Renvela® U.S.	464	531	(67)	-12.6%
Lovenox® U.S.	130	187	(57)	-30.5%
Taxotere® U.S.	8	42	(34)	-81.0%
Ambien® U.S.	74	88	(14)	-15.9%
Allegra® Japan	178	280	(102)	-36.4%
Amaryl® Japan	54	81	(27)	-33.3%
Myslee® Japan	125	192	(67)	-34.9%
Taxotere® Japan	87	131	(44)	-33.6%
Total	**1,527**	**2,127**	**(600)**	**-28.2%**

We expect the erosion caused by generic competition to continue in 2015, with a negative impact on net income. Products susceptible to the effects of such competition in 2015 include:

those for which new generic competition can reasonably be expected in 2015 based on expiration dates, patents or other regulatory or commercial exclusivity: Lantus® and Renagel®/ Renvela® in Europe; and Plavix® in Japan;

those which already faced generic competition in 2014, but whose sales can reasonably be expected to be subject to further sales erosion in 2015: Plavix® and Aprovel® in Europe; Lovenox®, Ambien®, Taxotere® and Renagel®/ Renvela® in the United States; and Allegra®, Amaryl®, Myslee® and Taxotere® in Japan.

With respect to the particular case of Lantus® in the United States, a generic of Lantus® is not expected on the market before the expiration of the "30 month stay" in June 2016 or a court decision favorable to Eli Lilly before that date (See Item 8 "Information on Legal or Arbitration Proceedings Lantus® and Lantus Solostar® Patent Litigation"). As regards Europe, the patent covering Lantus® expired in most of Western Europe in November 2014 but benefits from a pediatric extension until May 2015.

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In 2014, the aggregate consolidated net sales of these products in countries where generic competition currently exists or is expected in 2015 were €3,290 million (€676 million in the United States, €1,411 million in Europe and €1,203 million in Japan). This 2014 figure includes Lantus® sales of €871 million and Renagel®/ Renvela® sales of €133 million in Western Europe, and Plavix® sales of €759 million in Japan. The negative impact on our 2014 net sales is liable to represent a substantial portion of this amount, but the actual impact will depend on a number of factors such as the actual launch dates of generic products in 2014, 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, 2014, 2013 and 2012 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 (€874 million in 2014, €1,199 million in 2013, and €1,489 million in 2012). The Genzyme business combination has given rise to significant amortization of intangible assets (€811 million in 2014, €930 million in 2013 and €976 million in 2012) and impairment of intangible assets (net reversal of €309 million in 2014, expenses of €665 million in 2013 and €25 million in 2012).

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, 2014, 2013 and 2012, 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, animal health products 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, vaccines and animal health products 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 overall level of sales of the products and on the arrangements governing those alliances. For more information about our alliances, see " Financial Presentation of Alliances" below. When we sell products 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 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 business 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 segments as "Pharmaceuticals", "Human Vaccines" (Vaccines) and "Animal Health". Our other identified segments are categorized as "Other".

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The Pharmaceuticals segment covers research, development, production and marketing of medicines, including activities acquired with Genzyme. Sanofi's 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 Pharmaceuticals, Inc. 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..

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 "Operating Segments"; it also includes the effects of retained commitments in respect of divested businesses.

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) 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
- a non-recurring adjustment (unrelated to segmental performance) is made for the annual Branded Prescription Drug Fee in the United States, recognized in 2014 following publication by the U.S. Internal Revenue Service in July 2014 of the final regulations on that fee.

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The following table (in accordance with IFRS 8) reconciles our Business Operating Income to our Income before tax and associates and joint ventures for the years ended December 31, 2014, 2013 and 2012:

(€ million)	**2014**	**2013(1)**	**2012(1)**
Business Operating Income	**9,449**	**9,323**	**11,446**
Share of profit/(loss) of associates and joint ventures[(2)]	(147)	(85)	(424)
Net income attributable to non-controlling interests[(3)]	127	162	172
Amortization of intangible assets	(2,482)	(2,914)	(3,291)
Impairment of intangible assets	26	(1,387)	(117)
Fair value remeasurement of contingent consideration liabilities	(303)	314	(192)
Expenses arising from the impact of acquisitions on inventories[(4)]		(8)	(23)
Restructuring costs	(411)	(300)	(1,141)
Other gains and losses and litigation			
Additional expense related to US Branded Prescription Drug Fee[(5)]	(116)		
Operating Income	**6,143**	**5,105**	**6,430**
Financial expense	(605)	(612)	(751)
Financial income	193	109	93
Income before tax and associates and joint ventures	**5,731**	**4,602**	**5,772**

(1) *Includes the impact of applying IFRIC 21 (see Note A.2.2. to our consolidated financial statements included at Item 18 of this annual report).*

(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.*

The following table presents our Business Operating Income for the year ended December 31, 2014.

(€ million)	**Pharmaceuticals**	**Vaccines**	**Animal Health**	**Other**	**Total**
Net sales	**27,720**	**3,974**	**2,076**		**33,770**
Other revenues	272	33	34		339
Cost of sales	(8,282)	(1,948)	(799)		(11,029)
Research and development expenses	(4,174)	(493)	(157)		(4,824)
Selling and general expenses	(7,692)	(614)	(682)	(3)	(8,991)
Other operating income and expenses	194	2	20	(52)	164
Share of profit/(loss) of associates and joint ventures	106	40	1		147
Net income attributable to non-controlling interests	(126)		(1)		(127)
Business operating income	**8,018**	**994**	**492**	**(55)**	**9,449**

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The following table presents our Business Operating Income for the year ended December 31, 2013[(1)].

(€ million)	**Pharmaceuticals**	**Vaccines**	**Animal Health**	**Other**	**Total**
Net sales	**27,250**	**3,716**	**1,985**		**32,951**
Other revenues	295	30	30		355
Cost of sales	(8,518)	(1,776)	(689)		(10,983)
Research and development expenses	(4,087)	(518)	(165)		(4,770)
Selling and general expenses	(7,362)	(588)	(653)		(8,603)
Other operating income and expenses	422	3	(1)	26	450
Share of profit/(loss) of associates and joint ventures	48	41	(4)		85
Net income attributable to non-controlling interests	(162)	1	(1)		(162)
Business operating income	**7,886**	**909**	**502**	**26**	**9,323**

(1) *Includes the impact of applying of IFRIC 21 (see Note A.2.2. to our consolidated financial statements included at Item 18 of this annual report).*

The following table presents our Business Operating Income for the year ended December 31, 2012[(1)].

(€ million)	**Pharmaceuticals**	**Vaccines**	**Animal Health**	**Other**	**Total**
Net sales	**28,871**	**3,897**	**2,179**		**34,947**
Other revenues	933	44	33		1,010
Cost of sales	(8,745)	(1,629)	(701)		(11,075)
Research and development expenses	(4,203)	(538)	(164)		(4,905)
Selling and general expenses	(7,652)	(609)	(669)	(1)	(8,931)
Other operating income and expenses	134	(7)	3	18	148
Share of profit/(loss) of associates and joint ventures	432	(1)	(7)		424
	(171)		(1)		(172)

Net income attributable to non-controlling interests					
Business operating income	**9,599**	**1,157**	**673**	**17**	**11,446**

(1) *Includes the impact of applying IFRIC 21 (see Note A.2.2. to our consolidated financial statements included at Item 18 of this annual report).*

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.

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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);
- fair value remeasurement of contingent consideration liabilities related to business acquisitions;
- other impacts associated with acquisitions (including impacts of acquisitions on associates and joint ventures);
- restructuring costs[(1)];
- other gains and losses (including gains and losses on disposals of non-current assets);
- costs of provisions associated with litigation;
- tax effects related to the items listed above as well as effects of major tax disputes;
- tax (3%) on dividends distributed to Sanofi shareholders;
- the share attributable to non-controlling interests related to the items listed above.

Additionally, the business net income was adjusted by the one-time additional expense, unrelated to segment performance and recorded in 2014 on the income statement line selling and general expenses, following the final US IRS regulation related to annual Branded Prescription Drug Fee issued in July 2014.

The following table reconciles our business net income to our Net income attributable to equity holders of Sanofi for the years ended December 31, 2014, 2013 and 2012:

(€ million)	**2014**	**2013(1)**	**2012(1)**
Business net income	**6,847**	**6,686**	**8,100**
Amortization of intangible assets	(2,482		