

Sanofi
Form 20-F
March 11, 2015

Use these links to rapidly review the document

[TABLE OF CONTENTS](#)

[Table of Contents](#)

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

FORM 20-F

**(Mark
One)**

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

or

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

For the fiscal year ended December 31, 2014

or

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

or

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

Date of event requiring this shell company report

**For the transition period from _____ to
Commission File Number: 001-31368**

Sanofi

(Exact name of registrant as specified in its charter)

N/A

(Translation of registrant's name into English)

France

(Jurisdiction of incorporation or organization)

54, Rue La Boétie, 75008 Paris, France

(Address of principal executive offices)

Karen Linehan, Executive Vice President Legal Affairs and General Counsel
54, Rue La Boétie, 75008 Paris, France. Fax: 011 + 33 1 53 77 43 03. Tel: 011 + 33 1 53 77 40 00
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

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

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

The number of outstanding shares of each of the issuer's classes of capital or common stock as of December 31, 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 NO

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

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

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

U.S. GAAP

International Financial Reporting Standards
as issued by
the International Accounting Standards
Board

Other

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

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

Table of Contents

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 Farmaceutici S.p.A.; Liberty®, Liberty® Herbicide, LibertyLink® Rice 601, LibertyLink® Rice 604 and StarLink® trademarks of Bayer; Maalox® a trademark of Novartis in the United States, Canada and Puerto Rico; and Sculptra® a trademark of Valeant; and,

other third party trademarks such as Advantage® and Advantix® trademarks of Bayer; Atelvia® trademark of Actavis in the United States; DDAVP® a trademark of Ferring (except in the United States where it is a trademark of the Group); Enbrel® a trademark of Immunex in the United States and of Wyeth on other geographical areas; GLAAS® a trademark of Immune Design; Humalog®, Humulin® 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 Israel 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.

Edgar Filing: Sanofi - Form 20-F

Table of Contents

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.

Edgar Filing: Sanofi - Form 20-F

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.

Table of Contents**Abbreviations used in the Form 20-F**

ADR/ADS	American Depositary Receipt/American Depositary Share
AFEP	<i>Association française des entreprises privées</i> (French association of large companies)
AMF	<i>Autorité des marchés financiers</i> (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	<i>Fonds commun de placement d'entreprise</i> (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	<i>Mouvement des entreprises de France</i> (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

Table of Contents

TABLE OF CONTENTS

Part I

<u>Item 1.</u>	<u>Identity of Directors, Senior Management and Advisers</u>	<u>1</u>
<u>Item 2.</u>	<u>Offer Statistics and Expected Timetable</u>	<u>1</u>
<u>Item 3.</u>	<u>Key Information</u>	<u>1</u>
	<u>A. Selected Financial Data</u>	<u>1</u>
	<u>B. Capitalization and Indebtedness</u>	<u>3</u>
	<u>C. Reasons for Offer and Use of Proceeds</u>	<u>3</u>
	<u>D. Risk Factors</u>	<u>4</u>
<u>Item 4.</u>	<u>Information on the Company</u>	<u>19</u>
	<u>A. History and Development of the Company</u>	<u>20</u>
	<u>B. Business Overview</u>	<u>21</u>
	<u>C. Organizational Structure</u>	<u>80</u>
	<u>D. Property, Plant and Equipment</u>	<u>81</u>
<u>Item 4A.</u>	<u>Unresolved Staff Comments</u>	<u>87</u>
<u>Item 5.</u>	<u>Operating and Financial Review and Prospects</u>	<u>88</u>
<u>Item 6.</u>	<u>Directors, Senior Management and Employees</u>	<u>137</u>
	<u>A. Directors and Senior Management</u>	<u>137</u>
	<u>B. Compensation</u>	<u>160</u>
	<u>C. Board Practices</u>	<u>178</u>
	<u>D. Employees</u>	<u>183</u>
	<u>E. Share Ownership</u>	<u>185</u>
<u>Item 7.</u>	<u>Major Shareholders and Related Party Transactions</u>	<u>189</u>
	<u>A. Major Shareholders</u>	<u>189</u>
	<u>B. Related Party Transactions</u>	<u>190</u>
	<u>C. Interests of Experts and Counsel</u>	<u>190</u>
<u>Item 8.</u>	<u>Financial Information</u>	<u>191</u>
	<u>A. Consolidated Financial Statements and Other Financial Information</u>	<u>191</u>
	<u>B. Significant Changes</u>	<u>195</u>
<u>Item 9.</u>	<u>The Offer and Listing</u>	<u>196</u>
	<u>A. Offer and Listing Details</u>	<u>196</u>
	<u>B. Plan of Distribution</u>	<u>197</u>
	<u>C. Markets</u>	<u>197</u>
	<u>D. Selling Shareholders</u>	<u>197</u>
	<u>E. Dilution</u>	<u>197</u>
	<u>F. Expenses of the Issue</u>	<u>197</u>
<u>Item 10.</u>	<u>Additional Information</u>	<u>198</u>
	<u>A. Share Capital</u>	<u>198</u>
	<u>B. Memorandum and Articles of Association</u>	<u>198</u>
	<u>C. Material Contracts</u>	<u>214</u>
	<u>D. Exchange Controls</u>	<u>215</u>
	<u>E. Taxation</u>	<u>215</u>
	<u>F. Dividends and Paying Agents</u>	<u>220</u>
	<u>G. Statement by Experts</u>	<u>220</u>
	<u>H. Documents on Display</u>	<u>220</u>
	<u>I. Subsidiary Information</u>	<u>220</u>
<u>Item 11.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	<u>221</u>
<u>Item 12.</u>	<u>Description of Securities other than Equity Securities</u>	<u>225</u>

Part II

<u>Item 13.</u>	<u>Defaults, Dividend Arrearages and Delinquencies</u>	<u>233</u>
<u>Item 14.</u>	<u>Material Modifications to the Rights of Security Holders</u>	<u>233</u>
<u>Item 15.</u>	<u>Controls and Procedures</u>	<u>233</u>
<u>Item 16.</u>	<u>[Reserved]</u>	<u>233</u>
<u>Item 16A.</u>	<u>Audit Committee Financial Expert</u>	<u>233</u>
<u>Item 16B.</u>	<u>Code of Ethics</u>	<u>234</u>

Edgar Filing: Sanofi - Form 20-F

<u>Item 16C.</u>	<u>Principal Accountants' Fees and Services</u>	<u>234</u>
<u>Item 16D.</u>	<u>Exemptions from the Listing Standards for Audit Committees</u>	<u>234</u>
<u>Item 16E.</u>	<u>Purchases of Equity Securities by the Issuer and Affiliated Purchasers</u>	<u>234</u>
<u>Item 16F.</u>	<u>Change in Registrant's Certifying Accountant</u>	<u>234</u>
<u>Item 16G.</u>	<u>Corporate Governance</u>	<u>235</u>
<u>Item 16H.</u>	<u>Mine Safety Disclosure</u>	<u>235</u>
<u>Part III</u>		
<u>Item 17.</u>	<u>Financial Statements</u>	<u>236</u>
Item 18.	Financial Statements	236
Item 19.	Exhibits	236

Table of Contents

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.

Table of Contents

Sanofi reports its financial results in euros.

SELECTED CONDENSED FINANCIAL INFORMATION

As of and for the year ended December 31,

<i>(€ million, except per share data)</i>	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 Meril, 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 Meril 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.

Table of Contents**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

Table of Contents

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

Table of Contents

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

Table of Contents

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

Table of Contents

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.

Table of Contents

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

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Edgar Filing: Sanofi - Form 20-F

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

Table of Contents

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

(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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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

Edgar Filing: Sanofi - Form 20-F

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,

Table of Contents

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 depository 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.

Table of Contents

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;

Edgar Filing: Sanofi - Form 20-F

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.

Table of Contents

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.

Edgar Filing: Sanofi - Form 20-F

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

-
- (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®*

Edgar Filing: Sanofi - Form 20-F

Table of Contents

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

Edgar Filing: Sanofi - Form 20-F

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.

Table of Contents

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®).

Table of Contents

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.

Edgar Filing: Sanofi - Form 20-F

Table of Contents

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® (aronidase)	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 malignancies
Zaltrap® (afibercept)	69	Recombinant fusion protein Oxaliplatin resistant metastatic colorectal cancer

Table of Contents

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.

Table of Contents

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 JP II). 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 JP II (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.

Table of Contents

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 KlikSTAR® 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.

Table of Contents

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

Table of Contents

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® (aronidase) is an enzyme replacement therapy used to treat Mucopolysaccharidosis 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 (TEMPO 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.

Table of Contents

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

Table of Contents

(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.

Table of Contents

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.

Table of Contents

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® / Telfast® 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.

Table of Contents

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.

Table of Contents

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 billion, 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.

Table of Contents

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 miliardi, 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

Edgar Filing: Sanofi - Form 20-F

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®, Rolaid®, 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 nutraceuticals 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.

Table of Contents

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.

Table of Contents

The table below lists net vaccine sales by product range:

<i>(€ million)</i>	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, developed by Shantha, is a fully-liquid 5-in-1 vaccine, protecting against five diseases (diphtheria, tetanus, pertussis, polio and Hepatitis B). Following improvements made to key manufacturing steps in the production of the antigen components of the vaccine, Shan5 regained its prequalification from the WHO in May 2014 and was launched on the Indian market in the last quarter of 2014.

Edgar Filing: Sanofi - Form 20-F

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.

Table of Contents

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 unprecedented quantities of IPV for use in GAVI countries. IPV routine immunization in GAVI countries began in September 2014 in Nepal. Beyond GAVI countries, the expanded use of Sanofi Pasteur's Imovax® Polio 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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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;

Meril 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.

Edgar Filing: Sanofi - Form 20-F

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.

Edgar Filing: Sanofi - Form 20-F

Table of Contents

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		fresolimumab	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 JP II). 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

Table of Contents

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

Table of Contents

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

Edgar Filing: Sanofi - Form 20-F

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.

Table of Contents

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-β 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

Edgar Filing: Sanofi - Form 20-F

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.

Table of Contents

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, double-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.

Table of Contents

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.

Table of Contents*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 <i>clostridium difficile</i>	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

Edgar Filing: Sanofi - Form 20-F

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.

Table of Contents

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).

Table of Contents

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 communicated 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

Edgar Filing: Sanofi - Form 20-F

Table of Contents

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	Compound Patent Term(2)			Comments
	Phase III(1)	U.S.	E.U.	Japan	
	(month/year)				
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.*

Table of Contents

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.

Table of Contents

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.

Table of Contents

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

Table of Contents

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.

Table of Contents

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.

Table of Contents

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

Table of Contents

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).

Table of Contents

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. Pharmacovigilance 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 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

Table of Contents

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

Table of Contents

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.

Table of Contents

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.

Table of Contents

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, currently 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.

Edgar Filing: Sanofi - Form 20-F

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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).

Edgar Filing: Sanofi - Form 20-F

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

Table of Contents

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.

Table of Contents

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

Table of Contents

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)

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

Aldurazyme® (laronidase)

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

Allegra® (fexofenadine hydrochloride)

<p>U.S. Compound: expired Generics on the market Converted to Over-the-Counter</p>	<p>E.U. Compound: expired Generics on the market</p>	<p>Japan⁽¹⁾ Compound: expired Generics on the market Converted to over-the counter</p>
---	---	--

(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)

<p>U.S. Compound: expired</p>	<p>E.U. Compound: expired</p>	<p>Japan Compound: expired</p>
--	--	---

Table of Contents

Apidra® (insulin glulisine)

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

Aprovel® (irbesartan)

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

Aubagio® (teriflunomide)

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

Cerezyme® (imiglucerase)

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

Depakine® (sodium valproate)

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

(1)

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

Fabrazyme® (agalsidase beta)

U.S. Compound: N/A Later filed patents: coverage ranging through September 2015 Biologics Regulatory Exclusivity: April 2015	E.U. Compound: N/A	Japan Compound: N/A Later filed patents: expired Orphan regulatory exclusivity: expired
--	------------------------------	---

Insuman® (human insulin)

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

Table of Contents

Jevtana® (cabazitaxel)

<p>U.S. Compound: March 2021</p> <p>Later filed patents: coverage ranging through October 2030</p> <p>Regulatory exclusivity: June 2015</p>	<p>E.U. Compound: March 2016</p> <p>Later filed patents: coverage ranging through March 2026 with SPC granted in some EU countries</p> <p>Regulatory exclusivity: March 2021</p>	<p>Japan Compound: March 2016 (2021 with PTE when granted)</p> <p>Later filed patents: coverage ranging through October 2030</p> <p>Regulatory exclusivity: July 2022</p>
--	---	--

Lantus® (insulin glargine)

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

(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)

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

Lovenox® (enoxaparin sodium)

<p>U.S. Compound: none Generics on the market</p>	<p>E.U. Compound: expired</p>	<p>Japan Compound: expired Regulatory exclusivity: January 2016</p>
--	--	--

Lumizyme® / Myozyme® (alglucosidase alpha)

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

Lyxumia® (lixisenatide)

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

Edgar Filing: Sanofi - Form 20-F

Table of Contents

Mozobil® (plerixafor)

U.S.
Compound: N/A
Later filed patents: coverage ranging through July 2023

Orphan Drug Exclusivity: December 2015
Multaq® (dronedarone hydrochloride)

U.S.
Compound: July 2016 with PTE
Later filed patents: coverage ranging through December 2031

Regulatory exclusivity: expired
Plavix® (clopidogrel bisulfate)

U.S.
Compound: expired
Generics on the market
Renagel® (sevelamer hydrochloride)

U.S.
Compound: N/A
Later filed patent: October 2020
Renvela® (sevelamer carbonate)

U.S.
Compound: N/A
Later filed patent: October 2025
Stilnox® (zolpidem tartrate)

U.S.
Compound patent: expired
Generics on the market

Synvisc® (hyaline G-F 20)

U.S.
Compound: expired
Synvisc-One® (hyaline G-F 20)

U.S.
Compound: expired

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

E.U.
Compound: expired
Later filed patent: formulation June 2018 extended with SPC up to June 2023 in most of the countries
Regulatory exclusivity: November 2019

E.U.
Compound: expired
Generics on the market

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

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

E.U.
Compound patent: expired
Generics on the market

E.U.
Compound: N/A

E.U.
Compound: N/A

Japan
Compound: N/A
Later filed patents: July 2022

Japan
Compound: expired
Later filed patent: formulation (June 2018)

Japan
Compound: expired
Regulatory exclusivity: expired

Japan
Compound: N/A
Later filed patent: ranging through October 2020

Japan
Compound: N/A
Later filed patent: October 2026

Japan
Compound patent: expired

Regulatory exclusivity: expired
Later filed patent: Ambien® CR formulation (December 2019); not commercialized

Japan
Compound: expired

Japan
Compound: expired

Table of Contents

Toujeo® (insulin glargine)

<p>U.S. Compound: expired</p> <p>Later filed patents: coverage ranging through April 2034 (applications pending) Regulatory exclusivity: February 2018</p> <p>Zaltrap® (aflibercept)</p>	<p>E.U. Compound: May 2015 with SPC and Pediatric Extensions</p> <p>Later filed patents: coverage ranging through April 2034 (applications pending)</p>	<p>Japan Compound: expired</p> <p>Later filed patents: coverage ranging through April 2034 (applications pending)</p>
--	--	--

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

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

Table of Contents

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

Table of Contents

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.

Edgar Filing: Sanofi - Form 20-F

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

Table of Contents

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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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

Table of Contents

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 CO₂ 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 CO₂ 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%

Edgar Filing: Sanofi - Form 20-F

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

Table of Contents

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.

Table of Contents

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:

Edgar Filing: Sanofi - Form 20-F

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).

Edgar Filing: Sanofi - Form 20-F

Table of Contents

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 (Septrafilm®, hyaluronic acid), Ridgefield (Synvisc®, Hectorol®, Mozobil®, Jonexa®, Kynamro®), Woburn (LeGoo®), and Lynnwood, Washington (Leukine®).

Industrial Sites: Vaccines (Sanofi Pasteur)

Edgar Filing: Sanofi - Form 20-F

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.

Table of Contents

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 (ivermectin-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.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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

Table of Contents

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.*

Table of Contents

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.

<i>(€ million)</i> 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:

Edgar Filing: Sanofi - Form 20-F

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.

Table of Contents

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".

Table of Contents

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.

Table of Contents

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:

<i>(€ million)</i>	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.

<i>(€ million)</i>	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

Edgar Filing: Sanofi - Form 20-F

Table of Contents

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

<i>(€ million)</i>	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⁾.

<i>(€ million)</i>	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.

Edgar Filing: Sanofi - Form 20-F

Table of Contents

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:

<i>(€ million)</i>	2014	2013(1)	2012(1)
Business net income	6,847	6,686	8,100
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		(8)	(23)
Restructuring costs	(411)	(300)	(1,141)
Other gains and losses, and litigation ⁽²⁾	35		
Additional expense related to US Branded Prescription Drug Fee ⁽³⁾	(116)		

Edgar Filing: Sanofi - Form 20-F

Tax effects on the items listed above, comprising:	1,094	1,480	1,580
<i>amortization of intangible assets</i>	728	939	1,159
<i>impairment of intangible assets</i>	(18)	527	42
<i>fair value remeasurement of contingent consideration liabilities</i>	254	(85)	2
<i>expenses arising from the impact of acquisitions on inventories</i>		2	7
<i>restructuring costs</i>	143	97	370
<i>other gains and losses, and litigation</i>	(13)		
Other tax items ⁽⁴⁾	(110)	(109)	
Share of items listed above attributable to non-controlling interests	8	4	3
Restructuring costs and expenses arising from the impact of acquisitions on associates and joint ventures	(198)	(50)	(31)
Net income attributable to equity holders of Sanofi	4,390	3,716	4,888

- (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) *Profit related to the acquisition of Alnylam.*
- (3) *Annual fee relating to 2013 sales: the IRS reforms of July 2014 altered the date on which the liability is recognized, such that the expense recognized during 2014 was based on both 2013 and 2014 sales.*
- (4) *This line corresponds to the tax on dividends distributed to Sanofi shareholders.*

-
- (1) *Reported in the income statement line items "Restructuring costs", and "Other gains and losses, and litigation", as defined in Note B.20. to our consolidated financial statements.*

Table of Contents

The following table sets forth the calculation of our business net income for the years ended December 31, 2014, 2013 and 2012:

<i>(€ million)</i>	2014	2013(1)	2012(1)
Business operating income	9,449	9,323	11,446
Financial income and expenses	(447)	(503)	(658)
Income tax expense	(2,155)	(2,134)	(2,689)
Business net income	6,847	6,686	8,100

(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).

The most significant reconciliation items in the table above (reconciling our business net income to our Net income attributable to equity holders of Sanofi) relate to the purchase accounting effect of our acquisitions, particularly the amortization and impairment of intangible assets (other than software). We believe that excluding these non-cash charges enhances an investor's understanding of our underlying economic performance because we do not consider that the excluded charges reflect the combined entity's ongoing operating performance. Rather, we believe that each of the excluded charges reflects the decision to acquire the businesses concerned.

The purchase-accounting effects on net income primarily relate to:

charges related to the amortization and impairment of intangible assets (other than software), net of tax and non-controlling interests;

charges to cost of sales resulting from the workdown of acquired inventories remeasured at fair value, net of tax; and

charges related to the impairment of goodwill.

We believe (subject to the limitations described below) that disclosing business net income enhances the comparability of our operating performance, for the following reasons:

the elimination of charges related to the purchase accounting effect of our acquisitions (particularly amortization and impairment of finite-lived intangible assets other than software) enhances the comparability of our ongoing operating performance relative to our peers in the pharmaceutical industry that carry these intangible assets (principally patents and trademarks) at low book values either because they are the result of in-house research and development that has already been expensed in prior periods or because they were acquired through business combinations that were accounted for as poolings-of-interest;

the elimination of selected items, such as the increase in cost of sales arising from the workdown of inventories remeasured at fair value, gains and losses on disposals of non-current assets and costs and provisions associated with major litigation, improves comparability from one period to the next; and

the elimination of restructuring costs relating to the implementation of our transformation strategy enhances comparability because these costs are directly, and only, incurred in connection with transformation processes such as the rationalization of

our research and development structures.

We remind investors, however, that business net income should not be considered in isolation from, or as a substitute for, net income attributable to equity holders of Sanofi reported in accordance with IFRS. In addition, we strongly encourage investors and potential investors not to rely on any single financial measure but to review our financial statements, including the notes thereto, and our other publicly filed reports, carefully and in their entirety.

There are material limitations associated with the use of business net income as compared to the use of IFRS net income attributable to equity holders of Sanofi in evaluating our performance, as described below:

The results presented by business net income cannot be achieved without incurring the following costs that the measure excludes:

?

Amortization of intangible assets. Business net income excludes the amortization charges related to intangible assets (other than software). Most of these amortization charges relate to intangible assets that we have acquired. Although amortization is a non-cash charge, it is important for investors to consider it because it represents an allocation in each reporting period of a portion of the purchase price that we paid for certain intangible assets that we have acquired through acquisitions. For example, in connection with our acquisition of Aventis in 2004, we paid an aggregate of €31,279 million for these amortizable intangible

Table of Contents

assets (which, in general, were to be amortized over their useful lives, representing an average amortization period of eight years) and €5,007 million for in-progress research & development. In connection with our acquisition of Genzyme in April 2011, we paid an aggregate of €7,873 million for amortizable intangible assets (average amortization period of eight and a half years) and €2,148 million for in-progress research & development. A large part of our revenues could not be generated without owning acquired intangible assets.

?

Restructuring costs. Business net income does not reflect restructuring costs even though it does reflect the benefits of the optimization of our activities, such as our research and development activities, much of which we could not achieve in the absence of restructuring costs.

In addition, the results presented by business net income are intended to represent the Group's underlying performance, but items such as gains and losses on disposals and provisions associated with major litigation may recur in future years.

We compensate for the above-described material limitations by using business net income only to supplement our IFRS financial reporting and by ensuring that our disclosures provide sufficient information for a full understanding of all adjustments included in business net income.

In determining the level of future dividend payments, and in analyzing dividend policy on the basis of business net income, our management intends to take into account the fact that many of the adjustments reflected in business net income have no effect on the underlying amount of cash available to pay dividends. However, although the adjustments relating to the elimination of the effect of the purchase accounting treatment of the Aventis acquisition and other acquisitions represent non-cash charges, the adjustments relating to restructuring costs represent significant cash charges.

This Item 5 contains a discussion and analysis of business net income on the basis of consolidated financial data. Because our business net income is not a standardized measure, it may not be comparable with the non-GAAP financial measures of other companies using the same or a similar non-GAAP financial measure.

Presentation of Net Sales

In the discussion below, we present our consolidated net sales for 2014, 2013 and 2012. We break down our net sales among various categories, including by business segment, product and geographic region. We refer to our consolidated net sales as "reported" sales.

In addition to reported sales, we analyze non-GAAP financial measures designed to isolate the impact on our net sales of currency exchange rates and changes in group structure.

When we refer to changes in our net sales "at constant exchange rates", we exclude the effect of exchange rates by recalculating net sales for the relevant period using the exchange rates that were used for the previous period. See Note B.2 to our consolidated financial statements for further information relating to the manner in which we translate into euros transactions recorded in other currencies.

When we refer to our net sales on a "constant structure basis", we eliminate the effect of changes in structure by restating the net sales for the previous period as follows:

by including sales from an entity or with respect to product rights acquired in the current period for a portion of the previous period equal to the portion of the current period during which we owned them, based on sales information we receive from the party from whom we made the acquisition;

similarly, by excluding sales for a portion of the previous period when we have sold an entity or rights to a product in the current period; and

for a change in consolidation method, by recalculating the previous period on the basis of the method used for the current period.

Edgar Filing: Sanofi - Form 20-F

A reconciliation of our reported net sales to our net sales at constant exchange rates is provided at " Results of Operations Year Ended December 31, 2014 Compared with Year Ended December 31, 2013 Net Sales" and at " Results of Operations Year Ended December 31, 2013 Compared with Year Ended December 31, 2012 Net Sales" below.

Table of Contents

Financial Presentation of Alliances

We have entered into a number of alliances for the development, co-promotion and/or co-marketing of our products. We believe that a presentation of our three principal alliances is useful to an understanding of our financial statements.

The financial impact of the alliances on the Company's income statement is described in " Results of Operations Year Ended December 31, 2014 Compared with Year Ended December 31, 2013" and " Year Ended December 31, 2013 Compared with Year Ended December 31, 2012", in particular in " Net sales", " Other Revenues", " Share of Profit/ Loss of Associates and Joint Ventures" and " Net Income Attributable to Non-Controlling Interests".

Alliance Arrangements with Regeneron

Our relationship with Regeneron began in 2003 with an agreement for the co-development of the anti-angiogenic agent Zaltrap®. We expanded our relationship in 2007 with the signature of an Investment Agreement and created a strategic R&D collaboration on fully human monoclonal antibodies.

Collaboration agreement on Zaltrap® (aflibercept)

Zaltrap® (aflibercept) is a solution administered by intravenous perfusion, used in association with 5-fluorouracil, leucovorin and irinotecan (FOLFIRI) as a treatment for metastatic colorectal cancer that is resistant to or has progressed following an oxaliplatin-containing regimen.

In September 2003, Sanofi and Regeneron signed an agreement to collaborate on the development and commercialization of Zaltrap®. Under the terms of this agreement (as amended in 2005), Sanofi is responsible for funding 100% of the development costs, co-promotion rights are shared between Sanofi and Regeneron, and the profits generated from sales of Zaltrap® worldwide (except Japan) are shared equally. Sales of Zaltrap® made by subsidiaries under the control of Sanofi are recognized in consolidated net sales, and the associated costs incurred by those subsidiaries are recognized as operating expenses in the consolidated income statement. Regeneron's share of the profits/losses generated by Zaltrap® is recognized in the line item "Other operating expenses", a component of operating income.

Under the terms of the same agreement, Regeneron agreed to refund 50% of the development costs initially funded by Sanofi. Contractually, this amount is capped at 5% of the residual refunding obligation per quarter, but may not exceed Regeneron's profit share for the quarter unless Regeneron voluntarily decides to make a larger payment in a given quarter. Sanofi may terminate this agreement by giving twelve months' notice. If the agreement is terminated, Regeneron's residual reimbursement obligation will lapse.

The agreement also stipulates milestone payments to be made by Sanofi on receipt of specified marketing approvals for Zaltrap® in the United States, the European Union and Japan.

In the United States, Zaltrap® is a registered trademark of Regeneron Pharmaceuticals, Inc. The product was approved by the U.S. Food and Drug Administration ("FDA") in August 2012, and has been marketed in the United States since that date. Zaltrap® was approved by the European Commission in February 2013, and has been marketed in that territory since then. Regeneron has not elected to co-promote Zaltrap® at launch in the major market countries defined as United States, France, Italy, Spain, United Kingdom, Germany and Canada.

On February 23, 2015, Sanofi and Regeneron entered into an amended and restated collaboration agreement, which amended and restated the agreement dated September 5, 2003, as amended. Under the terms of the amended collaboration agreement, Sanofi will be solely responsible for the development and commercialization of Zaltrap® (ziv-aflibercept) Injection for Intravenous Infusion for cancer indications worldwide. Sanofi will bear the cost of all development and commercialization activities and will reimburse Regeneron for its costs for any such activities. Sanofi will pay Regeneron a percentage of aggregate net sales of Zaltrap® during each calendar year, which percentage shall be from 15% to 30%, depending on the aggregate net sales of Zaltrap® in such calendar year. Regeneron will also be paid for all quantities of Zaltrap® manufactured by it pursuant to the supply agreement described below. Regeneron will no longer be required to reimburse Sanofi for fifty percent (50%) of the development expenses that Sanofi funded for the development of Zaltrap® under the original collaboration agreement.

Unless terminated earlier in accordance with its provisions, the amended collaboration agreement will continue to be in effect until such time as neither Sanofi nor its affiliates or sublicensees is developing or commercializing

Table of Contents

Zaltrap® and such discontinuation of development and commercialization is acknowledged by both Regeneron and Sanofi to be permanent.

In connection with entering into this amended and restated collaboration agreement, Regeneron and Sanofi also entered into an amended and restated commercial manufacturing and supply agreement for Zaltrap® pursuant to which Regeneron will manufacture and supply to Sanofi quantities of Zaltrap®, as described in the agreement, through the earlier of 2021 or the date Sanofi or one of its affiliates receives regulatory approval to manufacture Zaltrap® at one of its facilities, or a facility of a third-party.

Collaboration agreement on the discovery, development and commercialization of human therapeutic antibodies

In November 2007, Sanofi and Regeneron signed new agreements (amended in November 2009) for the discovery, development and commercialization of fully human therapeutic antibodies. Under the 2009 agreements Sanofi committed to funding the discovery and pre-clinical development of fully human therapeutic antibodies by up to \$160 million per year through 2017 (see Note D.21. to our consolidated financial statements included at Item 18 of this annual report). Sanofi has a license option to develop and commercialize antibodies discovered by Regeneron.

If such an option were to be exercised, Sanofi would co-develop the antibody with Regeneron and be responsible for funding. Sanofi and Regeneron would share co-promotion rights and profits on sales of the co-developed antibodies. On receipt of the first positive Phase III trial results for any such antibody, the subsequent Phase III costs for that antibody would be split 80% Sanofi, 20% Regeneron (see Note D.21. to our consolidated financial statements included at Item 18 of this annual report). Amounts received from Regeneron under these arrangements are recognized by Sanofi in the line item "*Research and development expenses*". Once a product begins to be marketed, Regeneron progressively refunds 50% of the development costs borne by Sanofi, up to a maximum of 10% of Regeneron's share of the quarterly profits. Sanofi may also be required to make milestone payments based on aggregate sales of all antibodies.

Sanofi will recognize sales of products marketed under the terms of the license agreement. Sanofi and Regeneron share co-promotion rights and profits/losses on sales of jointly-developed antibodies. Profits and losses arising from commercial operations in the United States are split 50/50. Outside the United States, Sanofi's share is between 65% and 55% of the profit according to the level of sales achieved for the antibodies, or 55% in the event of a loss. The share of profits/losses attributable to Regeneron under the terms of the agreement is recognized in the line items "*Other operating income*" or "*Other operating expenses*", which are components of operating income. In addition, Regeneron is entitled to receive payments of up to \$250 million contingent on the attainment of specified levels of sales outside the United States.

If Sanofi opts not to exercise its license option for an antibody, then Sanofi would receive a royalty from Regeneron on sales of that antibody.

Investor Agreement

In January 2014, Sanofi and Regeneron amended the investor agreement that has existed between the two companies since 2007. Under the terms of the amended agreement, Sanofi retains the right to acquire up to 30% of Regeneron's capital stock (consisting of the outstanding shares of common stock and the shares of Class A stock). Having passed the threshold of 20% ownership of the capital stock, Sanofi exercised its right under the amended agreement to designate an independent director, who has been appointed to the Board of Directors of Regeneron. The interest held by Sanofi in Regeneron has been consolidated by the equity method since the start of April 2014. On July 31, 2014, Sanofi disclosed its intent to purchase, directly or through its subsidiaries, additional shares of Regeneron Common Stock to progressively increase its beneficial ownership in 2014 and 2015 up to the maximum allowed under the Amended Investor Agreement entered into in January 2014 (30% of Shares of Then Outstanding Common Stock, as defined therein). Sanofi made no commitments either concerning the price and availability of shares of Common Stock, or any other factors considered relevant to Sanofi. On December 31, 2014, Sanofi had an equity interest of 22.3% in Regeneron. On the conditions set out in the amended and restated investor agreement entered into in January 2014, Sanofi's right to designate a Regeneron board member is contingent on Sanofi maintaining its percentage share of Regeneron's outstanding capital stock (measured on a quarterly basis) at a level no lower than the highest percentage level previously achieved, with the maximum requirement capped at 25%.

Table of Contents

The Amended Investor Agreement also gives Sanofi the right to receive certain reasonable information as may be agreed upon by the parties and which will facilitate Sanofi's ability to account for their investment in the Company using the equity method of accounting under International Financial Reporting Standards.

Alliance Arrangements with Bristol-Myers Squibb (BMS)

Our revenues, expenses and operating income are affected by the presentation of our alliance with BMS in our consolidated financial statements.

Initial Alliance Agreement

Under the initial alliance agreements, the relationship between Sanofi and BMS on clopidogrel and irbesartan (both discovered by Sanofi) was organized as follows:

- (a) The world excluding Japan was divided into three territories, each of which was managed by one of the partners, with that partner having a casting vote and consolidating sales of the product:

Territory A, managed by Sanofi: Western & Eastern Europe, Asia, Africa, Middle East (clopidogrel and irbesartan);

Territory B, managed by BMS: North, Central & South America, Australia, New Zealand (clopidogrel and irbesartan, except in the United States and Puerto Rico);

U.S. irbesartan joint venture, managed by BMS (irbesartan in the United States and Puerto Rico).

Depending on the country, the commercialization of clopidogrel products and irbesartan products was organized i) through co-promotion agreements through local joint ventures, ii) through co-marketing agreements with local affiliates of either BMS or Sanofi, or iii) by Sanofi alone in some countries ("opt out" countries) with exclusive marketing rights.

- (b) Financial flows were organized through territorial joint ventures and local joint ventures (in the case of co-promotion), which were used as vehicles for sharing revenues between the two partners in co-promotion or co-marketing countries. In the "opt out" countries, Sanofi paid a straightforward "opt out" royalty to BMS.

The initial alliance arrangements included two royalty streams applied on a worldwide basis (excluding Japan and other opt out countries), regardless of the marketing system and regardless of which company has majority ownership and operational management:

Discovery Royalty. As inventor of the two molecules, we earned an adjustable discovery royalty on sales of Aprovel®/Avapro®/Karvea®/Karvezide® and Plavix®/Iscover® in alliance countries regardless of the marketing system.

Development Royalty. In addition to the discovery royalty, Sanofi and BMS were each entitled to a development royalty related to certain know-how and other intellectual property in connection with sales of Aprovel®/Avapro®/Karvea®/Karvezide® and Plavix®/Iscover®.

Revised Alliance Agreement effective January 1, 2013

On September 27, 2012 Sanofi and BMS restructured their alliance following the loss of exclusivity of Plavix® and Avapro®/Avalide® in many major markets. Under the terms of the revised agreement, which came into effect on January 1, 2013, BMS has returned to Sanofi its rights to Plavix® and Avapro®/Avalide® in all markets worldwide with the exception of Plavix® in the U.S. and Puerto Rico, giving Sanofi sole control and freedom to operate commercially. In exchange, starting January 1, 2013 BMS receives royalty payments on Sanofi's sales of branded and unbranded Plavix® worldwide, excluding the U.S. and Puerto Rico, and on sales of branded and unbranded Avapro®/Avalide®

Edgar Filing: Sanofi - Form 20-F

worldwide, in each case through 2018; BMS will also receive a terminal payment of \$200 million from Sanofi in December 2018. Plavix® rights in the U.S. and Puerto Rico will continue unchanged under the terms of the existing agreement through December 2019.

In addition, under the terms of this new agreement ongoing disputes between the companies related to the alliance have been resolved. The resolution of these disputes includes various commitments by both companies, including a one-time payment of \$80 million by BMS to Sanofi in relation to the Avalide® supply disruption in the U.S. in 2011.

Table of Contents

In the territory managed by BMS (the United States and Puerto Rico for Plavix®), the accounting policies applied by Sanofi remain unchanged and in accordance with the terms of the initial agreement. Marketing is handled through co-promotion entities majority owned by and under the operational management of BMS. Sanofi does not recognize the sales, but invoices these entities for its promotional expenses, recognizes its royalty income in "*Other revenues*", and recognizes its share of profits (net of tax) in "*Share of profit/(loss) of associates and joint ventures*".

In all of the territories managed by Sanofi (including the United States and Puerto Rico for Avapro®/ Avalide®) as defined in the new agreement, the Group recognizes in its financial statements the revenue and expenses generated by its own operations. Payments due to BMS are recognized in "*Cost of sales*".

See also note C.2. to our consolidated financial statements included at Item 18 of this annual report.

Alliance arrangements with Warner Chilcott (previously with Procter & Gamble Pharmaceuticals (P&G))

Under our Alliance arrangements with Warner Chilcott (as the assignee of P&G in 2009), Sanofi and Warner Chilcott have collaborated to jointly develop and commercialize Actonel® on a global basis, excluding Japan.

In October 2013, after Actavis plc acquired Warner Chilcott plc, the parent company of Warner Chilcott, Sanofi and Warner Chilcott have agreed on an early buy-back of Sanofi's interest in the product in the United States and Puerto Rico. As a consequence, the parties have amended the U.S. amendment (arising from a 2010 restructuring for the U.S. and Puerto Rico) with a view to restructure the parties' economic rights and obligations for the contract year 2014. As such, Warner Chilcott has paid to Sanofi a terminal payment of \$125 million.

In accordance with the Alliance arrangements terms, the Alliance was terminated on January 1st, 2015 and Sanofi returned to Warner Chilcott all its rights, title and interests in and to Actonel® worldwide, except in a limited number of countries where Sanofi has been appointed Warner Chilcott's exclusive distributor of Actonel® as of this date under new distributor agreements.

Impact of Exchange Rates

We report our consolidated financial statements in euros. Because we earn a significant portion of our revenues in countries where the euro is not the local currency, our results of operations can be significantly affected by exchange rate movements between the euro and other currencies, primarily the U.S. dollar and, to a lesser extent, the Japanese yen, and currencies in emerging countries. We experience these effects even though certain of these countries do not account for a large portion of our net sales. In 2014, we earned 33.6% of our net sales in the United States. An increase in the value of the U.S. dollar against the euro has a positive impact on both our revenues and our operating income. A decrease in the value of the U.S. dollar against the euro has a negative impact on our revenues, which is not offset by an equal reduction in our costs and therefore negatively affects our operating income. A variation in the value of the U.S. dollar has a particularly significant impact on our operating income, which is higher in the United States than elsewhere, and on the contribution to net income of our collaborations with Regeneron and BMS in the United States (see " Financial Presentation of Alliances" above).

For a description of positions entered into to manage operational foreign exchange risks as well as our hedging policy, see "Item 11. Quantitative and Qualitative Disclosures about Market Risk", and "Item 3. Key Information D. Risk Factors Risks Related to Financial Markets Fluctuations in currency exchange rates could adversely affect our results of operations and financial condition".

Divestments

There were no material divestments in 2014.

In 2013, Sanofi sold its U.S. commercial rights of five pharmaceutical products to Covis Pharma. The gain on this sale amounted to €165 million.

In August 2012, Sanofi sold its 39.1% interest in Société Financière des Laboratoires de Cosmétologie Yves Rocher, in line with the Group's desire to focus on strategic activities.

Table of Contents

Acquisitions

The principal acquisitions during 2014 are described below:

In 2014, Sanofi acquired 7 million shares of Regeneron Pharmaceuticals, Inc. As of December 31, 2014, Sanofi held 22.3% of the company's share capital (versus 15.9% on December 31, 2013). The acquisition price amounted to €1,629 million. See Note D.1.1. to our consolidated financial statements included at Item 18 of this annual report.

The impact of other acquisitions in 2014 on our consolidated financial statements is not material.

The principal acquisitions during 2013 are described below:

In January 2013, Sanofi (via Chattem) completed the acquisition of the worldwide rights to the Roloids® brand from the McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. Roloids® is an over-the-counter antacid that helps relieve heartburn and acid reflux.

In March 2013, Sanofi acquired Genfar S.A. (Genfar), a Colombian pharmaceutical company that is a significant player in Colombia and other countries in Latin America. Genfar is the second-largest generics manufacturer in Colombia by sales, with annual sales around €100 million. See Note D.1.2. to our consolidated financial statements included at Item 18 of this annual report.

In June 2013, Merial announced the completion of its acquisition of the animal health division of the Indian company Dosch Pharmaceuticals Private Limited, which markets 86 animal health products and 50 specialities for ruminants, poultry and companion animals.

Other than Genfar, the impact of these acquisitions on our consolidated financial statements is not material.

The principal acquisitions during 2012 are described below:

In April 2012, Sanofi acquired a 100% equity interest in Pluromed, Inc. (Pluromed), an American medical devices company. Pluromed has developed a proprietary polymer technology Rapid Transition Polymers (RTP) pioneering the use of plugs that can be injected into blood vessels to improve the safety, efficacy and economics of medical interventions.

In March 2012, Merial completed the acquisition of Newport Laboratories, a privately held company based in Worthington, Minnesota (United States), which was a leader in autogenous vaccines for the bovine and swine markets.

The impact of these two acquisitions on our consolidated financial statements is not material.

Table of Contents**Results of Operations*****Year Ended December 31, 2014 Compared with Year Ended December 31, 2013***

The consolidated income statements for the years ended December 31, 2014 and December 31, 2013 break down as follows:

(under IFRS) <i>(€ million)</i>	2014	as % of net sales	2013 (1)	as % of net sales
Net sales	33,770	100.0%	32,951	100.0%
Other revenues	339	1.0%	355	1.1%
Cost of sales	(11,029)	(32.7%)	(10,991)	(33.4%)
Gross profit	23,080	68.3%	22,315	67.7%
Research & development expenses	(4,824)	(14.3%)	(4,770)	(14.5%)
Selling & general expenses	(9,107)	(27.0%)	(8,603)	(26.1%)
Other operating income	327		691	
Other operating expenses	(163)		(241)	
Amortization of intangible assets	(2,482)		(2,914)	
Impairment of intangible assets	26		(1,387)	
Fair value remeasurement of contingent consideration liabilities	(303)		314	
Restructuring costs	(411)		(300)	
Other gains and losses, and litigation				
Operating income	6,143	18.2%	5,105	15.5%
Financial expenses	(605)		(612)	
Financial income	193		109	
Income before tax and associates and joint ventures	5,731	17.0%	4,602	14.0%
Income tax expense	(1,171)		(763)	
Share of profit/(loss) of associates and joint ventures	(51)		35	
Net income	4,509	13.4%	3,874	11.8%
Net income attributable to non-controlling interests	119		158	

Edgar Filing: Sanofi - Form 20-F

Net income attributable to equity holders of Sanofi	4,390	13.0%	3,716	11.3%
Average number of shares outstanding (million)	1,315.8		1,323.1	
Average number of shares outstanding after dilution (million)	1,331.1		1,339.1	
Basic earnings per share (in euros)	3.34		2.81	
Diluted earnings per share (in euros)	3.30		2.77	

(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).

Net Sales

Consolidated net sales for the year ended December 31, 2014 amounted to €33,770 million, 2.5% higher than in 2013. Exchange rate movements had an unfavorable effect of 2.4 points, mainly reflecting the depreciation of the Japanese yen, the Russian rouble, the Brazilian real and the Argentine peso against the euro. At constant exchange rates, net sales rose by 4.9% year-on-year.

Table of Contents

The following table sets forth a reconciliation of our reported net sales for the years ended December 31, 2014 and December 31, 2013 to our net sales at constant exchange rates:

<i>(€ million)</i>	2014	2013	Change
Net sales	33,770	32,951	+2.5%
Effect of exchange rates	792		
Net sales at constant exchange rates	34,562	32,951	+4.9%

Our net sales comprise the net sales generated by our Pharmaceuticals, Human Vaccines (Vaccines) and Animal Health segments.

The following table breaks down our 2014 and 2013 net sales by business segment:

<i>(€ million)</i>	2014 Reported	2013 Reported	Change on a reported basis	Change at constant exchange rates
Pharmaceuticals	27,720	27,250	+1.7%	+4.4%
Vaccines	3,974	3,716	+6.9%	+7.2%
Animal Health	2,076	1,985	+4.6%	+6.7%
Total	33,770	32,951	+2.5%	+4.9%

Net Sales by Product *Pharmaceuticals segment*

In 2014, net sales for the Pharmaceuticals segment were €27,720 million, up 1.7% on a reported basis and 4.4% at constant exchange rates. The year-on-year change (increase of €470 million) reflects the negative effect of exchange rates (€739 million) on the one hand, and the following impacts at constant exchange rates on the other hand:

a positive performance from our growth platforms (€1,873 million), mainly for the Diabetes division and our Genzyme and Consumer Health Care businesses (excluding the impact of changes in scope of consolidation in Consumer Health Care);

a recovery in sales for our Generics operations in Brazil (€309 million), by comparison with 2013 when we experienced temporary difficulties with our distribution channels in that country;

negative effects totaling €973 million, including the residual impact of generic competition (primarily for Aprovel®, Allegra® and Taxotere®) and lower sales of other prescription products.

Our flagship products (Lantus® and Apidra®; Cerezyme®, Myozyme®/ Lumizyme®, Fabrazyme®, Aubagio® and Lemtrada®; Jevtana®, Taxotere®, Eloxatin®, Mozobil® and Zaltrap®; Plavix®, Lovenox®, Aprovel®/ CoAprovel®, Renagel®/ Renvela®, Allegra®, Stilnox®/ Ambien®/ Myslee®, Synvisc®/ Synvisc-One®, Multaq® and Auvi-Q®/Allerject) are discussed below.

Edgar Filing: Sanofi - Form 20-F

Table of Contents

The following table breaks down our 2014 and 2013 net sales for the Pharmaceuticals segment by product:

<i>(€ million)</i> Product	Indication	2014 Reported	2013 Reported	Change on a reported basis	Change at constant exchange rates
Lantus®	Diabetes	6,344	5,715	+11.0%	+12.1%
Apidra®	Diabetes	336	288	+16.7%	+19.1%
Amaryl®	Diabetes	360	375	-4.0%	+0.3%
Insuman®	Diabetes	137	132	+3.8%	+6.8%
Blood glucose meters	Diabetes	64	48	+33.3%	+33.3%
Lyxumia®	Diabetes	27	9	+200.0%	+211.1%
Other products		5	1		
Total: Diabetes	Diabetes	7,273	6,568	+10.7%	+12.1%
Jevtana®	Prostate cancer	273	231	+18.2%	+19.5%
Taxotere®	Breast, lung, prostate, stomach, and head & neck cancer	266	409	-35.0%	-31.5%
Thymoglobulin®	Organ rejection	217	198	+9.6%	+11.1%
Eloxatin®	Colorectal cancer	210	221	-5.0%	-2.7%
Mozobil®	Hematologic malignancies	111	101	+9.9%	+9.9%
Zaltrap®	Colorectal cancer	69	53	+30.2%	+30.2%
Other products		255	252	+1.2%	+2.4%
Total: Oncology		1,401	1,465	-4.4%	-2.5%
Cerezyme®	Gaucher disease	715	688	+3.9%	+8.3%
Cerdelga®	Gaucher disease	4			
Myozyme®/Lumizyme®	Pompe disease	542	500	+8.4%	+9.8%

Edgar Filing: Sanofi - Form 20-F

Fabrazyme®	Fabry disease	460	383	+20.1%	+23.0%
Aldurazyme®	Mucopolysaccharidosis	172	159	+8.2%	+11.3%
Other products		244	244	0.0%	+2.9%
Sub-total: Rare diseases		2,137	1,974	+8.3%	+11.2%
Aubagio®	Multiple sclerosis	433	166	+160.8%	+160.8%
Lemtrada®	Multiple sclerosis	34	2		
Sub-total: Multiple sclerosis		467	168	+178.0%	+178.0%
Total: Genzyme		2,604	2,142	+21.6%	+24.3%
Plavix®	Atherothrombosis	1,862	1,857	+0.3%	+4.7%
Lovenox®	Thrombosis	1,699	1,703	-0.2%	+2.1%
Aprovel®/CoAprovel®	Hypertension	727	882	-17.6%	-16.6%
Renagel®/Renvela®	Hyperphosphatemia	684	750	-8.8%	-8.7%
Depakine®	Epilepsy	395	405	-2.5%	+0.5%
Synvisc®/Synvisc-One®	Arthritis	352	371	-5.1%	-4.6%
Stilnox®/Ambien®/Myslee®	Sleep disorders	306	391	-21.7%	-18.4%
Multaq®	Atrial fibrillation	290	269	+7.8%	+7.8%
Tritace®	Hypertension	281	307	-8.5%	-5.9%
Allegra®	Allergic rhinitis, urticaria	192	406	-52.7%	-48.3%
Lasix®	Edema, hypertension	164	172	-4.7%	-0.6%
Targocid®	Bacterial infections	162	166	-2.4%	-0.6%
Orudis®	Rheumatoid arthritis, osteoarthritis	160	144	+11.1%	+17.4%
Cordarone®	Arrhythmia	129	141	-8.5%	-2.8%
Xatral®	Benign prostatic hypertrophy	94	101	-6.9%	-5.0%
Actonel®	Osteoporosis, Paget's disease	82	100	-18.0%	-14.0%
Auvi-Q®/Allerject	Severe allergies, anaphylaxis	72	60	+20.0%	+21.7%

Other products	3,649	4,221	-13.6%	-11.2%
Total: Other prescription products	11,300	12,446	-9.2%	-6.7%
Consumer Health Care	3,337	3,004	+11.1%	+16.5%
Generics	1,805	1,625	+11.1%	+16.2%
Total Pharmaceuticals	27,720	27,250	+1.7%	+4.4%

Table of Contents*Diabetes division*

Net sales for the **Diabetes** division were €7,273 million, up 12.1% at constant exchange rates, driven by double-digit growth for Lantus® and Apidra®.

Lantus® increased its net sales by 12.1% (at constant exchange rates) to €6,344 million in 2014 due to strong performances in the United States (+12.4% at constant exchange rates, at €4,225 million), where Lantus® SoloSTAR® accounted for 62% of full-year sales, and in Emerging Markets (+17.6% at constant exchange rates), especially in China (+33.6% at constant exchange rates), the Africa/Middle East region (+17.3% at constant exchange rates) and in Eastern Europe (+15.9% at constant exchange rates). Western Europe turned in a good performance as net sales rose by 7.7% at constant exchange rates to €871 million.

The product's sales growth during 2014 reflected both an increase in volume and a generally favorable price effect. In volume terms, sales of Lantus® increased across all geographical areas in 2014 (by 4.8% overall). For 2015, we expect a rise in prescription rates across all geographical areas in line with the increasing prevalence of type 2 diabetes, including (though to a lesser extent) in the United States. In the medium to long term, volume growth will depend on various factors, such as the number of new rival products entering the market and the prevalence of type 2 diabetes. Volume growth is expected to be particularly strong in Emerging Markets, reflecting increased diagnosis of diabetes and better access to drugs.

Price effects on sales of Lantus® were favorable overall in 2014 (+7.3% at constant exchange rates); the biggest effect was felt in the United States. However, we encountered a tougher pricing environment in the U.S. basal insulins market in the second half of 2014, which was reflected in mounting price pressure from payers. During that period, we conducted negotiations with payers in the United States, securing favorable positions for Lantus® in the formularies of the key payers. To maintain those positions, we had to significantly increase the level of discounts offered in order to match the substantial rebates offered by our competitors. We expect that the high level of rebates in the United States, coupled with the impact of the Affordable Care Act, will have a negative overall price effect on sales of Lantus® in 2015.

We cannot predict the long-term price effects in the diabetes market, as these will depend on the impact of new rival products on the pricing of diabetes treatments across all geographic areas. In 2015, we anticipate that the negative price effects impacting our diabetes business in the United States will be cushioned by new product launches and further strong growth in Emerging Markets.

Net sales of **Apidra®** totaled €336 million in 2014, up 19.1% at constant exchange rates, driven by a strong performance in the United States (+16.1% at constant exchange rates, at €131 million) and in Emerging Markets (+28.6% at constant exchange rates, at €75 million).

Net sales of **Amaryl®** were flat year-on-year (+0.3% at constant exchange rates, at €360 million), reflecting the effect of generic competition in Japan (-27.2% at constant exchange rates, at €54 million), but also a good performance in Emerging Markets (+8.9% at constant exchange rates, at €283 million).

Blood glucose meters posted a surge in net sales of 33.3% at constant exchange rates to €64 million, largely as a result of recent launches of MyStar Extra® in Western Europe.

Lyxumia®, which continued to be rolled out worldwide during 2014, generated sales of €27 million. In Germany, the product was withdrawn from the market in April 2014 due to a negative outcome on the pricing level set by the authorities.

Oncology business

Net sales for the **Oncology** business were €1,401 million, down 2.5% at constant exchange rates.

Jevtana® reported net sales of €273 million in 2014, up 19.5% at constant exchange rates, boosted by recent launches in Western Europe where sales rose by 28.2% at constant exchange rates to €142 million.

Net sales of **Taxotere®** fell sharply, by 31.5% at constant exchange rates, to €266 million. The product is facing competition from generics in Emerging Markets (-23.2% at constant exchange rates, at €156 million), the United States (-81.0% at constant exchange rates, at €8 million) and in Japan (-28.2% at constant exchange rates, at €87 million).

Sales of **Eloxatin®** were €210 million, down 2.7% at constant exchange rates, mainly as a result of competition from generics in the United States.

Table of Contents

Sales of **Mozobil®** rose by 9.9% at constant exchange rates to €111 million.

Net sales of **Zaltrap®** (afibercept, developed in collaboration with Regeneron) totaled €69 million, up 30.2% at constant exchange rates, on the back of recent launches in Western Europe (+146.7%, at €37 million) that more than offset lower sales in the United States (-25.0% at constant exchange rates, at €27 million).

Jevtana®, Zaltrap® and Mozobil®, along with the other pharmaceutical products Multaq® and Auvi-Q®/Allerject⁽¹⁾ (see " Other pharmaceutical products" below), constitute the "Other Innovative Products" growth platform, which in 2014 generated €815 million of net sales, up 14.7% at constant exchange rates.

Genzyme business

The **Genzyme** business generated net sales of €2,604 million, up 24.3% at constant exchange rates, driven by strong growth in sales of Aubagio® and Fabrazyme®.

Cerezyme® increased its net sales by 8.3% at constant exchange rates to €715 million, driven by Emerging Markets (+14.5% at constant exchange rates, at €248 million) and Western Europe (+6.7% at constant exchange rates, at €241 million).

Net sales of **Myozyme®/ Lumizyme®** rose by 9.8% at constant exchange rates to €542 million, reflecting the product's performance in Emerging Markets (+41.9% at constant exchange rates, at €98 million).

Fabrazyme® reported strong net sales growth of 23.0% at constant exchange rates, to €460 million. Net sales were up 13.8% at constant exchange rates in the United States (at €223 million), 26.4% at constant exchange rates in Western Europe (at €110 million), and 49.0% at constant exchange rates in Emerging Markets (at €69 million).

In multiple sclerosis, **Aubagio®** recorded net sales of €433 million during 2014, including €326 million in the United States (where the product was launched in October 2012) and €83 million in Western Europe (where launches began at the end of 2013). Sales of **Lemtrada®** were €34 million, of which €28 million was generated in Western Europe.

Other pharmaceutical products

Net sales of **Plavix®** were up 4.7% at constant exchange rates at €1,862 million. Growth was driven by Japan (+10.0% at constant exchange rates, at €759 million) and Emerging Markets (+8.8% at constant exchange rates, at €862 million), especially China (+18.0% at constant exchange rates, at €498 million). However, the effects were mitigated by generic competition in Western Europe (-15.6% at constant exchange rates, at €217 million). Sales of Plavix® in the United States and Puerto Rico are handled by BMS under the terms of the Sanofi-BMS alliance (see " Financial presentation of alliances Alliance Arrangements with Bristol-Myers Squibb" above).

Lovenox® posted net sales growth of 2.1% in 2014 at constant exchange rates, to €1,699 million. Lower net sales in the United States, where sales of the branded product fell by 30.5% at constant exchange rates to €130 million in the face of generic competition, were offset by good performances in Western Europe (+4.3% at constant exchange rates, at €898 million) and in Emerging Markets (+10.1% at constant exchange rates, at €584 million), especially in China and Latin America. Sales of the generic version of Lovenox® launched by Sanofi in 2012 are recorded by our Generics business (see below).

Aprovel®/ CoAprovel® reported a drop in net sales of 16.6% at constant exchange rates to €727 million, mainly as a result of competition from generics in Western Europe, where sales were 43.8% lower at €190 million. Net sales in Emerging Markets were relatively stable year-on-year, rising by 1.7% at constant exchange rates to €409 million.

Net sales of **Renagel®/ Renvela®** fell by 8.7% at constant exchange rates to €684 million due to lower sales in the United States (-13.6% at constant exchange rates, at €464 million), reflecting the effects of the agreement whereby Sanofi granted Impax the right to sell a limited number of authorized generics of Renvela® from April 2014.

Allegra® posted a fall in prescription net sales (-48.3% at constant exchange rates, at €192 million), affected by competition from generics in Japan (-30.0% at constant exchange rates, at €178 million) and by the reclassification of sales of the product in some countries of Emerging Markets to our Consumer Health Care business. On a constant structure basis and at constant exchange rates, Emerging Markets net sales were stable year-on-year, but at constant exchange rates they were down 95.8% at €5 million. Net sales of Allegra® OTC in the United States and in

Japan are also recorded by our Consumer Health Care business.

(1) *Sanofi U.S. has in-licensed the North American commercialization rights for Auvi-Q®/ Allerject from Intelliject, Inc.*

Table of Contents

Net sales of **Stilnox®/Ambien®/Myslee®** fell by 18.4% at constant exchange rates to €306 million, reflecting competition from generics of Myslee (-29.2% at constant exchange rates, at €125 million).

Synvisc®/ Synvisc-One® posted net sales of €352 million, down 4.6% at constant exchange rates, on lower sales in the United States (-7.5% at constant exchange rates, at €274 million).

Net sales of **Multaq®** increased by 7.8% at constant exchange rates to €290 million, driven by sales in the United States (+8.8% at constant exchange rates, at €235 million).

Auvi-Q®/ Allerject recorded net sales of €72 million (+21.7% at constant exchange rates), including €61 million in the United States where the product was launched in January 2013.

We have no comments on our other prescription medicines.

Consumer Health Care business

In 2014, net sales for the **Consumer Health Care** business segment were €3,337 million, up 11.1% on a reported basis and 16.5% at constant exchange rates.

Some products that were accounted for as prescription products in 2013 (aggregate net sales: €273 million) were reclassified in 2014 to Consumer Health Care. Excluding the effects of this category change, Consumer Health Care net sales rose by 1.8% in 2014 (or by 6.8% at constant exchange rates), driven by growth in Emerging Markets and in the United States, where the Nasacort® Allergy 24H OTC nasal spray has been on the market since February 2014.

The following table breaks down our 2014 and 2013 net sales for the Consumer Health Care business by product:

<i>(€ million)</i> Product	2014 Reported	2013 Reported	Change on a reported basis	Change at constant exchange rates
Doliprane®	310	290	+6.9%	+7.2%
Allegra®	350	264	+32.6%	+37.1%
Essentiale®	235	207	+13.5%	+27.1%
Enterogermina®	156	130	+20.0%	+24.6%
Nasacort®	114	1		
No Spa®	109	117	-6.8%	+6.0%
Lactacyd®	104	105	-1.0%	+5.7%
Maalox®	98	94	+4.3%	+9.6%
Dorflex®	90	93	-3.2%	+6.5%
Other products	1,771	1,703	+4.0%	+8.5%
Total Consumer Health Care	3,337	3,004	+11.1%	+16.5%

Generics business

The **Generics** business reported net sales of €1,805 million in 2014, up 16.2% at constant exchange rates, reflecting a recovery in sales in Brazil by comparison with 2013 when sales were adversely affected by temporary difficulties in our distribution channels in that country. Excluding Brazil, Generics net sales fell by 2.8% year-on-year at constant exchange rates.

In Emerging Markets, the Generics business generated net sales of €1,106 million, up 38.8% at constant exchange rates (or 2.7% excluding Brazil). In the United States, net sales fell by 31.3% at constant exchange rates to €123 million, reflecting a decline in sales of authorized generics of Lovenox® and Taxotere®.

Edgar Filing: Sanofi - Form 20-F

Table of Contents

The following table breaks down net sales of our Pharmaceutical segment products by geographical region in 2014:

<i>(€million)</i> Product	Western Europe (1) Reported	Change at constant exchange rates	United States Reported	Change at constant exchange rates	Emerging Markets (2) Reported	Change at constant exchange rates	Rest of the world (3) Reported	Change at constant exchange rates
Lantus®	871	+7.7%	4,225	+12.4%	970	+17.6%	278	+3.1%
Apidra®	98	+16.7%	131	+16.1%	75	+28.6%	32	+17.2%
Amaryl®	19	-13.6%	4	+100.0%	283	+8.9%	54	-26.8%
Insuman®	82	-8.9%	1	0.0%	54	+38.1%		-100.0%
Blood glucose meters	58	+28.9%			3	+200.0%	3	+50.0%
Lyxumia®	15	+150.0%			4		8	+200.0%
Other products					1	0.0%	4	
Total: Diabetes	1,143	+8.3%	4,361	+12.6%	1,390	+17.4%	379	+1.0%
Jevtana®	142	+28.2%	91	+5.8%	33	+19.4%	7	+75.0%
Taxotere®	15	-31.8%	8	-81.0%	156	-23.2%	87	-29.1%
Thymoglobulin®	32	+3.2%	108	+5.9%	64	+26.4%	13	+8.3%
Eloxatin®	5	-16.7%	22	+5.3%	121	-2.4%	62	-4.3%
Mozobil®	34	+3.1%	62	+8.9%	12	+20.0%	3	+66.7%
Zaltrap®	37	+146.7%	27	-25.0%	5	+150.0%		
Other products	55	0.0%	151	+1.3%	32	+6.7%	17	+10.5%
Total: Oncology	320	+17.4%	469	-4.9%	423	-5.4%	189	-14.1%
Cerezyme®	241	+6.7%	186	+4.5%	248	+14.5%	40	-2.3%
Cerdelga®			4					
Myozyme®/Lumizyme®	270	-1.8%	142	+14.6%	98	+41.9%	32	+17.2%
Fabrazyme®	110	+26.4%	223	+13.8%	69	+49.0%	58	+26.5%

Edgar Filing: Sanofi - Form 20-F

Aldurazyme®	64	+6.7%	33	+13.8%	58	+16.7%	17	+6.3%
Other products	43	+7.7%	89	-10.1%	49	+25.6%	63	+6.0%
Sub-total Rare diseases	728	+5.8%	677	+8.0%	522	+24.0%	210	+10.7%
Aubagio®	83	+600.0%	326	+112.5%	10	+550.0%	14	
Lemtrada®	28		2		2		2	
Sub-total Multiple sclerosis	111	+692.9%	328	+113.8%	12	+650.0%	16	
Total: Genzyme	839	+19.6%	1,005	+28.7%	534	+26.7%	226	+18.5%
Plavix®	217	-15.6%	1*	-80.0%	862	+8.8%	782	+7.6%
Lovenox®	898	+4.3%	130	-30.5%	584	+10.1%	87	-2.1%
Aprovel®/CoAprovel®	190	-43.8%	18*	+5.9%	409	+1.7%	110	-5.1%
Renagel®/Renvela®	133	-0.8%	464	-13.6%	68	+9.0%	19	+10.5%
Depakine®	139	0.0%			243	+1.2%	13	-6.7%
Synvisc®/Synvisc-One®	28	+12.0%	274	-7.5%	39	+24.2%	11	-33.3%
Stilnox®/Ambien®/Myslee®	40	-2.4%	74	-17.0%	63	+1.5%	129	-29.1%
Multaq®	44	+2.3%	235	+8.8%	9	+12.5%	2	0.0%
Tritace®	127	-6.6%			147	-3.8%	7	-27.3%
Allegra®	10	0.0%			5	-95.8%	177	-30.1%
Lasix®	78	+4.0%	3	0.0%	51	+12.0%	32	-22.7%
Targocid®	84	+5.1%			71	-2.7%	7	-25.0%
Orudis®	20	-16.7%			137	+23.9%	3	+33.3%
Cordarone®	24	-4.0%			71	+2.7%	34	-11.9%
Xatral®	38	-2.6%		-100.0%	56	-1.7%		
Actonel®	17	-22.7%			41	-10.4%	24	-13.3%
Auvi-Q®/Allerject	2	-33.3%	61	+21.6%			9	+50.0%
Other products	1,547	-6.2%	344	-29.8%	1,397	-7.9%	361	-20.2%
	3,636	-6.8%	1,604	-15.2%	4,253	-1.5%	1,807	-9.8%

Total: Other prescription products

Consumer Health Care	676	+1.7%	708	+15.4%	1,756	+28.4%	197	-13.2%
Generics	533	+4.3%	123	-31.3%	1,106	+38.8%	43	+27.8%
Total pharmaceuticals	7,147	-0.1%	8,270	+5.6%	9,462	+11.1%	2,841	-6.9%

(1)

France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark.

(2)

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

(3)

Japan, Canada, Australia and New Zealand.

*

Sales of active ingredient to the entity majority-owned by BMS in the United States.

Table of Contents**Net Sales Human Vaccines (Vaccines) segment**

In 2014, net sales for the Vaccines segment were €3,974 million, up 6.9% on a reported basis and 7.2% at constant exchange rates.

The following table presents the 2014 and 2013 sales of our Vaccines segment by range of products:

<i>(€million)</i>	2014 Reported	2013 Reported	Change on a reported basis	Change at constant exchange rates
Polio/Pertussis/Hib Vaccines (including Pentacel® and Pentaxim®)	1,154	1,148	+0.5%	+1.9%
Influenza Vaccines (including Vaxigrip® and Fluzone®)	1,178	929	+26.8%	+25.2%
Meningitis/Pneumonia Vaccines (including Menactra®)	455	496	-8.3%	-7.5%
Adult Booster Vaccines (including Adacel®)	398	391	+1.8%	+2.0%
Travel and Other Endemics Vaccines	377	382	-1.3%	+1.6%
Other Vaccines	412	370	+11.4%	+9.7%
Total Vaccines	3,974	3,716	+6.9%	+7.2%

Polio/Pertussis/Hib vaccines reported net sales up 1.9% at constant exchange rates, at €1,154 million. This reflected a good performance in the United States (€411 million, up 46.9% at constant exchange rates) as shipments of Pentacel® recovered following the supply limitations experienced in 2013. On the downside, negative factors included (i) lower net sales in Japan (-23.5% at constant exchange rates, at €127 million) due to the end of the 2013 catch-up vaccination campaigns that followed the launch of Imovax® and (ii) a fall in net sales in Emerging Markets (-8.1% at constant exchange rates, at €581 million) due mainly to Pentaxim® and Imovax® in China.

Net sales of **Influenza** vaccines were up 25.2% at constant exchange rates at €1,178 million, helped by a fine performance in the United States (+25.7% at €694 million) as the differentiated vaccine strategy paid off, and also in Emerging Markets (+28.5% at constant exchange rates, at €368 million) on the back of seasonal influenza in Latin America.

Meningitis/Pneumonia vaccines posted net sales of €455 million, down 7.5% at constant exchange rates, hampered by a poor performance in Emerging Markets (-32.6% at constant exchange rates, at €84 million) due mainly to a drop in sales of Menactra® in the Middle East.

Net sales of **Adult Booster** vaccines rose by 2.0% at constant exchange rates to €398 million. Net sales of **Travel and Other Endemics** vaccines were up 1.6% at constant exchange rates at €377 million.

Other Vaccines saw net sales rise by 9.7% at constant exchange rates to €412 million, reflecting the growth of VaxServe, a Sanofi Pasteur company that supplies vaccines in the United States.

In addition to the Vaccines activity reflected in our consolidated net sales, sales generated by Sanofi Pasteur MSD, our joint venture with Merck & Co., Inc. in Europe, reached €848 million in 2014, down 3.3% (on a reported basis). Sales generated by Sanofi Pasteur MSD are not included in our consolidated net sales. Sales of Gardasil® were down 15.4% on a reported basis, at €186 million. Zostavax®, launched at the end of 2012, posted 50.6% growth in net sales to €77 million (versus €51 million in 2013).

Table of Contents

The following table presents the 2014 sales of our Vaccines segment by range of products and by region:

<i>(€ million)</i>	Western Europe (1) Reported	Change at constant exchange rates	United States Reported	Change at constant exchange rates	Emerging Markets (2) Reported	Change at constant exchange rates	Rest of the world (3) Reported	Change at constant exchange rates
Polio/Pertussis/Hib Vaccines <i>(inc. Pentacel® and Pentaxim®)</i>	24	-31.4%	411	+46.9%	581	-8.1%	138	-22.7%
Influenza Vaccines <i>(inc. Vaxigrip® and Fluzone®)</i>	93	+12.0%	694	+25.7%	368	+28.5%	23	+18.2%
Meningitis/Pneumonia Vaccines <i>(inc. Menactra®)</i>	3	-40.0%	361	+2.3%	84	-32.6%	7	0.0%
Adult Booster Vaccines <i>(inc. Adacel®)</i>	59	-1.7%	276	+2.6%	49	+4.2%	14	0.0%
Travel and Other Endemics Vaccines	21	+16.7%	95	-2.1%	211	+1.4%	50	+3.8%
Other Vaccines	4	+33.3%	393	+11.8%	8	-27.3%	7	-33.3%
Total Vaccines	204	0.0%	2,230	+17.1%	1,301	-0.7%	239	-13.7%

(1)

France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark. Net sales in Europe generated by Sanofi Pasteur MSD (the joint venture between Sanofi and Merck & Co., Inc.) are not consolidated.

(2)

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

(3)

Japan, Canada, Australia and New Zealand.

Net Sales Animal Health segment

Net sales for the Animal Health segment in 2014 amounted to €2,076 million, up 4.6% on a reported basis and 6.7% at constant exchange rates.

The following table presents the 2014 and 2013 sales of our Animal Health segment by product range:

<i>(€ million)</i>	2014 Reported	2013 Reported	Change on a reported basis	Change at constant exchange rates
Companion animals	1,281	1,195	+7.2%	+8.8%
Production animals	795	790	+0.6%	+3.5%
Total Animal Health	2,076	1,985	+4.6%	+6.7%
<i>Of which fipronil-based products</i>	597	611	-2.3%	-0.2%
<i>Of which NexGard®</i>	113			
<i>Of which Vaccines</i>	720	727	-1.0%	+1.2%
<i>Of which avermectin-based products</i>	398	413	-3.6%	-1.7%
<i>Of which Other products</i>	248	234	+6.0%	+8.1%

Net sales for the **Companion Animals** franchise rose by 8.8% at constant exchange rates to €1,281 million, reflecting the resilience of the **fipronil** range (-0.2% at constant exchange rates, at €597 million) in the face of competition and the success of **NexGard®**, a new product launched in 2014 that generated €113 million in net sales.

Net sales for the **Production Animals** franchise rose by 3.5% at constant exchange rates to €795 million, driven by growth in products for ruminants in the United States.

Table of Contents

The following table breaks down net sales of our Animal Health segment by product and by geographical region in 2014:

(<i>€ million</i>) Product	Western Europe(1) Reported	Change at constant exchange rates	United States Reported	Change at constant exchange rates	Emerging Markets(2) Reported	Change at constant exchange rates	Rest of The World(3) Reported	Change at constant exchange rates
Fipronil-based products	181	+1.1%	272	-4.5%	104	+12.1%	40	-4.3%
NexGard®	9		98		1		5	
Vaccines	185	+1.1%	155	+2.0%	361	+0.8%	19	+5.3%
Avermectin-based products	55	-6.9%	225	+0.9%	56	+1.7%	62	-8.5%
Other products	84	0.0%	89	+7.4%	62	+21.8%	13	+7.7%
Total Animal Health	514	+1.8%	839	+13.0%	584	+4.9%	139	-1.3%

(1)

France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark.

(2)

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

(3)

Japan, Canada, Australia and New Zealand.

Net Sales by Geographical Region

We divide our sales geographically into four regions: the United States, Emerging Markets, Western Europe and the Rest of the World. The following table breaks down our 2014 and 2013 net sales by region:

(<i>€ million</i>)	2014 Reported	2013 Reported	Change on a reported basis	Change at constant exchange rates
Emerging Markets ⁽¹⁾	11,347	10,957	+3.6%	+9.3%
<i>Of which Eastern Europe and Turkey</i>	2,541	2,673	-4.9%	+5.0%
<i>Of which Asia (excl. Pacific region)</i>	3,205	3,040	+5.4%	+6.3%

Edgar Filing: Sanofi - Form 20-F

<i>Of which Latin America</i>	3,363	3,013	+11.6%	+21.1%
<i>Of which Africa</i>	1,032	1,028	+0.4%	+3.8%
<i>Of which Middle East</i>	1,063	1,071	-0.7%	+1.2%
United States	11,339	10,433	+8.7%	+8.2%
Western Europe ⁽²⁾	7,865	7,831	+0.4%	0.0%
Rest of the World ⁽³⁾	3,219	3,730	-13.7%	-7.2%
<i>Of which Japan</i>	2,119	2,507	-15.5%	-8.6%
Total	33,770	32,951	+2.5%	+4.9%

(1) *World excluding United States, Canada, Western Europe, Japan, Australia and New Zealand.*

(2) *France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark.*

(3) *Japan, Canada, Australia and New Zealand.*

In Emerging Markets, net sales reached €11,347 million, up 3.6% on a reported basis and 9.3% at constant exchange rates; excluding the Generics business in Brazil, growth in the region was 6.5% at constant exchange rates, driven by Diabetes (+17.4% at constant exchange rates), Genzyme (+26.7% at constant exchange rates) and Consumer Health Care (+28.4% at constant exchange rates). Net sales in Latin America surged by 21.1% at constant exchange rates, largely as a result of the effect of the recovery in generics sales on our performance in Brazil (+34.8% at constant exchange rates); excluding generics, sales in Brazil advanced by 6.9% at constant exchange rates, reflecting the performance of the Consumer Health Care, Genzyme and Vaccines businesses. In China, net sales were up 8.8% at constant exchange rates at €1,603 million, reflecting strong performances in Diabetes and Consumer Health Care but also lower vaccine sales due mainly to delays in shipments of Pentaxim®. Russia posted sales of €813 million, up 7.1% at constant exchange rates, propelled by Consumer Health Care and Diabetes.

Table of Contents

In the United States, net sales rose by 8.7% on a reported basis and 8.2% at constant exchange rates to €11,339 million on fine performances in Diabetes (+12.6% at constant exchange rates), Genzyme (+28.7% at constant exchange rates) and Vaccines (+17.1% at constant exchange rates). Other growth drivers included Consumer Health Care (+15.4% at constant exchange rates), boosted by the switch of Nasacort® to the OTC market, and the launch of the new animal health product NexGard®. These factors more than offset declining sales for Generics (-31.3% at constant exchange rates), Oncology (-4.9% at constant exchange rates), and other prescription products (-15.2% at constant exchange rates).

Net sales in Western Europe were steady at €7,865 million. Positive factors included the performances of Genzyme (+19.6% at constant exchange rates) and Diabetes (+8.3% at constant exchange rates), and the recent launches of Jevtana® and Zaltrap® in Oncology. The main negative factor was competition from generics of Aprovel® (-43.8% at constant exchange rates).

In the Rest of the World, net sales were €3,219 million, down 13.7% on a reported basis and 7.2% at constant exchange rates. In Japan, net sales came to €2,119 million (-8.6% at constant exchange rates), reflecting the impact of generic competition on sales of Allegra (-30.0% at constant exchange rates) and Myslee (-29.2% at constant exchange rates) and lower sales of the Imovax® vaccine.

Other Revenues

Other revenues, which mainly comprise royalties under licensing agreements contracted in connection with ongoing operations, fell by 4.5% to €339 million (compared with €355 million in 2013). The year-on-year change was mainly due to the ending of royalty streams from Amgen on Enbrel® in the United States during the first quarter of 2013.

Gross Profit

Gross profit amounted to €23,080 million in 2014 (68.3% of net sales), versus €22,315 million in 2013 (67.7% of net sales). This represents a year-on-year increase of 3.4%, and an improvement of 0.6 of a point in the gross margin ratio.

The gross margin ratio for the Pharmaceuticals segment was 1.3 points higher at 71.1%, reflecting on the downside a dip in royalty revenue (0.1 of a point), but on the upside an improvement in the ratio of cost of sales to net sales (1.4 points) due largely to the recovery in generics sales in Brazil, a stronger industrial performance by Genzyme and favorable price effects on net sales of Lantus®.

The gross margin ratio for the Vaccines segment was 1.2 points lower at 51.8%, reflecting a less favorable product mix.

The gross margin ratio for the Animal Health segment was 3.6 points lower at 63.2%, also due to a less favorable product mix.

Research and Development Expenses

Research and development (R&D) expenses amounted to €4,824 million in 2014 (versus €4,770 million in 2013) and represented 14.3% of net sales (versus 14.5% in 2013). Overall, R&D expenses increased by €54 million (+1.1%) year-on-year.

In the Pharmaceuticals segment, R&D expenses increased by €87 million (+2.1%), driven by investment in the advanced development pipeline (mainly monoclonal antibodies).

R&D expenses for the Vaccines segment fell by €25 million (-4.8%), largely due to the end of the Phase III clinical trials of the dengue fever vaccine.

In the Animal Health segment, R&D expenses were €8 million (-4.8%) lower than in 2013.

Selling and General Expenses

Selling and general expenses totaled €9,107 million, versus €8,603 million in 2013, an increase of €504 million (+5.9%). They represented 27.0% of net sales, versus 26.1% in 2013.

Table of Contents

In the Pharmaceuticals segment, selling and general expenses rose by €330 million (+4.5%) due to promotional spend in the Genzyme (multiple sclerosis and rare diseases) and Consumer Health Care businesses.

In the Vaccines segment, selling and general expenses were €26 million (+4.4%) higher due to increased promotional spend.

Selling and general expenses in the Animal Health segment increased by €29 million (+4.4%) as a result of higher promotional spend on NexGard®.

Other Operating Income and Expenses

In 2014, other operating income totaled €327 million (versus €691 million in 2013), and other operating expenses €163 million (versus €241 million in 2013).

Overall, other operating income and expenses represented net income of €164 million in 2014, versus net income of €450 million in 2013. This year-on-year decrease of €286 million was mainly attributable to a €165 million gain booked in 2013 on the sale to Covis Pharma of commercial rights to five pharmaceutical products in the United States, and also to a fall in revenues from the alliance with Warner Chilcott on Actonel®.

This line item also includes a net operating foreign exchange loss of €102 million, versus €64 million in 2013.

Amortization of Intangible Assets

Amortization charged against intangible assets totaled €2,482 million in 2014, versus €2,914 million in 2013. The year-on-year decrease of €432 million was mainly due to a reduction in amortization charged against intangible assets recognized on the acquisitions of Aventis (€874 million in 2014, versus €1,199 million in 2013) and of Genzyme (€811 million in 2014, versus €930 million in 2013) as some pharmaceutical products reached the end of their life cycles (in particular Actonel®, Lovenox® and Renegel®/Renvela®).

Impairment of Intangible Assets

In 2014, this line item showed a net reversal of impairment losses against intangible assets of €26 million, versus a net expense of €1,387 million in 2013. The 2014 figure includes a gain of €356 million arising because the impairment loss taken in 2013 against Lemtrada® (alemtuzumab) was reversed following approval of the product by the FDA in November 2014. It also includes the negative effects of (i) a net impairment loss of €203 million arising from various research projects in Pharmaceuticals and Vaccines, in particular the discontinuation of collaborative development programs with Alopexx (SAR 279 356) and Kalobios (*Pseudomonas aeruginosa* vaccine), and from revised commercial prospects (especially for the rotavirus vaccine project; and (ii) the impairment losses of €127 million taken against rights to a number of marketed products in the Pharmaceuticals, Vaccines and Animal Health segments (mainly Consumer Health Care assets in the Emerging Markets region).

The impairment losses recognized in 2013 related primarily to (i) Lemtrada® (alemtuzumab) in the United States, following the refusal by the FDA to approve the U.S. marketing application for this product in its then current form (€612 million); (ii) the discontinuation of the iniparib R&D project in non-small cell lung cancer and ovarian cancer (€384 million); and (iii) the discontinuation of the project on fedratinib, a selective JAK2 inhibitor in the treatment of polycythemia vera (€170 million).

Fair Value Remeasurement of Contingent Consideration Liabilities

Fair value remeasurements of contingent consideration liabilities recognized on acquisitions in accordance with the revised IFRS 3 represented a net expense of €303 million in 2014, versus a net gain of €314 million in 2013. This item mainly relates to the contingent consideration payable to Bayer as a result of an acquisition made by Genzyme prior to the latter's acquisition by Sanofi and to the contingent value rights (CVRs) issued by Sanofi in connection with the Genzyme acquisition (see Note D.18. to our consolidated financial statements). In 2013, these remeasurements also related to contingent consideration that arose on the acquisition of TargeGen but that was cancelled following discontinuation of the fedratinib project.

Restructuring Costs

Restructuring costs amounted to €411 million in 2014, versus €300 million in 2013, and relate primarily to measures associated with the major transformation program that we initiated in 2009 to adapt our structures to the

Table of Contents

challenges of the future. In both 2014 and 2013, these costs mainly comprised employee-related expenses arising from headcount adjustment plans in France and the rest of Europe.

Other Gains and Losses, and Litigation

Nothing was recognized on this line in either 2014 or 2013.

Operating Income

Operating income totaled €6,143 million for 2014, versus €5,105 million for 2013, an improvement of 20.3% attributable mainly to lower charges for amortization and impairment of intangible assets.

Financial Income and Expenses

Net financial expenses for 2014 were €412 million, versus €503 million for 2013, a decrease of €91 million.

Financial expenses directly related to our debt, net of cash and cash equivalents (see the definition in section "3. Consolidated Balance sheet" below) amounted to €293 million in 2014, versus €317 million in 2013, mainly reflecting a slight fall in the average level of net debt during 2014.

Net gains on disposals of non-current financial assets totaled €68 million (versus €42 million in 2013), and mainly related to divestments by Genzyme.

Net financial expenses for 2014 also included a gain of €35 million arising on the acquisition of shares in Alnylam in February 2014.

Income before Tax and Associates and Joint Ventures

Income before tax and associates and joint ventures amounted to €5,731 million in 2014, versus €4,602 million in 2013, an increase of 24.5%.

Income Tax Expense

Income tax expense represented €1,171 million in 2014, versus €763 million in 2013, giving an effective tax rate (based on consolidated net income) of 20.4% in 2014 compared with 16.6% in 2013 (see Note D.30. to our consolidated financial statements).

The level of income tax expense was significantly impacted by the positive tax effects arising on the amortization and impairment of intangible assets (€710 million in 2014, versus €1,466 million in 2013) and on restructuring costs (€143 million in 2014, versus €97 million in 2013). In addition, the tax effect of the fair value remeasurement of contingent consideration liabilities represented a benefit of €254 million in 2014, compared with an expense of €85 million in 2013. Overall, these effects increased our income tax expense by €371 million.

The effective tax rate based on our business net income is calculated on the basis of business operating income minus net financial expenses and before the share of profit/loss of associates and joint ventures and net income attributable to non-controlling interests. This effective tax rate was 24.0% in both 2014 and 2013. The tax rate is mainly impacted by the geographical mix of the results from Group entities, the tax effects of the elimination of intragroup margin on inventory, and settlements and recent proceedings involving the tax authorities in various countries that had a positive effect in both 2013 and 2014.

Share of Profit/Loss of Associates and Joint Ventures

Associates and joint ventures contributed a net loss of €51 million in 2014, versus net income of €35 million in 2013.

Since April 2014, this line item has included our share of the profits and losses of Regeneron (impact: expense of €126 million), including the impact of the fair value remeasurement of our share of the acquired intangible assets of Regeneron. It also includes our share of after-tax profits from territories managed by BMS under the Plavix® and Avapro® alliance (€31 million in 2014, versus €25 million in 2013), plus immaterial amounts for our share of profits and losses from other associates and joint ventures.

Table of Contents**Net Income**

Net income amounted to €4,509 million in 2014, versus €3,874 million in 2013.

Net Income Attributable to Non-Controlling Interests

Net income attributable to non-controlling interests was €119 million in 2014, versus €158 million in 2013. This line mainly comprises the share of pre-tax profits paid to BMS from territories managed by Sanofi (€109 million, versus €141 million in 2013). The year-on-year decrease was directly related to competition from generics of clopidogrel (active ingredient of Plavix®) and irbesartan (active ingredient of Aprovel®) in Europe.

Net Income Attributable to Equity Holders of Sanofi

Net income attributable to equity holders of Sanofi amounted to €4,390 million, versus €3,716 million in 2013.

Basic earnings per share for 2014 was €3.34, 18.9% higher than the 2013 figure of €2.81, based on an average number of shares outstanding of 1,315.8 million in 2014 (1,323.1 million in 2013). Diluted earnings per share for 2014 was €3.30 (versus €2.77 in 2013), based on an average number of shares outstanding after dilution of 1,331.1 million in 2014 and 1,339.1 million in 2013.

Business Operating Income

We report segment results on the basis of "Business Operating Income". This indicator, adopted in compliance with IFRS 8, is used internally to measure operational performance and to allocate resources. See "Item 5. Operating and Financial Review and Prospects – Segment information" above for the definition of business operating income and a reconciliation to Income before tax and associates and joint ventures.

Business operating income amounted to €9,449 million in 2014, 1.4% higher than in 2013 (€9,323 million) and represented 28.0% of net sales, versus 28.3% in 2013.

Business operating income for 2014 and 2013 is set forth below:

<i>(€ million)</i>	2014	2013(1)	Change
Pharmaceuticals	8,018	7,886	+1.7%
Vaccines	994	909	+9.4%
Animal Health	492	502	-2.0%
Other	(55)	26	
Business operating income	9,449	9,323	+1.4%

(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

Business net income is a non-GAAP financial measure that we use to evaluate our Group's performance. See "Item 5. Operating and Financial Review and Prospects – Business Net Income" above for the definition of business net income and a reconciliation to Net income attributable to equity holders of Sanofi.

Edgar Filing: Sanofi - Form 20-F

Business net income totaled €6,847 million in 2014, versus €6,686 million in 2013, an increase of 2.4%; it represented 20.3% of net sales in both 2014 and 2013.

Business Earnings Per Share

We also report business earnings per share, a non-GAAP financial measure which we define as business net income divided by the weighted average number of shares outstanding (see " Business Net Income" above).

Business earnings per share was €5.20 in 2014, 3.0% higher than the 2013 figure of €5.05, based on an average number of shares outstanding of 1,315.8 million in 2014 and 1,323.1 million in 2013.

Edgar Filing: Sanofi - Form 20-F

Table of Contents

Year Ended December 31, 2013 Compared with Year Ended December 31, 2012

The consolidated income statements for the years ended December 31, 2013 and December 31, 2012 break down as follows:

(under IFRS) <i>(€ million)</i>	2013(1)	as % of net sales	2012(1)	as % of net sales
Net sales	32,951	100.0%	34,947	100.0%
Other revenues	355	1.1%	1,010	2.9%
Cost of sales	(10,991)	(33.4%)	(11,098)	(31.8%)
Gross profit	22,315	67.7%	24,859	71.1%
Research & development expenses	(4,770)	(14.5%)	(4,905)	(14.0%)
Selling & general expenses	(8,603)	(26.1%)	(8,931)	(25.6%)
Other operating income	691		562	
Other operating expenses	(241)		(414)	
Amortization of intangible assets	(2,914)		(3,291)	
Impairment of intangible assets	(1,387)		(117)	
Fair value remeasurement of contingent consideration liabilities	314		(192)	
Restructuring costs	(300)		(1,141)	
Other gains and losses, and litigation				
Operating income	5,105	15.5%	6,430	18.4%
Financial expenses	(612)		(751)	
Financial income	109		93	
Income before tax and associates and joint ventures	4,602	14.0%	5,772	16.5%
Income tax expense	(763)		(1,108)	
Share of profit/(loss) of associates and joint ventures	35		393	
Net income	3,874	11.8%	5,057	14.5%
Net income attributable to non-controlling interests	158		169	
Net income attributable to equity holders of Sanofi	3,716	11.3%	4,888	14.0%

Edgar Filing: Sanofi - Form 20-F

Average number of shares outstanding (million)	1,323.1	1,319.5
Average number of shares outstanding after dilution (million)	1,339.1	1,329.6
Basic earnings per share (in euros)	2.81	3.70
Diluted earnings per share (in euros)	2.77	3.68

(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).

Net Sales

Consolidated net sales for the year ended December 31, 2013 amounted to €32,951 million, 5.7% lower than in 2012. Exchange rate movements had an unfavorable effect of 5.2 points, mainly reflecting the depreciation of the Japanese yen, the U.S. dollar, the Brazilian real, the Venezuelan bolivar, the Australian dollar and the South African rand against the euro. At constant exchange rates, net sales fell by 0.5% year-on-year.

The following table sets forth a reconciliation of our reported net sales for the years ended December 31, 2013 and December 31, 2012 to our net sales at constant exchange rates:

<i>(€ million)</i>	2013	2012	Change
Net sales	32,951	34,947	-5.7%
Effect of exchange rates	1,806		
Net sales at constant exchange rates	34,757	34,947	-0.5%

Table of Contents

Our net sales comprise the net sales generated by our Pharmaceuticals, Human Vaccines (Vaccines) and Animal Health segments.

The following table breaks down our 2013 and 2012 net sales by business segment:

<i>(€ million)</i>	2013 Reported	2012 Reported	Change on a reported basis	Change at constant exchange rates
Pharmaceuticals	27,250	28,871	-5.6%	-0.2%
Vaccines	3,716	3,897	-4.6%	-0.1%
Animal Health	1,985	2,179	-8.9%	-5.3%
Total	32,951	34,947	-5.7%	-0.5%

Net Sales by Product Pharmaceuticals segment

In 2013, net sales for the Pharmaceuticals segment were €27,250 million, down 5.6% on a reported basis and 0.2% at constant exchange rates.

The year-on-year change (decrease of €1,621 million) reflects the negative effect of exchange rates (€1,551 million) on the one hand, and the following impacts at constant exchange rates on the other hand:

the positive performance of growth platforms (€1,684 million), mainly our Diabetes and Genzyme businesses;

the negative effects of generic competition (mainly on sales of Eloxatin® and Lovenox® in the United States, and of Aprovel® and Plavix® in Western Europe), totaling €1,253 million of net sales lost; and

other impacts (negative evolution of €501 million), including the negative impact of austerity measures in the European Union and temporary difficulties in distribution channels for our Generics business in Brazil.

Our flagship products (Lantus® and Apidra®; Cerezyme®, Myozyme® / Lumizyme®, Fabrazyme®, Aubagio® and Lemtrada®; Jevtana®, Taxotere®, Eloxatin®, Mozobil® and Zaltrap®; Plavix®, Lovenox®, Aprovel® / CoAprovel®, Renagel® / Renvela®, Allegra®, Stilnox® / Ambien® / Myslee®, Synvisc® / Synvisc-One®, Multaq® and Auvi-Q®) are discussed below.

Table of Contents

The following table breaks down our 2013 and 2012 net sales for the Pharmaceuticals segment by product:

<i>(€ million)</i>				Change on a reported basis	Change at constant exchange rates
Product	Indication	2013 Reported	2012 Reported		
Lantus®	Diabetes	5,715	4,960	+15.2%	+20.0%
Apidra®	Diabetes	288	230	+25.2%	+31.7%
Amaryl®	Diabetes	375	421	-10.9%	-1.0%
Insuman®	Diabetes	132	135	-2.2%	0.0%
Blood glucose meters	Diabetes	48	36	+33.3%	+36.1%
Lyxumia®	Diabetes	9			
Other products		1			
Total: Diabetes	Diabetes	6,568	5,782	+13.6%	+18.7%
Taxotere®	Breast, lung, prostate, stomach, and head & neck cancer	409	563	-27.4%	-19.5%
Jevtana®	Prostate cancer	231	235	-1.7%	+1.3%
Eloxatin®	Colorectal cancer	221	956	-76.9%	-76.0%
Thymoglobulin®	Organ rejection	198	193	+2.6%	+7.3%
Mozobil®	Hematologic malignancies	101	96	+5.2%	+8.3%
Zaltrap®	Colorectal cancer	53	25	+112.0%	+116.0%
Other products		252	326	-22.7%	-18.7%
Total: Oncology		1,465	2,394	-38.8%	-35.3%
Cerezyme®	Gaucher disease	688	633	+8.7%	+13.9%
Myozyme®/Lumizyme®	Pompe disease	500	462	+8.2%	+11.9%
Fabrazyme®	Fabry disease	383	292	+31.2%	+39.0%
Aldurazyme®	Mucopolysaccharidosis	159	150	+6.0%	+11.3%

Edgar Filing: Sanofi - Form 20-F

Other products		244	241	+1.2%	+8.7%
Sub-total: Rare diseases		1,974	1,778	+11.0%	+16.6%
Aubagio®	Multiple sclerosis	166	7		
Lemtrada®	Multiple sclerosis	2			
Sub-total: Multiple sclerosis		168	7		
Total: Genzyme		2,142	1,785	+20.0%	+25.9%
Plavix®	Atherothrombosis	1,857	2,066	-10.1%	+1.1%
Lovenox®	Thrombosis	1,703	1,893	-10.0%	-7.2%
Aprovel®/CoAprovel®	Hypertension	882	1,151	-23.4%	-20.9%
Renagel®/Renvela®	Hyperphosphatemia	750	653	+14.9%	+19.0%
Allegra®	Allergic rhinitis, urticaria	406	553	-26.6%	-12.1%
Depakine®	Epilepsy	405	410	-1.2%	+2.7%
Stilnox®/Ambien®/Myslee®	Sleep disorders	391	497	-21.3%	-9.5%
Synvisc®/Synvisc-One®	Arthritis	371	363	+2.2%	+6.1%
Tritace®	Hypertension	307	345	-11.0%	-7.2%
Multaq®	Atrial fibrillation	269	255	+5.5%	+8.2%
Lasix®	Edema, hypertension	172	210	-18.1%	-9.5%
Targocid®	Bacterial infections	166	198	-16.2%	-11.1%
Orudis®	Rheumatoid arthritis, osteoarthritis	144	184	-21.7%	-9.8%
Cordarone®	Arrhythmia	141	163	-13.5%	-4.3%
Xatral®	Benign prostatic hypertrophy	101	130	-22.3%	-20.0%
Actonel®	Osteoporosis, Paget's disease	100	134	-25.4%	-20.1%
Auvi-Q®	Severe allergies, anaphylaxis	51			

Edgar Filing: Sanofi - Form 20-F

Other products	4,230	4,853	-12.8%	-8.1%
Total: Other prescription products	12,446	14,058	-11.5%	-5.5%
Consumer Health Care	3,004	3,008	-0.1%	+5.2%
Generics	1,625	1,844	-11.9%	-8.2%
Total Pharmaceuticals	27,250	28,871	-5.6%	-0.2%

Table of Contents

Diabetes division

Net sales for the Diabetes division were €6,568 million, up 18.7% at constant exchange rates, driven by double-digit growth for Lantus® and Apidra®.

Lantus® increased its net sales by 20.0% (at constant exchange rates) to €5,715 million in 2013 due to robust growth in the United States (up 25.6% at constant exchange rates, at €3,747 million) driven by Lantus® SoloSTAR®, which accounted for 57% of full-year sales, and to a solid performance in Emerging Markets (up 16.8% at constant exchange rates), especially in the Africa/Middle East region (up 34.6% at constant exchange rates) and in Eastern Europe (up 14.5% at constant exchange rates). In Western Europe, growth was once again modest (up 4.1% at constant exchange rates).

The product's sales growth reflected both an increase in volumes and a generally favorable price effect. Volumes grew in all geographic segments during 2013 (+9.8% overall), especially in Emerging Markets but also in the United States, reflecting continued strength in prescription rates. We expect continued strength in prescription rates in all geographic segments in the medium term. In the longer term, volume growth will be dependent on a number of factors such as new competing products entering the markets and prevalence of type 2 diabetes. We expect the Emerging Markets zone to continue to be a robust contributor to volume growth going forward, reflecting increased diagnosis of Diabetes and better access to drugs.

Price effects were overall favorable (+10.2% at constant exchange rates), with price rises in the United States and other key markets more than offsetting price pressure in some countries, such as China. We cannot foresee what the long-term price effects will be, as these will depend on the impact of new competing products on the pricing of diabetes treatments across all geographic treatments. However, favorable price effects are expected in the United States in the short term.

Net sales of **Apidra®** totaled €288 million in 2013, up 31.7% at constant exchange rates, due to a strong performance in the United States (up 58.9% at constant exchange rates, at €112 million).

Amaryl® posted a 1.0% fall in net sales at constant exchange rates to €375 million, reflecting the effect of generic competition in Japan (down 18.4% at constant exchange rates, at €81 million), but also a good performance in Emerging Markets (up 9.9% at constant exchange rates, at €269 million).

Lyxumia® (lixisenatide, in-licensed from Zealand Pharma) was launched in various Western European countries, in Japan and in Mexico in 2013, and generated net sales of €9 million.

Oncology business

The Oncology business posted net sales of €1,465 million, down 35.3% at constant exchange rates, due mainly to the effects of the expected expiration of exclusivity for Eloxatin® in the United States.

Eloxatin® saw net sales fall sharply in 2013, by 76.0% at constant exchange rates to €221 million, triggered by increased competition from generics in the United States beginning in August 2012.

Net sales of **Taxotere®** fell by 19.5% at constant exchange rates to €409 million. The product is facing competition from generics in Western Europe (down 56.6% at constant exchange rates, at €22 million), in the United States (down 18.9% at constant exchange rates, at €42 million) and in Emerging Markets (down 18.5% at constant exchange rates, at €211 million).

Jevtana® reported net sales of €231 million in 2013, up 1.3% at constant exchange rates, reflecting competitive pressure in the United States, where sales slipped by 19.3% at constant exchange rates to €86 million, counteracted by a strong performance in Western Europe (up 22.0% at constant exchange rates, at €110 million).

Sales of **Mozobil®** rose by 8.3% at constant exchange rates to €101 million.

Net sales of **Zaltrap®** reached €53 million, up 116.0% at constant exchange rates. The product generated sales of €36 million in the United States, where it was launched in the third quarter of 2012 (up 54.2% at constant exchange rates), and sales of €15 million in Western Europe, where launches began during the first half of 2013.

Net sales of other Oncology products fell by 18.7% at constant exchange rates to €252 million, due mainly to the withdrawal of Campath® from the market in the second half of 2012.

Table of Contents

Jevtana®, Zaltrap® and Mozobil®, along with the other pharmaceutical products Multaq® and Auvi-Q®⁽¹⁾ (see " Other pharmaceutical products" below), constitute the "Other Innovative Products" growth platform, which in 2013 generated €705 million of net sales, up 18.8% at constant exchange rates.

Genzyme business

The Genzyme business generated net sales of €2,142 million, up 25.9% at constant exchange rates, reflecting the return to full supply capacity for Cerezyme® and Fabrazyme®, an increased number of patients in rare diseases, and the launch of Aubagio® in the United States.

For more information regarding the manufacturing issues related to Cerezyme® and Fabrazyme® see "Item 4 Information on the Company B.8. Production and Raw Materials."

In rare diseases, **Cerezyme®** increased its net sales by 13.9% at constant exchange rates to €688 million, driven by Emerging Markets (up 36.3% at constant exchange rates, at €241 million) and the United States (up 10.8% at constant exchange rates, at €178 million).

Net sales of **Myozyme®/Lumizyme®** rose by 11.9% at constant exchange rates to €500 million, due to an increase in sales in Emerging Markets (up 43.6% at constant exchange rates, at €74 million) and increased sales in Western Europe (up 7.4% at constant exchange rates, at €274 million).

Fabrazyme® reported strong net sales growth of 39.0% at constant exchange rates, to €383 million. The product was boosted by a rebound in the United States (up 33.6% at constant exchange rates, at €196 million) and Western Europe (up 69.2% at constant exchange rates at €87 million), mainly due to an increase in the number of new patients.

In multiple sclerosis, **Aubagio®**, which was launched in the United States in October 2012, and in some Western European countries in the fourth quarter of 2013, generated net sales of €166 million in 2013 (of which €152 million came from the United States). **Lemtrada®**, launched in Germany in October 2013, posted sales of €2 million.

Other pharmaceutical products

Net sales of **Plavix®** were up 1.1% at constant exchange rates at €1,857 million. Growth was limited by the effect of a fall in sales of the active ingredient to the entity majority owned by BMS in the United States (down 93.4% at constant exchange rates, at €5 million), where the product lost its exclusivity on May 17, 2012. Sales of Plavix® in the United States and Puerto Rico are handled by BMS under the terms of the Sanofi-BMS alliance (see " Financial presentation of alliances Alliance Arrangements with Bristol-Myers Squibb" above). In Emerging Markets, Plavix® reported net sales growth of 4.6% at constant exchange rates to €807 million, driven by sales in China (up 14.3% at constant exchange rates, at €422 million). In Japan, sales rose by 13.3% at constant exchange rates to €748 million. In Western Europe, sales fell year-on-year (down 16.3% at constant exchange rates, at €257 million) as a result of competition from generics.

Lovenox® saw net sales fall in 2013 by 7.2% at constant exchange rates to €1,703 million due to competition from generics in the United States, where sales of the branded product were down 39.5% at constant exchange rates at €187 million (sales of the generic version of Lovenox® launched by Sanofi in 2012 are recorded by our Generics business). Sales rose by 0.9% at constant exchange rates in Western Europe to €858 million, while in Emerging Markets sales were down 2.6% at €563 million.

Aprovel®/CoAprovel® reported a drop in net sales of 20.9% at constant exchange rates to €882 million, mainly as a result of competition from generics in Western Europe, where sales were 39.1% lower at €338 million. Emerging Markets net sales increased by 9.1% at constant exchange rates to €410 million.

Net sales of **Renagel®/Renvela®** rose by 19.0% at constant exchange rates to €750 million, driven by a strong performance in the United States (up 22.0% at constant exchange rates, at €531 million) and in Emerging Markets (up 35.8% at constant exchange rates, at €67 million).

Allegra® posted a fall in prescription net sales (down 12.1% at constant exchange rates, at €406 million), affected by competition from generics in Japan (down 18.4% at constant exchange rates, at €280 million). Net sales of Allegra® OTC in the United States and in Japan are recorded by the Consumer Health Care business.

(1) *Sanofi U.S. has in-licensed the North American commercialization rights for Auvi-Q® from Intelliject, Inc.*

Table of Contents

Net sales of **Stilnox®/Ambien®/Myslee®** fell by 9.5% at constant exchange rates to €391 million, reflecting competition from generics of Myslee® in Japan (down 17.1% at constant exchange rates at €192 million).

Synvisc®/Synvisc-One® achieved net sales of €371 million, up 6.1% at constant exchange rates. Sales held fairly steady in the United States (up 1.0% at constant exchange rates, at €295 million).

Net sales of **Multaq®** increased by 8.2% at constant exchange rates to €269 million, of which €216 million was generated in the United States (up 11.5% at constant exchange rates).

Auvi-Q® recorded net sales of €51 million in the United States, where it was launched in January 2013.

No comments are called for in respect of our other prescription medicines.

Consumer Health Care business

During 2013, the **Consumer Health Care** business increased its net sales by 5.2% at constant exchange rates to €3,004 million, driven by growth in Emerging Markets (up 7.9% at constant exchange rates, at €1,482 million) and the United States (up 4.8% at constant exchange rates, at €616 million).

Net sales of Allegra® OTC rose by 7.4% at constant exchange rates, reflecting the product's launch in Japan at the end of 2012. Essentiale®, Enterogermina® and No Spa® all achieved double-digit net sales growth (at constant exchange rates).

The following table breaks down our 2013 and 2012 net sales for the Consumer Health Care business by product:

<i>(€ million)</i>			Change on a reported basis	Change at constant exchange rates
Product	2013 Reported	2012 Reported		
Doliprane®	290	268	+8.2%	+9.0%
Allegra®	264	256	+3.1%	+7.4%
Essentiale®	207	178	+16.3%	+21.9%
Enterogermina®	130	119	+9.2%	+21.8%
No Spa®	117	110	+6.4%	+10.0%
Lactacyd®	105	110	-4.5%	+3.6%
Dorflex®	93	101	-7.9%	+5.0%
Other products	1,798	1,866	-3.6%	+1.4%
Total Consumer Health Care	3,004	3,008	-0.1%	+5.2%

Generics business

The **Generics** business reported net sales of €1,625 million in 2013, down 8.2% at constant exchange rates, with the performance adversely affected by temporary difficulties in distribution channels in Brazil.

Edgar Filing: Sanofi - Form 20-F

During the second quarter of 2013, Sanofi became aware that distribution channels in Brazil were holding inventory levels substantially and inappropriately in excess of the volumes needed to meet demand. Consequently, an adjustment was booked for product returns, discounts and chargebacks, the net impact of which was to reduce net sales by €122 million. An additional provision of €79 million was also booked to cover inventory write-downs and other associated costs.

However, the business was boosted by organic sales growth in Western Europe (up 11.4% at constant exchange rates, at €552 million), principally in the French market, where the penetration of generics increased. In Emerging Markets, the business generated sales of €858 million (down 12.8% at constant exchange rates), hampered by the adjustment to net sales in Brazil. In the United States, net sales fell by 32.4% at constant exchange rates to €179 million, reflecting a decline in sales of authorized generics of Lovenox®, Aprovel® and Taxotere®, due partly to unfavorable price effects.

Table of Contents

The following table breaks down net sales of our Pharmaceutical segment products by geographical region in 2013:

<i>(€ million)</i>		Change at		Change at		Change at	Rest of	Change at
Product	Western Europe(1) Reported	constant exchange rates	United States Reported	constant exchange rates	Emerging Markets(2) Reported	constant exchange rates	the world(3) Reported	constant exchange rates
Lantus®	804	+4.1%	3,747	+25.6%	874	+16.8%	290	+12.3%
Apidra®	84	+7.7%	112	+58.9%	63	+31.4%	29	+28.6%
Amaryl®	22	-21.4%	2	-33.3%	269	+9.9%	82	-18.1%
Insuman®	90	-8.2%	1	0.0%	42	+18.9%	(1)	-100.0%
Blood glucose meters	45	+50.0%		-100.0%	1		2	
Lyxumia®	6						3	
Other products					1			
Total: Diabetes	1,051	+4.4%	3,862	+26.1%	1,250	+16.1%	405	+5.7%
Taxotere®	22	-56.6%	42	-18.9%	211	-18.5%	134	-10.7%
Jevtana®	110	+22.0%	86	-19.3%	31	+3.0%	4	150.0%
Eloxatin®	6	-53.8%	19	-97.4%	127	-14.4%	69	+1.4%
Thymoglobulin®	31	+6.9%	102	+8.2%	53	+10.0%	12	-6.3%
Mozobil®	32	+6.7%	56	+3.6%	10	+42.9%	3	+33.3%
Zaltrap®	15		36	+54.2%	2			-100.0%
Other products	54	-26.7%	149	-15.8%	30	-28.9%	19	+4.3%
Total: Oncology	270	-6.2%	490	-59.3%	464	-13.3%	241	-5.3%
Cerezyme®	225	+5.1%	178	+10.8%	241	+36.3%	44	-16.1%
Myozyme®/Lumizyme®	274	+7.4%	123	+9.4%	74	+43.6%	29	+3.0%
Fabrazyme®	87	+69.2%	196	+33.6%	51	+31.7%	49	+29.8%
Aldurazyme®	60	+5.2%	29	+15.4%	54	+21.3%	16	0.0%

Edgar Filing: Sanofi - Form 20-F

Other products	39	+14.7%	99	+5.2%	39	+13.9%	67	+8.0%
Sub-total Rare diseases	685	+12.0%	625	+16.0%	459	+32.8%	205	+4.7%
Aubagio®	12		152		2			
Lemtrada®	2							
Sub-total Multiple sclerosis	14		152		2			
Total: Genzyme	699	+14.3%	777	+42.6%	461	+33.3%	205	+5.1%
Plavix®	257	-16.3%	5*	-93.4%	807	+4.6%	788	+12.1%
Lovenox®	858	+0.9%	187	-39.5%	563	-2.6%	95	-1.9%
Aprovel®/CoAprovel®	338	-39.1%	17*	-60.0%	410	+9.1%	117	-20.8%
Renagel®/Renvela®	133	+4.7%	531	+22.0%	67	+35.8%	19	0.0%
Allegra®	10	-9.1%	(3)		120	+12.5%	279	-18.7%
Depakine®	138	-2.1%			252	+5.6%	15	0.0%
Stilnox®/Ambien®/Myslee®	42	-8.7%	88	-7.1%	65	0.0%	196	-16.6%
Synvisc®/Synvisc-One®	25	+25.0%	295	+1.0%	33	+45.8%	18	+17.6%
Tritace®	136	-9.3%			160	-4.4%	11	-20.0%
Multaq®	43	-6.5%	216	+11.5%	8	+12.5%	2	0.0%
Lasix®	75	-5.1%	3	0.0%	50	-11.3%	44	-13.6%
Targocid®	79	-8.1%			75	-10.0%	12	-27.3%
Orudis®	24	-52.9%			117	+7.8%	3	-25.0%
Cordarone®	25	-10.7%			74	+2.6%	42	-10.2%
Xatral®	39	-13.3%	3	-85.0%	58	-3.2%	1	-33.3%
Actonel®	22	-33.3%			48	-22.7%	30	-2.9%
Auvi-Q®			51					
Other products	1,645	-13.1%	497	-12.0%	1,607	-0.3%	481	-11.1%
Total: Other prescription products	3,889	-13.0%	1,890	-6.1%	4,514	+1.8%	2,153	-5.4%

Consumer Health Care	664	-0.2%	616	+4.8%	1,482	+7.9%	242	+3.9%
Generics	552	+11.4%	179	-32.4%	858	-12.8%	36	+51.9%
Total Pharmaceuticals	7,125	-5.4%	7,814	+1.8%	9,029	+3.2%	3,282	-2.6%

(1)

France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark.

(2)

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

(3)

Japan, Canada, Australia and New Zealand.

*

Sales of active ingredient to the entity majority-owned by BMS in the United States.

Table of Contents**Net Sales Human Vaccines (Vaccines) segment**

In 2013, the Vaccines segment posted net sales of €3,716 million, down 4.6% on a reported basis and 0.1% at constant exchange rates.

The following table presents the 2013 and 2012 sales of our Vaccines segment by range of products:

<i>(€million)</i>	2013 Reported	2012 Reported	Change on a reported basis	Change at constant exchange rates
Polio/Pertussis/Hib Vaccines (including Pentacel® and Pentaxim®)	1,148	1,184	-3.0%	+3.2%
Influenza Vaccines (including Vaxigrip® and Fluzone®)	929	884	+5.1%	+9.3%
Meningitis/Pneumonia Vaccines (including Menactra®)	496	650	-23.7%	-20.8%
Adult Booster Vaccines (including Adacel®)	391	496	-21.2%	-18.5%
Travel and Other Endemics Vaccines	382	364	+4.9%	+9.9%
Other Vaccines	370	319	+16.0%	+21.0%
Total Vaccines	3,716	3,897	-4.6%	-0.1%

Polio/Pertussis/Hib vaccines reported net sales up 3.2% at constant exchange rates, to €1,148 million. This reflected a good performance in Emerging Markets (€644 million, up 33.9% at constant exchange rates), driven by the success of Pentaxim®, especially in China, but also a decline in net sales of 23.8% at constant exchange rates in the United States (to €275 million) triggered by supply limitations for Pentacel® and Adacel® lasting from April 2012 until October 2013.

Net sales of **Influenza** vaccines were up 9.3% at constant exchange rates at €929 million, helped by a strong performance in the United States (up 20.4% at €533 million) with the Fluzone® range; in Emerging Markets, net sales were down 5.7% at constant exchange rates at €291 million.

Meningitis/Pneumonia vaccines posted net sales of €496 million, down 20.8% at constant exchange rates, affected by a contraction in sales of Menactra® (down 21.5% at constant exchange rates, at €424 million), largely in the United States where the timing of public procurement tenders was less favorable than in 2012. In Emerging Markets, sales for the franchise fell by 17.6% at constant exchange rates to €132 million.

Net sales of **Adult Booster** vaccines were 18.5% lower at constant exchange rates at €391 million, mainly due to reduced sales of Adacel® in the United States (down 25.3% at constant exchange rates, at €234 million) following the temporary restrictions on shipments.

Net sales of **Travel and Other Endemics** vaccines were up 9.9% at constant exchange rates at €382 million, driven by vaccines against rabies and hepatitis A.

Other Vaccines saw net sales rise by 21.0% at constant exchange rates to €370 million, reflecting the expansion of VaxServe, a Sanofi Pasteur company that supplies vaccines in the United States.

In addition to the Vaccines activity reflected in our consolidated net sales, sales generated by Sanofi Pasteur MSD, our joint venture with Merck & Co., Inc. in Europe, reached €876 million in 2013, up 3.7% (on a reported basis), boosted by sales of the Zostavax® vaccine launched at the end of 2012. Sales generated by Sanofi Pasteur MSD are not included in our consolidated net sales.

Table of Contents

The following table presents the 2013 sales of our Vaccines segment by range of products and by region:

<i>(€ million)</i>	Western Europe (1) Reported	Change at constant exchange rates	United States Reported	Change at constant exchange rates	Emerging Markets (2) Reported	Change at constant exchange rates	Rest of the world (3) Reported	Change at constant exchange rates
Polio/Pertussis/Hib Vaccines <i>(inc. Pentacel® and Pentaxim®)</i>	35	-34.5%	275	-23.8%	644	+33.9%	194	-8.5%
Influenza Vaccines <i>(inc. Vaxigrip® and Fluzone®)</i>	83	+5.1%	533	+20.4%	291	-5.7%	22	+4.5%
Meningitis/Pneumonia Vaccines <i>(inc. Menactra®)</i>	5	+25.0%	352	-22.4%	132	-17.6%	7	-12.5%
Adult Booster Vaccines <i>(inc. Adacel®)</i>	60	+3.4%	268	-25.3%	48	+11.1%	15	-25.0%
Travel and Other Endemics Vaccines	18	-14.3%	97	+5.2%	215	+11.4%	52	+23.9%
Other Vaccines	3	-88.9%	347	+30.0%	11	-33.3%	9	-13.3%
Total Vaccines	204	-10.1%	1,872	-5.2%	1,341	+11.5%	299	-4.9%

(1)

France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark. Net sales in Europe generated by Sanofi Pasteur MSD (the joint venture between Sanofi and Merck & Co., Inc.) are not consolidated.

(2)

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

(3)

Japan, Canada, Australia and New Zealand.

In the United States, sales of vaccines were down 5.2% at constant exchange rates at €1,872 million, reflecting the supply limitations for Pentacel® and Adacel® coupled with weaker sales of Menactra®. In Emerging Markets, sales growth (up 11.5% at constant exchange rates) was driven by the success of Pentaxim®, especially in China. In the Rest of the World, the fall of 4.9% at constant exchange rates was due largely to lower sales of Imovax® in Japan, reflecting the end of the catch-up vaccinations that followed the launch of this product in September 2012.

Net Sales Animal Health segment

Net sales for the Animal Health segment in 2013 amounted to €1,985 million, down 5.3% at constant exchange rates or 8.9% on a reported basis.

The following table presents the 2013 and 2012 sales of our Animal Health segment by range of products:

<i>(€million)</i>	2013 Reported	2012 Reported	Change on a reported basis	Change at constant exchange rates
Companion animals	1,195	1,372	-12.9%	-9.8%
Production animals	790	807	-2.1%	+2.1%
Total Animal Health	1,985	2,179	-8.9%	-5.3%
<i>Of which other fipronil-based products</i>	<i>611</i>	<i>775</i>	<i>-21.2%</i>	<i>-17.8%</i>
<i>Of which Vaccines</i>	<i>727</i>	<i>730</i>	<i>-0.4%</i>	<i>+3.0%</i>
<i>Of which avermectin-based products</i>	<i>413</i>	<i>423</i>	<i>-2.4%</i>	<i>+1.7%</i>
<i>Of which Other products</i>	<i>234</i>	<i>251</i>	<i>-6.8%</i>	<i>-2.8%</i>

Net sales for the **Companion Animals** franchise were 9.8% lower at constant exchange rates, at €1,195 million. Sales of products in the **fipronil** range (down 17.8% at constant exchange rates, at €611 million) were affected by increased competition from prescription products and branded generics, and by unfavorable weather conditions in the United States and Western Europe; however, they performed well in Emerging Markets (up 16.1% at constant exchange rates, at €99 million).

Sales of **Production Animals** franchise products rose by 2.1% at constant exchange rates to €790 million, driven by growth for avermectin products in the United States (up 3.6% at constant exchange rates, at €225 million).

Table of Contents

The following table breaks down net sales of our Animal Health segment by product and by geographical region in 2013:

(€ million) Product	Western Europe(1)	Change at constant exchange rates	United States	Change at constant exchange rates	Emerging Markets(2)	Change at constant exchange rates	Rest of The World(3)	Change at constant exchange rates
Fipronil-based products	177	-13.9%	289	-28.0%	99	+16.1%	46	-14.3%
Vaccines	182	+1.1%	152	+3.3%	374	+4.3%	19	-4.5%
Avermectin-based products	58	-6.5%	225	+3.6%	59	-1.5%	71	+5.5%
Other products	85	-2.3%	81	-11.7%	55	+28.3%	13	-30.4%
Total Animal Health	502	-6.1%	747	-12.8%	587	+7.4%	149	-7.2%

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

Net Sales by Geographical Region

We divide our sales geographically into four regions: the United States, Emerging Markets, Western Europe and the Rest of the World. The following table breaks down our 2013 and 2012 net sales by region:

(€ million)	2013 Reported	2012 Reported	Change on a reported basis	Change at constant exchange rates
United States	10,433	10,873	-4.0%	-0.7%
Emerging Markets ⁽¹⁾	10,957	11,145	-1.7%	+4.4%
<i>Of which Eastern Europe and Turkey</i>	2,673	2,721	-1.8%	+2.2%
<i>Of which Asia (excl. Pacific region)</i>	3,040	2,841	+7.0%	+10.1%

Edgar Filing: Sanofi - Form 20-F

<i>Of which Latin America</i>	3,013	3,435	-12.3%	-1.5%
<i>Of which Africa</i>	1,028	1,018	+1.0%	+7.7%
<i>Of which Middle East</i>	1,071	1,001	+7.0%	+10.6%
Western Europe ⁽²⁾	7,831	8,335	-6.0%	-5.6%
Rest of the World ⁽³⁾	3,730	4,594	-18.8%	-2.9%
<i>Of which Japan</i>	2,507	3,274	-23.4%	-4.3%
Total	32,951	34,947	-5.7%	-0.5%

(1) *World excluding United States, Canada, Western Europe, Japan, Australia and New Zealand.*

(2) *France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark.*

(3) *Japan, Canada, Australia and New Zealand.*

In the United States, net sales fell by 4.0% on a reported basis (down 0.7% at constant exchange rates) to €10,433 million. Negative factors included the loss of exclusivity of Eloxatin® in August 2012 (down 97.4% at constant exchange rates), competition from generics of Lovenox® (down 39.5% at constant exchange rates), and supply limitations for Pentacel® and Adacel® in the Polio/ Pertussis/Hib vaccines franchise (down 23.8% at constant exchange rates). Positive factors included strong performances by the Genzyme business (up 42.6% at constant exchange rates, at €777 million) and the Diabetes division (up 26.1% at constant exchange rates, at €3,862 million).

In Emerging Markets, net sales were €10,957 million, down 1.7% on a reported basis and up 4.4% at constant exchange rates. Growth was slowed by temporary difficulties in the Generics business in Brazil, but was mainly driven increases by the Diabetes division (up 16.1% at constant exchange rates, at €1,250 million), by the Vaccines segment (up 11.5% at constant exchange rates, at €1,341 million) and by Genzyme (up 33.3% at constant exchange rates, at €461 million). In China, net sales totaled €1,471 million, up 18.6% at constant exchange rates, reflecting strong performances by Plavix®, Aprovel®, Lantus® and the Vaccines segment. Russia posted sales of €901 million, up

Table of Contents

12.0% at constant exchange rates, with Consumer Health Care and Generics having the most impact. Net sales in Brazil slipped by 18.2% at constant exchange rates to €1,111 million, affected by temporary difficulties in distribution channels for the Generics business.

Western Europe saw net sales fall by 6.0% on a reported basis and 5.6% at constant exchange rates to €7,831 million, hit by competition from generics of Aprovel® (down 39.1% at constant exchange rates) and Plavix® (down 16.3% at constant exchange rates) and by the impact of austerity measures.

In the Rest of the World, net sales were €3,730 million, down 18.8% on a reported basis (largely due to the depreciation of the Japanese yen against the euro) and 2.9% at constant exchange rates. In Japan, net sales came to €2,507 million (down 4.3% at constant exchange rates), reflecting on the one hand the impact of generic competition on sales of Allegra® (down 18.4% at constant exchange rates, at €280 million) and Myslee® (down 17.1% at constant exchange rates, at €192 million) combined with lower sales of the Imovax® vaccine, but on the other hand a fine performance by Plavix® (up 13.3% at constant exchange rates, at €748 million).

Other Revenues

Other revenues, which mainly comprise royalties under licensing agreements contracted in connection with ongoing operations, fell by 64.9% to €355 million (compared with €1,010 million in 2012).

The decrease was largely due to lower licensing revenue under the worldwide alliance with BMS on Plavix® and Aprovel®, which represented €4 million in 2013 versus €532 million in 2012 (down 99.2% on a reported basis), due to the loss of exclusivity in the United States for Aprovel® (from March 30, 2012) and Plavix® (from May 17, 2012).

A further factor was a drop in royalties received from Amgen under a worldwide license for Enbrel®, reflecting the contractual termination of royalty payments on U.S. sales of the product in February 2013.

Gross Profit

Gross profit amounted to €22,315 million in 2013 (67.7% of net sales), versus €24,859 million in 2012 (71.1% of net sales). This represents a year-on-year fall of 10.2%, equivalent to a 3.4-point drop in the gross margin ratio.

The gross margin ratio for the Pharmaceuticals segment was 3.1 points lower at 69.8%, reflecting not only the drop in royalty revenue (2.1 points) but also a deterioration in the ratio of cost of sales to net sales (1.0 point), due in particular to the adverse impact of generic competition and exchange rates, coupled with temporary difficulties in distribution channels for our generics in Brazil.

The gross margin ratio for the Vaccines segment was 6.3 points lower at 53.0%, as a result of an unfavorable product mix that was due partly to the temporary supply limitations for Pentacel® and Adacel®.

The gross margin ratio for the Animal Health segment fell by 2.5 points to 66.8%, reflecting lower sales of fipronil products.

Research and Development Expenses

Research and development (R&D) expenses amounted to €4,770 million in 2013 (versus €4,905 million in 2012) and represented 14.5% of net sales (versus 14.0% in 2012). The year-on-year reduction was €135 million, or 2.8%.

In the Pharmaceuticals segment, R&D expenses decreased by €116 million (2.8%), the principal factors being favorable exchange rate effects and ongoing transformation and project portfolio rationalization initiatives.

R&D expenses for the Vaccines segment fell by €20 million (3.7%), largely due to the end of enrollment of patients for clinical trials of the dengue fever vaccine.

In the Animal Health segment, R&D expenses were €1 million (0.6%) higher than in 2012.

Selling and General Expenses

Selling and general expenses totaled €8,603 million, versus €8,931 million in 2012, a reduction of €328 million or 3.7%. These expenses represented 26.1% of net sales, versus 25.6% in 2012.

Table of Contents

The Pharmaceuticals segment recorded a reduction of €290 million (3.8%), reflecting favorable exchange rate effects, despite increased spend on the Diabetes Solutions and Genzyme growth platforms in North America.

In the Vaccines segment, selling and general expenses were €21 million (3.4%) lower, again helped by favorable exchange rate effects and despite an increase in promotional spending, especially in China and Japan.

In the Animal Health segment, selling and general expenses were down €16 million (2.4%), due to a reduction in promotional spending and favorable exchange rate effects.

Other Operating Income and Expenses

In 2013, other operating income totaled €691 million (versus €562 million in 2012), and other operating expenses €241 million (versus €414 million in 2012).

Overall, other operating income and expenses represented net income of €450 million in 2013, versus net income of €148 million in 2012. This €302 million increase was mainly due to receipt of a payment of €92 million (\$125 million) arising from a change to the contractual terms of the alliance with Warner Chilcott on Actonel® (see Note C.3. to our consolidated financial statements), a €93 million gain arising on the settlement of a dispute between Hoechst and Genentech relating to Rituxan®, and a €165 million gain on the sale to Covis Pharma of commercial rights to some pharmaceutical products in the United States.

This line item also includes a net operational foreign exchange loss of €64 million, versus €41 million in 2012.

Amortization of Intangible Assets

Amortization charged against intangible assets totaled €2,914 million in 2013, versus €3,291 million in 2012. The year-on-year decrease of €377 million was mainly due to a reduction in amortization charged against intangible assets recognized on the acquisition of Aventis (€1,199 million in 2013, versus €1,489 million in 2012) as some pharmaceutical products reached the end of their life cycles in the face of competition from generics, plus (to a lesser extent) favorable exchange rate effects.

Impairment of Intangible Assets

In 2013, this line showed impairment losses of €1,387 million against intangible assets, versus €117 million in 2012. The impairment losses recognized in 2013 related primarily to (i) Lemtrada® (alemtuzumab) in the United States, following the refusal by the FDA to approve the U.S. marketing application for this product as it stands (€612 million); (ii) the discontinuation of the iniparib R&D project in non-small cell lung cancer and ovarian cancer (€384 million); and (iii) the discontinuation of the project on fedratinib, a selective JAK2 inhibitor in the treatment of polycythemia vera (€170 million).

In 2012, impairment losses related mainly to the discontinuation of R&D projects in the Pharmaceuticals segment, in particular development programs in oncology.

Fair Value Remeasurement of Contingent Consideration Liabilities

Fair value remeasurements of contingent consideration liabilities recognized on acquisitions in accordance with the revised IFRS 3 represented a net gain of €314 million in 2013, versus a net expense of €192 million in 2012. This item mainly relates to changes in the fair value of (i) the CVRs issued in connection with the Genzyme acquisition, (ii) the contingent consideration payable to Bayer as a result of an acquisition made by Genzyme prior to the latter's acquisition by Sanofi, and (iii) the contingent consideration arising from the acquisition of TargeGen (see Note D.18. to our consolidated financial statements).

Restructuring Costs

Restructuring costs amounted to €300 million in 2013, versus €1,141 million in 2012, and relate primarily to measures associated with the major transformation program that we initiated in 2009 to adapt our structures to the challenges of the future.

In 2013, these costs related mainly to employee-related expenses arising from headcount adjustment plans in France and the rest of Europe.

Table of Contents

In 2012, these costs mainly related to measures taken to adapt our resources in France, transform our industrial facilities in Europe and make adjustments to our sales forces worldwide, along with the integration of Genzyme and impairment losses against property, plant and equipment in France.

Other Gains and Losses, and Litigation

Nothing was recognized on this line in either 2013 or 2012.

Operating Income

Operating income totaled €5,105 million for 2013, versus €6,430 million for 2012, a fall of 20.6%. This year-on-year change reflected the drop in gross profit, but also the reduction in selling and general expenses, research and development expenses and restructuring costs.

Financial Income and Expenses

Net financial expense for 2013 was €503 million, versus €658 million for 2012, a decrease of €155 million.

Financial expenses directly related to our debt, net of cash and cash equivalents (see the definition in section " Consolidated Balance Sheet and Debt" below) amounted to €317 million in 2013, compared with €349 million in 2012. This decrease mainly reflects a reduction in both the average level of our total debt, and the average financing rate.

The reduction in net financial expense was mainly attributable to a decrease in the net interest cost on defined-benefit pension plans (€159 million, versus €198 million in 2012); a lower level of impairment losses on investments and financial assets (€8 million, versus €30 million in 2012), which related mainly to available-for-sale financial assets; and a net financial foreign exchange gain of €5 million (versus a net loss of €17 million in 2012).

Net gains on disposals of non-current financial assets totaled €42 million (versus €7 million in 2012), and mainly related to divestments by Genzyme.

Income before Tax and Associates and Joint Ventures

Income before tax and associates and joint ventures amounted to €4,602 million in 2013, versus €5,772 million in 2012, a fall of 20.3%.

Income Tax Expense

Income tax expense represented €763 million in 2013, versus €1,108 million in 2012, giving an effective tax rate (based on consolidated net income) of 16.6% in 2013 compared with 19.2% in 2012 (see Note D.30. to our consolidated financial statements).

The level of income tax expense was significantly impacted by the positive tax effect relating to the amortization and impairment of intangible assets (€1,466 million in 2013, versus €1,201 million in 2012) and to restructuring costs (€97 million in 2013, versus €370 million in 2012).

In 2013, this line also includes the "contribution on distributed income", a new French tax levied on the dividend payout to Sanofi shareholders (3%, equivalent to €109 million).

The effective tax rate based on our business net income is calculated on the basis of business operating income minus net financial expenses and before the share of profit/loss of associates and joint ventures and net income attributable to non-controlling interests. The effective tax rate was 24.0% in 2013, versus 25.5% in 2012. This decrease was mainly due to the geographical mix of the results from Group entities, and to recent proceedings involving the tax authorities of various countries that had a positive net effect in 2013.

Share of Profit/Loss of Associates and Joint Ventures

The share of profits from associates and joint ventures was €35 million in 2013, versus €393 million in 2012. This line mainly includes our share of after-tax profits from territories managed by BMS under the Plavix® and Avapro® alliance, which fell by 94.0% to €25 million (versus €420 million in 2012). The decline in our share was mainly

Table of Contents

attributable to the drop in sales of Plavix® in the United States due to the loss of exclusivity and competition from generics.

Net Income

Net income amounted to €3,874 million in 2013, versus €5,057 million in 2012.

Net Income Attributable to Non-Controlling Interests

Net income attributable to non-controlling interests was to €158 million in 2013, versus €169 million in 2012. This line mainly comprises the share of pre-tax profits paid to BMS from territories managed by Sanofi (€141 million, versus €149 million in 2012).

Net Income Attributable to Equity Holders of Sanofi

Net income attributable to equity holders of Sanofi amounted to €3,716 million, versus €4,888 million in 2012.

Basic earnings per share for 2013 was €2.81, 24.1% lower than the 2012 figure of €3.70, based on an average number of shares outstanding of 1,323.1 million in 2013 (1,319.5 million in 2012). Diluted earnings per share for 2013 was €2.77 in 2013 (versus €3.68 in 2012), based on an average number of shares outstanding after dilution of 1,339.1 million in 2013 and 1,329.6 million in 2012.

Business Operating Income

Sanofi reports segment results on the basis of "Business Operating Income". This indicator, adopted in compliance with IFRS 8, is used internally to measure operational performance and to allocate resources. See "Item 5. Operating and Financial Review and Prospects – Segment information" above for the definition of business operating income and reconciliation to our Income before tax and associates and joint ventures.

Business operating income amounted to €9,323 million in 2013, 18.5% lower than in 2012 (€11,446 million) and represented 28.3% of net sales, versus 32.8% in 2012.

Business operating income for 2013 and 2012 is set forth below:

<i>(€million)</i>	2013(1)	2012(1)	Change
Pharmaceuticals	7,886	9,599	-17.8%
Vaccines	909	1,157	-21.4%
Animal Health	502	673	-25.4%
Other	26	17	+52.9%
Business operating income	9,323	11,446	-18.6%

(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

Business net income is a non-GAAP financial measure that we use to evaluate our Group's performance. See "Item 5. Operating and Financial Review and Prospects – Business Net Income" above for the definition of business net income and reconciliation to our Net income attributable to equity holders of Sanofi.

Edgar Filing: Sanofi - Form 20-F

Business net income totaled €6,686 million in 2013, versus €8,100 million in 2012, a fall of 17.5%; it represented 20.3% of net sales, against 23.2% in 2012.

Business Earnings Per Share

We also report business earnings per share, a non-GAAP financial measure which we define as business net income divided by the weighted average number of shares outstanding (see " Business Net Income" above).

Business earnings per share were €5.05 in 2013, 17.8% lower than the 2012 figure of €6.14, based on an average number of shares outstanding of 1,323.1 million in 2013 and 1,319.5 million in 2012.

Table of Contents**Liquidity and Capital Resources**

Our operations generate significant positive cash flows. We fund our day-to-day investments (with the exception of significant acquisitions) primarily with operating cash flow, and pay regular dividends on our shares. In addition, we increased our net debt during 2014 to finance our acquisitions of equity interests in Regeneron and Alnylam, following a reduction in our net debt in 2013 and 2012.

We define "debt, net of cash and cash equivalents" as (i) the sum total of short-term debt, long-term debt and interest rate and currency derivatives used to hedge debt, minus (ii) the sum total of cash and cash equivalents and interest rate and currency derivatives used to hedge cash and cash equivalents. As of December 31, 2014, our debt, net of cash and cash equivalents stood at €7,171 million versus €6,043 million as of December 31, 2013 and €7,719 million as of December 31, 2012. See Note D.17. to our consolidated financial statements included at Item 18 of this annual report.

In order to assess the Company's financing risk, we also use the "gearing ratio", a non-GAAP financial measure. The gearing ratio is defined as the ratio of debt, net of cash and cash equivalents, to total equity. As of December 31, 2014, our gearing ratio was 12.7% of our net equity versus 10.6% as of December 31, 2013 and 13.4% as of December 31, 2012.

Consolidated Statement of Cash Flows

The table below shows our summarized cash flows for the years ended December 31, 2014, 2013 and 2012:

<i>(€ million)</i>	2014	2013	2012
Net cash provided by/(used in) operating activities	7,690	6,954	8,171
Net cash provided by/(used in) investing activities	(3,460)	(1,273)	(1,587)
Net cash provided by/(used in) financing activities	(5,180)	(3,726)	(4,351)
Impact of exchange rates on cash and cash equivalents	34	(79)	24
Net change in cash and cash equivalents (decrease)/increase	(916)	1,876	2,257

Generally, factors that affect our earnings for example, pricing, volume, costs and exchange rates flow through to cash from operations. The most significant source of cash from operations is sales of our branded pharmaceutical products and human vaccines. Receipts of royalty payments also contribute to cash from operations.

Year Ended December 31, 2014 Compared with Year Ended December 31, 2013

Net cash provided by operating activities amounted to €7,690 million in 2014, versus €6,954 million in 2013.

Operating cash flow before changes in working capital for 2014 was €6,733 million, versus €6,818 million in 2013. Working capital requirements fell by €957 million in 2014, compared with a reduction of €136 million in 2013, due mainly to an increase in trade accounts payable.

Our operating cash flow before changes in working capital is generally affected by the same factors that affect "Operating income", which is discussed in detail above under "Results of Operations Year Ended December 31, 2014 Compared with Year Ended December 31, 2013". The principal difference is that operating cash flow before changes in working capital reflects our share of the profits and losses of associates and joint ventures, net of dividend and similar income received.

Net cash used in investing activities totaled €3,460 million in 2014, compared with €1,273 million in 2013.

Acquisitions of property, plant and equipment and intangible assets totaled €1,557 million, versus €1,398 million in 2013. The main items were investments in industrial and research facilities (€1,085 million, versus €1,096 million in 2013) and contractual payments for intangible rights under license and collaboration agreements (€334 million, versus €200 million in 2013).

Edgar Filing: Sanofi - Form 20-F

Acquisitions of investments during 2014 amounted to €2,292 million, net of cash acquired and after including assumed liabilities and commitments. The main items were our acquisitions of equity interests in Regeneron (€1,629 million) and Alnylam (€535 million). In 2013, acquisitions of investments totaled €319 million, net of cash

Table of Contents

acquired and after including assumed liabilities and commitments. The main items were our acquisitions of equity interests in Genfar and Dosch, and payments of contingent consideration arising from the acquisition of Genzyme.

After-tax proceeds from disposals (€269 million) related mainly to the divestment of Genzyme's equity interest in Isis Pharmaceuticals and to a payment received from Tolmar in exchange for the transfer of rights to Eligard and Aplenzin® in the United States. In 2013, after-tax proceeds from disposals (€409 million) mainly comprised the sale to Covis Pharma of commercial rights to pharmaceutical products in the United States, the receipt of a \$125 million payment associated with changes to the contractual terms of the alliance on Actonel®, and disposals of property, plant and equipment in the United States and France.

Net cash used in financing activities amounted to €5,180 million in 2014, compared with €3,726 million in 2013. The 2014 figure includes net external debt finance repaid (i.e. net change in short-term and long-term debt) of €376 million; this compares with net external debt finance raised of €599 million in 2013. It also includes the effect of changes in share capital (repurchases of own shares, net of capital increases), amounting to €1,121 million (versus €637 million in 2013), and the dividend payout to our shareholders of €3,676 million (versus €3,638 million in 2013).

The net change in cash and cash equivalents during 2014 was a decrease of €916 million, compared with an increase of €1,876 million in 2013.

Year Ended December 31, 2013 Compared with Year Ended December 31, 2012

Net cash provided by operating activities amounted to €6,954 million in 2013, versus €8,171 million in 2012.

Operating cash flow before changes in working capital for 2013 was €6,819 million, versus €8,503 million in 2012, reflecting the fall in consolidated net income (partly attributable to the decline in revenues from the BMS alliance). Working capital requirements fell by €135 million in 2013, after increasing by €332 million in 2012; the 2013 decrease was attributable mainly to changes in short-term provisions.

Our operating cash flow before changes in working capital is generally affected by the same factors that affect "Operating income", which is discussed in detail above under "Results of Operations Year Ended December 31, 2013 Compared with Year Ended December 31, 2012". The principal difference is that operating cash flow before changes in working capital reflects our share of the profits and losses of associates and joint ventures, net of dividend and similar income received.

Net cash used in investing activities decreased from €1,587 million in 2012 to €1,273 million in 2013.

Acquisitions of property, plant and equipment and intangible assets totaled €1,398 million (versus €1,612 million in 2012). The main items were investments in industrial and research facilities (€1,058 million, compared with €1,324 million in 2012), together with contractual payments for intangible rights under license and collaboration agreements (€310 million, versus €293 million in 2012).

Acquisitions of investments during 2013 amounted to €319 million, net of cash acquired and after including assumed liabilities and commitments. The main items were the acquisitions of Genfar and Dosch, plus contingent consideration arising from the acquisition of Genzyme. In 2012, acquisitions of investments totaled €328 million, net of cash acquired and after including assumed liabilities and commitments. The main items were a payment of contingent consideration to Bayer arising from the acquisition of Genzyme, the repurchase of some of the CVRs issued in connection with that acquisition, the acquisitions of Pluromed and Newport, and the purchase of an equity interest in Merrimack.

After-tax proceeds from disposals (€409 million) mainly comprised the sale to Covis Pharma of U.S. commercial rights to five pharmaceutical products, the receipt of a \$125 million payment associated with changes to the contractual terms of the alliance on Actonel®, and disposals of property, plant and equipment in the United States and France. In 2012, proceeds from disposals amounted to €358 million, related to divestitures of financial assets (in particular, our equity interests in Financière des Laboratoires de Cosmétologie Yves Rocher and Handok) and to disposals of various items of property, plant and equipment and intangible assets.

Net cash used in financing activities came to €3,726 million in 2013, versus €4,351 million in 2012. The 2013 figure includes net external debt finance raised (net change in short-term and long-term debt) of €599 million (versus €615 million in 2012); the effect of changes in share capital (repurchases of own shares, net of capital increases), amounting to €637 million (compared to €178 million in 2012); and the dividend payout to our shareholders of €3,638 million (€3,487 million in 2012).

Table of Contents

The net change in cash and cash equivalents during 2013 was a €1,876 million increase, compared with a €2,257 million increase in 2012.

Consolidated Balance Sheet and Debt

Total assets stood at €97,392 million as of December 31, 2014, versus €96,055 million a year earlier, an increase of €1,337 million.

Debt, net of cash and cash equivalents (see definition above) was €7,171 million as of December 31, 2014, versus €6,043 million as of December 31, 2013. The table below shows our financial position for the years ended December 31, 2014, 2013 and 2012:

<i>(€million)</i>	2014	2013	2012
Long-term debt	13,276	10,414	10,719
Short-term debt and current portion of long-term debt	1,538	4,176	3,812
Cash and cash equivalents	(7,341)	(8,257)	(6,381)
Related interest rate and currency derivatives	(302)	(290)	(431)
Debt, net of cash and cash equivalents	7,171	6,043	7,719

Our gearing ratio (debt, net of cash and cash equivalents as a proportion of total equity) rose from 10.6% in 2013 to 12.7% in 2014. Analyses of debt as of December 31, 2014 and December 31, 2013, by type, maturity, interest rate and currency, are provided in Note D.17. to our consolidated financial statements.

The financing arrangements in place as of December 31, 2014 at Sanofi parent company level are not subject to covenants regarding financial ratios and do not contain any clauses linking credit spreads or fees to our credit rating.

Other key movements in the balance sheet are described below.

Total equity stood at €56,268 million as of December 31, 2014, versus €57,033 million as of December 31, 2013. The net year-on-year decrease in equity was attributable primarily to:

decreases: the dividend payout to our shareholders in respect of the 2013 financial year (€3,676 million), the effect of the change in the method of accounting for the equity interest in Regeneron (€2,607 million), and repurchases of our own shares (€1,801 million);

increases: our net income for the year ended December 31, 2014 (€4,509 million) and the net change in currency translation differences (€2,506 million, mainly on the U.S. dollar).

As of December 31, 2014, we held 9.5 million of our own shares, recorded as a deduction from equity and representing 0.7% of our share capital.

Goodwill and Other intangible assets (€53,740 million in total) rose by €1,211 million year-on-year, the main factors being:

decreases: amortization and the net effect of impairment losses and reversals of impairment losses recognized during the period (€2,548 million);

increases: acquisitions of other intangible assets (€583 million), and currency translation differences on assets denominated in foreign currencies (€3,103 million, mainly on the U.S. dollar).

Edgar Filing: Sanofi - Form 20-F

Investments in associates and joint ventures increased by €1,936 million to €2,384 million, mainly because the interest in Regeneron (€1,942 million as of December 31, 2014) has been accounted for by the equity method, and hence included in this line item, since April 2014.

Other non-current assets were €2,251 million lower at €2,575 million, the main factors being:

decreases: the interest in Regeneron, which amounted to €3,157 million as of December 31, 2013 and was classified as an available-for-sale financial asset before April 2014;

increases: the interest in Alnylam acquired in January 2014, valued at €728 million as of December 31, 2014.

Table of Contents

Provisions and other non-current liabilities (€9,578 million) increased by €843 million, the main factor being a net rise in provisions for pensions and other post-employment benefits of €848 million due primarily to actuarial losses on defined benefit plans.

Deferred taxes represented a net asset of €755 million as of December 31, 2014, as opposed to a net liability of €916 million a year earlier. This represents an overall year-on-year change of €1,671 million in the deferred tax position, resulting from changes in the provisions for pensions and other post-employment benefits (€332 million) and in other provisions and accrued expenses (€328 million); tax effects associated with equity interests in subsidiaries and in other entities (€440 million); the effect of adopting the equity method to account for the interest in Regeneron (€294 million); and reversals of deferred tax liabilities arising on the remeasurement of acquired intangible assets (€87 million).

Liabilities related to business combinations and to non-controlling interests were €356 million higher year on year at €1,264 million. The main reason was the impact of fair value remeasurements of (i) the contingent consideration payable to Bayer as a result of an acquisition made by Genzyme prior to the latter's acquisition by Sanofi and (ii) the contingent value rights (CVRs) issued in connection with the Genzyme acquisition (see Note D.18. to our consolidated financial statements).

Liquidity

We expect that our existing cash resources and cash from operations will be sufficient to finance our foreseeable working capital requirements. At year-end 2014, we held cash and cash equivalents amounting to €7,341 million, substantially all of which were held in euros (see Note D.13. to our consolidated financial statements). As at December 31, 2014, our subsidiaries based in Venezuela held cash and cash equivalents in bolivars representing €242 million, which is subject to foreign exchange controls (see Note A.4. to our consolidated financial statements). As at December 31, 2014, €587 million of our cash and cash equivalents were held by our captive insurance and reinsurance companies in accordance with insurance regulations.

Since 2010, some countries in Southern Europe have been facing severe financial difficulties (see "Item 3.D Risk Factors 2. Risks Relating to Our Business We are subject to the risk of non-payment by our customers"). Deteriorating credit and economic conditions and other factors in these countries have resulted in, and may continue to result in an increase in the average length of time taken to collect our accounts receivable in these countries. Should these factors continue, it may require us to re-evaluate the collectability of these receivables in future periods. We carefully monitor sovereign debt issues and economic conditions and evaluate accounts receivable in these countries for potential collection risks. We have been conducting an active recovery policy, adapted to each country and including intense communication with customers, negotiations of payment plans, charging of interest for late payments, and legal action.

During 2013, the amount of our trade receivables in Europe decreased, primarily as a result of a reduction in the sums owed to us by public-sector customers in Italy and Greece. During 2014, the amount of our trade receivables in Europe continued to fall, primarily as a result of a reduction in the sums owed to us by public sector customers in Spain, Italy and Portugal. Over the Group as a whole, the amount of trade receivables overdue by more than 12 months which consists mainly of amounts due from public sector bodies rose from €168 million at December 31, 2013 to €170 million at December 31, 2014 (see Note D.10. to our consolidated financial statements), reflecting a decrease in Spain combined with an increase in non-European countries.

In November 2011, Sanofi obtained the necessary corporate authorizations to purchase any or all of the outstanding Contingent Value Rights ("CVR") and subsequently purchased CVRs in 2011. In 2012 following a tender offer initiated in September 2012 on the basis of the same corporate authorization, Sanofi purchased an additional 40,025,805 CVRs (for a total consideration of approximately \$70 million), followed by a further 10,928,075 CVRs (for approximately \$9 million) in 2013 and 1,879,774 CVRs (for approximately \$1 million) in 2014. As of December 31, 2014, a total of 236,420,665 CVRs were outstanding out of the 291,313,510 issued at the time of the Genzyme acquisition.

At year-end 2014, we had no commitments for capital expenditures that we consider to be material to our consolidated financial position. Undrawn confirmed credit facilities amounted to a total of €8.0 billion at December 31, 2014. For a discussion of our treasury policies, see "Item 11. Quantitative and Qualitative Disclosures about Market Risk."

We expect that cash from our operations will be sufficient to repay our debt. For a discussion of our liquidity risks, see "Item 11. Quantitative and Qualitative Disclosures about Market Risk."

Table of Contents**Off-Balance Sheet Arrangements/Contractual Obligations and Other Commercial Commitments**

We have various contractual obligations and other commercial commitments arising from our operations. Our contractual obligations and our other commercial commitments as of December 31, 2014 are shown in Notes D.3., D.17., D.18. and D.21. to our consolidated financial statements included at Item 18 of this annual report. Note D.21. to our consolidated financial statements included at Item 18 discloses details of commitments under our principal research and development collaboration agreements. For a description of the principal contingencies arising from certain business divestitures, refer to Note D.22.e) to our 2012 consolidated financial statements.

The Group's contractual obligations and other commercial commitments are set forth in the table below:

December 31, 2014 <i>(€ million)</i>	Payments due by period				
	Total	Under 1 year	From 1 to 3 years	From 3 to 5 years	Over 5 years
Future contractual cash-flows relating to debt and debt hedging instruments ⁽¹⁾	15,982	1,631	4,397	3,179	6,775
Operating lease obligations	1,235	249	391	189	406
Finance lease obligation ⁽²⁾	74	19	35	12	8
Irrevocable purchase commitment ⁽³⁾ given received	3,625 (243)	2,027 (179)	923 (41)	349 (3)	326 (20)
Research & development license agreements					
Future service commitment ⁽⁴⁾	480	165	283	7	25
Potential milestone payment ⁽⁵⁾	2,140	104	239	693	1,104
Obligations relating to business combination ⁽⁶⁾	4,745	94	889	943	2,819
Firm commitment related to the BMS agreement ⁽⁷⁾	95			95	
Estimated benefit payments on unfunded pensions and post employment benefits ⁽⁸⁾	1,369	61	123	138	1,047
Total contractual obligations and other commitments	29,502	4,171	7,239	5,602	12,490
Undrawn general-purpose credit facilities	8,013	12		8,000	1

(1) See Note D.17. to our consolidated financial statements included at Item 18 of this annual report.

(2) See Note D.3. to our consolidated financial statements included at Item 18 of this annual report.

(3) These comprise irrevocable commitments to suppliers of (i) property, plant and equipment, net of down payments (see Note D.3. to our consolidated financial statements included at Item 18 of this annual report) and (ii) goods and services.

(4)

Future service commitments relating to research & development license agreements mainly comprise research financing commitments, but also include consideration for access to technologies.

(5)

This line includes all potential milestone payments on projects regarded as reasonably possible, i.e., on projects in the development phase.

(6)

See Note D.18. to our consolidated financial statements included at Item 18 of this annual report.

(7)

See Note C.2. to our consolidated financial statements included at Item 18 of this annual report.

(8)

See Note D.19.1. to our consolidated financial statements included at Item 18 of this annual report. The table above does not include the ongoing annual employer's contributions to plan assets, estimated at €272 million in 2014.

We may have payments due to our current or former research and development partners under collaborative agreements. These agreements typically cover multiple products, and give us the option to participate in development on a product-by-product basis. When we exercise our option with respect to a product, we pay our collaboration partner a fee and receive intellectual property rights to the product in exchange. We are also generally required to fund some or all of the development costs for the products that we select, and to make payments to our partners when those products reach development milestones.

We have entered into collaboration agreements under which we have rights to acquire products or technology from third parties through the acquisition of shares, loans, license agreements, joint development, co-marketing and other contractual arrangements. In addition to upfront payments on signature of the agreement, our contracts frequently require us to make payments contingent upon the completion of development milestones by our alliance partner or upon the granting of approvals or licenses.

Table of Contents

Because of the uncertain nature of development work, it is impossible to predict (i) whether Sanofi will exercise further options for products, or (ii) whether the expected milestones will be achieved, or (iii) the number of compounds that will reach the relevant milestones. It is therefore impossible to estimate the maximum aggregate amount that Sanofi will actually pay in the future under existing collaboration agreements.

Given the nature of its business, it is highly unlikely that Sanofi will exercise all options for all products or that all milestones will be achieved.

The main collaboration agreements relating to development projects in the Pharmaceuticals segment are described in Note D.21.1. to our consolidated financial statements included at Item 18 of this annual report. Milestone payments relating to development projects under these agreements amounted to €1.9 billion in 2014. These exclude projects in the research phase (€4.2 billion in 2014, €3.8 billion in 2013) and payments contingent upon the attainment of sales targets once a product is on the market (€4.7 billion in 2014, €3.6 billion in 2013).

In the Vaccines segment, Sanofi Pasteur has entered into a number of collaboration agreements. Milestone payments relating to development projects under those agreements amounted to €0.2 billion in 2014 (see Note D.21.1. to our consolidated financial statements included at Item 18 of this annual report).

Critical accounting and reporting policies

Our consolidated financial statements are affected by the accounting and reporting policies that we use. Certain of our accounting and reporting policies are critical to an understanding of our results of operations and financial condition, and in some cases the application of these critical policies can be significantly affected by the estimates, judgments and assumptions made by management during the preparation of our consolidated financial statements. The accounting and reporting policies that we have identified as fundamental to a full understanding of our results of operations and financial condition are the following:

Revenue recognition. Our policies with respect to revenue recognition are discussed in Note B.14. to our consolidated financial statements included at Item 18 of this annual report. Revenue arising from the sale of goods is presented in the income statement under "Net sales". Net sales comprise revenue from sales of pharmaceutical products, vaccines, and active ingredients, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities. Revenue is recognized when all of the following conditions have been met: the risks and rewards of ownership have been transferred to the customer; the Group no longer has effective control over the goods sold; the amount of revenue and costs associated with the transaction can be measured reliably; and it is probable that the economic benefits associated with the transaction will flow to the Group.

We offer various types of price reductions on our products. In particular, products sold in the United States are covered by various programs (such as Medicare and Medicaid) under which products are sold at a discount. Rebates are granted to healthcare authorities, and under contractual arrangements with certain customers. Some wholesalers are entitled to chargeback incentives based on the selling price to the end customer, under specific contractual arrangements. Cash discounts may also be granted for prompt payment. The discounts, incentives and rebates described above are estimated on the basis of specific contractual arrangements with our customers or of specific terms of the relevant regulations and/or agreements applicable for transactions with healthcare authorities, and of assumptions about the attainment of sales targets. They are recognized in the period in which the underlying sales are recognized, as a reduction of sales revenue. We also estimate the amount of product returns, on the basis of contractual sales terms and reliable historical data; the same recognition principles apply to sales returns. For additional details regarding the financial impact of discounts, rebates and sales returns, see Note D.23. to our consolidated financial statements included at Item 18 of this annual report.

Non-product revenues, mainly comprising royalty income from license arrangements that constitute ongoing operations of the Group, are presented in "Other revenues".

Business combinations. As discussed in Note B.3. "Business combinations and transactions with non-controlling interests" to our consolidated financial statements included at Item 18 of this annual report, business combinations are accounted for by the acquisition method. The acquiree's identifiable assets, liabilities and contingent liabilities that satisfy the recognition criteria of IFRS 3 "Business combinations" are measured initially at their fair values as at the acquisition date, except for non-current assets classified as held for sale, which are measured at fair value less costs to sell. Business combinations completed on or after January 1, 2010 are accounted for in accordance with the revised IFRS 3 and the revised IAS 27, "Consolidated and individual financial statements", now superseded by IFRS 10 "Consolidated Financial

Table of Contents

Statements". In particular, contingent consideration to former owners agreed in a business combination, e.g. in the form of payments upon the achievement of certain R&D milestones, is recognized as a liability at fair value as of the acquisition date. Any subsequent changes in amounts recorded as a liability are recognized in the consolidated income statement (see Note D.18. "Liabilities related to business combinations and non-controlling interests" to our consolidated financial statements included at Item 18 of this annual report).

Goodwill impairment and intangible assets. As discussed in Note B.6. "Impairment of property, plant and equipment, intangible assets, and investments in associates and joint ventures" and in Note D.5. "Impairment of intangible assets and property, plant and equipment" to our consolidated financial statements included at Item 18 of this annual report, we test our intangible assets periodically for impairment. We test for impairment on the basis of the same objective criteria that were used for the initial valuation. Our initial valuation and ongoing tests are based on the relationship of the value of our projected future cash flows associated with the asset to either the purchase price of the asset (for its initial valuation) or the carrying amount of the asset (for ongoing tests). The determination of the underlying assumptions relating to the recoverability of intangible assets is subjective and requires the exercise of considerable judgment. Key assumptions relating to goodwill impairment and intangible assets are the perpetual growth rate and the post-tax discount rate. Any changes in key assumptions could result in an impairment charge. A sensitivity analysis to the key assumptions is disclosed in Note D.5. "Impairment of intangible assets and property, plant and equipment" to our consolidated financial statements included at Item 18 of this annual report.

Pensions and post-retirement benefits. As described in Note B.23. "Employee benefit obligations" to our consolidated financial statements included at Item 18 of this annual report, we recognize our pension and retirement benefit commitments as liabilities on the basis of an actuarial estimate of the potential rights vested in employees and retirees as of the balance sheet date, net of the valuation of funds to meet these obligations. We prepare this estimate at least on an annual basis taking into account financial assumptions (such as discount rates) and demographic assumptions (such as life expectancy, retirement age, employee turnover, and the rate of salary increases).

We recognize all actuarial gains and losses (including the impact of a change in discount rate) immediately through equity. A sensitivity analysis to discount rate is set forth in Note D.19.1. "Provisions for pensions and other benefits" to our consolidated financial statements included at Item 18 of this annual report.

Depending on the key assumptions used, the pension and post-retirement benefit expense could vary within a range of outcomes and have a material effect on reported earnings. A sensitivity analysis to these key assumptions is set forth in Note D.19.1. "Provisions for pensions and other benefits" to our consolidated financial statements included at Item 18 of this annual report.

Deferred taxes. As discussed in Note B.22. "Income tax expense" to our consolidated financial statements included at Item 18 of this annual report, we account for deferred taxes using the liability method, whereby deferred income taxes are recognized on tax loss carry-forwards, and on the difference between the tax base and carrying amount of assets and liabilities. We calculate our deferred tax assets and liabilities using enacted tax rates applicable for the years during which we estimate that the temporary differences are expected to reverse. We do not recognize deferred tax assets when it is more likely than not that the deferred tax assets will not be realized. The estimates of recognized deferred tax assets are based on our assumptions regarding future profits and the timing of reversal of temporary differences. These assumptions are regularly reviewed; however, final deferred income tax could differ from those estimates.

Provisions for risks. Sanofi and its subsidiaries and affiliates may be involved in litigation, arbitration or other legal proceedings. These proceedings typically are related to product liability claims, intellectual property rights, compliance and trade practices, commercial claims, employment and wrongful discharge claims, tax assessment claims, waste disposal and pollution claims, and claims under warranties or indemnification arrangements relating to business divestitures. As discussed in Note B.12. "Provisions for risks" at Item 18 of this annual report, we record a provision where we have a present obligation, whether legal or constructive, as a result of a past event; when it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation; and when a reliable estimate can be made of the amount of the outflow of resources. For additional details regarding the financial impact of provisions for risks see Notes D.19.3. "Other provisions" and D.22. "Legal and Arbitral Proceedings" to our consolidated financial statements included at Item 18 of this annual report.

Edgar Filing: Sanofi - Form 20-F

Provisions are estimated on the basis of events and circumstances related to present obligations at the balance sheet date, of past experience, and to the best of management's knowledge at the date of preparation of the financial statements. The assessment of provisions can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions. Given the inherent uncertainties related to these estimates and assumptions, the actual outflows resulting from the realization of those risks could differ from our estimates.

Table of Contents

Item 6. Directors, Senior Management and Employees

A. Directors and Senior Management

Since January 1, 2007, Sanofi has separated the offices of Chairman and Chief Executive Officer. The annual evaluations conducted since that date have indicated that this governance structure is appropriate to the Group's current configuration. This arrangement was maintained with the appointment of Serge Weinberg to the office of Chairman on May 17, 2010 and again with his reappointment on May 6, 2011. The Board of Directors continues to consider that this governance structure is appropriate in the Group's current context.

As an exception, resulting from the removal of Christopher Viehbacher from office as Chief Executive Officer on October 29, 2014, the Board of Directors asked Serge Weinberg to temporarily occupy the functions of both Chairman and Chief Executive Officer. As soon as a new Chief Executive Officer is appointed, the Group's governance will return to the separation of the offices of Chairman and Chief Executive Officer.

The **Chairman** represents the Board of Directors, organizes and directs the work of the Board, and is responsible for ensuring the proper functioning of the corporate decision-making bodies in compliance with good governance practices. The Chairman coordinates the work of the Board of Directors with its Committees. The Chairman is accountable to the Shareholders' General Meeting, which he chairs.

When the offices of Chairman and Chief Executive Officer are separated, the Chairman may remain in office until the Ordinary Shareholders' General Meeting called to approve the financial statements held during the calendar year in which he reaches the age of 70.

Due to the exceptional and temporary nature of the combination of the two offices, the Board of Directors, on recommendation of the Appointments and Governance Committee, did not consider it necessary or appropriate to appoint a lead independent director. However, the Directors' meeting held on November 18, 2014 decided to assign the chairmanship of the Appointments and Governance Committee to an independent director to replace the Chairman of the Board of Directors.

The **Chief Executive Officer** is responsible for the management of the Company, and represents the Company in dealings with third parties within the limit of the corporate purpose. The Chief Executive Officer has the broadest powers to act in all circumstances in the name of the Company, subject to the powers that are attributed by law to the Board of Directors and to the Shareholders' General Meeting and within the limits set by the Board of Directors.

The Chief Executive Officer may not be more than 65 years old.

Limitations on the powers of the Chief Executive Officer set by the Board

The Board of Directors Meeting of July 28, 2009 set limits on the powers of the Chief Executive Officer in a decision that supplements the Board Charter. The prior authorization of the Board of Directors is required to commit Sanofi to investments, acquisitions and divestments in the following cases:

a €500 million cap for each undertaking pertaining to a previously approved strategy; and

a €150 million cap for each undertaking not pertaining to a previously approved strategy.

When the consideration payable to the contracting parties for such undertakings includes potential installment payments contingent upon the achievement of future results or objectives, such as the registration of one or more products, the caps are calculated by aggregating the various payments due from signature of the contract until (and including) filing of the first application for marketing authorization in the United States or in Europe.

Board of Directors

Edgar Filing: Sanofi - Form 20-F

The Company is administered by a Board of Directors, comprising fifteen members as of December 31, 2014.

Subject to the powers expressly attributed to the Shareholders' General Meeting and within the scope of the Company's corporate purpose, the Board of Directors' powers cover all issues relating to the proper management of the Company, and through its decisions the Board determines all matters falling within its authority.

Since May 14, 2008, the terms of office of the directors have been staggered, in order to ensure that the directors are progressively re-elected.

Table of Contents

Each year, the Board of Directors conducts a review to ensure that there is an appropriate balance in its composition and in the composition of its Committees. In particular, the Board seeks to ensure a balanced representation of men and women and diversity of background and country of origin, since the business of the Group is both diversified and global. The Board investigates and evaluates potential candidates whenever individual directors are up for election. Above all, the Board seeks talented directors, who show independence of mind and who are competent, dedicated and committed.

Independence of Board Members

Under the terms of the AFEP-MEDEF corporate governance code (hereafter referred to as the "AFEP-MEDEF Code"), a director is deemed to be independent when he or she has no relationship of any nature whatsoever with the Company, the Group it belongs to or its senior management which could compromise the exercise of the director's freedom of decision. More specifically, in order to qualify as independent, directors may not:

be an employee or corporate officer of the Company, or a corporate officer of a related company;

be a customer, supplier, or investment banker or corporate banker of the Company;

have close family ties with any corporate officer of the Company;

have acted as auditor for the Company over the course of the last five years;

be representative of a significant shareholder or of a controlling interest of the Company.

The influence of other factors such as length of service on the Board, the ability to understand challenges and risks, and the courage to express ideas and form a judgment, is also evaluated before a director qualifies as independent.

In compliance with our Board Charter and pursuant to the AFEP-MEDEF Code, the Board of Directors' meeting of November 18, 2014 reviewed the independence of current directors. Of the fifteen directors, eleven were deemed to be independent directors with reference to the independence criteria used by the Board of Directors pursuant to the AFEP-MEDEF Code: Bonnie Bassler, Uwe Bicker, Robert Castaigne, Jean-René Fourtou, Claudie Haigneré, Patrick Kron, Fabienne Lecorvaisier, Suet-Fern Lee, Carole Piwnica, Klaus Pohle and Gérard Van Kemmel.

The Board's conclusions on particular situations are set out below.

Robert Castaigne

The Board of Directors considers that the situation of Robert Castaigne has changed since his first appointment to the Board. Prior to 2012, Robert Castaigne had not been regarded as an independent director due to his past relationship with Total. Since April 2008, when the independence criteria of the AFEP-MEDEF Code were adopted, his situation has changed in two ways:

Robert Castaigne retired from Total more than four years ago.

Total passed below the threshold of 5% of our voting rights as per notification of February 16, 2012. Since that date, Total has indeed ceased to have any equity interest in our Company.

Consequently, the Board of Directors took the view that Robert Castaigne's relationship with Total no longer created a presumption of non-independence.

Edgar Filing: Sanofi - Form 20-F

Moreover, the Board of Directors does not believe that belonging to the Board for more than 12 years of itself disqualifies a director from being independent. The length of service criterion is intended to address the concern that the passage of time may deprive a director of his ability to challenge senior management. This is a legitimate concern, which Sanofi takes very seriously.

This is why the Board of Directors applies this criterion pragmatically in light of the specific circumstances of each case. In the case of Robert Castaigne, the Board considers that this director has demonstrated a questioning approach, which is fundamentally what the AFEP-MEDEF criteria are seeking to check. The answer to the letter received by the Company from the *Haut Comité de Gouvernement d'Entreprise* (the body in charge of overseeing the implementation of the AFEP-MEDEF Code) is reported in " C. Board Practices ", below.

Finally, there was no other factor calling into question Robert Castaigne's independence.

Table of Contents

Consequently, the Board determined on this basis, at its meeting of May 4, 2012 and upon the recommendation of its Appointments and Governance Committee, that Robert Castaigne qualified as an independent director. This position was reconfirmed at its meeting of November 18, 2014.

It should be noted that this decision has no detrimental effect on compliance with the independence rules of the AFEP-MEDEF Code, which is the main objective of the Code. The fact that the proportion of independent directors on the Board is over 73% demonstrates that the Board in no way underestimates the importance of having a majority of independent directors in its governance.

Serge Weinberg

In 2013, the rules governing the office of the Chairman of the Board changed, allowing the Board to regard the Chairman as an independent director in accordance with the continuous assessment of the Board of Directors. Until 2013, Serge Weinberg had not been regarded as an independent director only because of the previous version of the AFEP-MEDEF Code which in its former article 8.4 did not distinguish the case where the functions of Chairman and Chief Executive Officer are separated from the case where both functions are combined. Effective June 2013, the AFEP-MEDEF Code (in its new article 9.4) stipulates that if the offices of Chairman and Chief Executive Officer are separated, the Chairman is not automatically regarded as non-independent, but his (or her) independence has to be scrutinized in the light of the criteria generally used to assess directors' independence. The Board of Directors took the view that no factor other than his role as Chairman is liable to undermine his independence, especially given that prior joining the Board he had no relationship with Sanofi. The Board assessment concerning his situation was reflected in the previous annual reports on Form 20-F. On October 29, 2013 the Board of Directors determined that Serge Weinberg was an independent director.

As a result of the temporary combination of the offices of Chairman of the Board and Chief Executive Officer, and therefore the Board of Directors determined that Serge Weinberg may no longer be regarded as independent.

Business Relationships Review

In its examination of the independence of each Director, the Board of Directors took into account the various relationships that could exist between Directors and the Group and concluded that no such relationships were of a nature that might undermine their independence. The Board of Directors noted that the Company and its subsidiaries had, in the normal course of business, over the last three years, sold products and provided services to, and/or purchased products and received services from, companies in which certain of the Company's directors who are classified as independent or members of their close family were senior managers or employees during 2014. On each occasion, the amounts paid to or received from such companies over the past three years were determined on an arm's length basis and did not represent amounts that the Board regarded as undermining the independence of the Directors in question. Similarly, the Board of Directors did not find the office of trustee held by Uwe Bicker and Klaus Pohle with the Aventis Foundation (Germany) was of such a nature as to undermine their independence as members of the Sanofi Board of Directors. Appointments to the Board of Trustees of the Foundation are made completely independently of Sanofi.

No more than one-third of the serving members of our Board of Directors may be over 70 years of age.

Board evaluation

The Board Charter provides that a discussion of the operating procedures of the Board must be included on the agenda of a Board meeting once a year and that a formal evaluation must be performed every three years.

Over the last years, the Board indicated in its evaluations that it wished its contributions to be systematically acted upon and implemented.

Areas for improvement identified:

Among other things, Directors proposed that:

R&D performance monitoring should be continued and intensified;

Edgar Filing: Sanofi - Form 20-F

The procedure whereby all acquisitions are reviewed by the Strategy Committee before presentation to the Board, and are subject to ex-post review by the Audit Committee, should be systematically applied;

Presentations from various Group activities should be given during Board meetings or Strategy Committee sessions so as to provide even more opportunities for contact with the Group's key managers;

Table of Contents

Directors should get more information about human resources management;

After the current transitional period, the size of the Board should be reduced;

The onboarding of more women should be continued and certain competencies, including in finance, science and the pharmaceutical sector should be reinforced; and

More time should be spent on presenting the competitive landscape and on discussing the Company's challenges and strategic alternatives.

Initiatives subsequently implemented and welcomed by the Board:

An annual business presentation program systematically involving Group managers has increased the frequency and quality of the Board's contacts with those managers; each business presentation now includes an overview of the market and the competitive environment;

A more in-depth analysis of R&D performance is being provided during the sessions of the Strategy Committee on the R&D portfolio;

Strategic seminars are being organized, reviewing topics such as the Group's research strategy in core disease areas or the analysis of the Group's positioning in China;

Changes in the composition of the Board are in line with the roadmap. Over the last two years this has resulted in Fabienne Lecorvaisier, Patrick Kron and Bonnie Bassler joining the Board (see Changes in the Composition of the Board below).

Directors' Training

Upon her arrival, Fabienne Lecorvaisier received several days' training during which she acclimatized herself to the Company's specific features, its businesses, the health sector background and the pharmaceutical industry.

Since his arrival, Patrick Kron met with several Group managers.

In July 2014, two of the five Group employee representatives who attend Board meetings without voting rights pursuant to the agreement implemented with the European Works Council signed on February 24, 2005 attended a three-day training program on governance principles and good practices provided by an external body.

2014 Evaluation

The annual discussion on the operating procedures of the Board and its Committees during 2014 delivered an overall positive self-assessment, but a more nuanced assessment of their relationship with the Chief Executive Officer.

The Board of Directors noted, in particular, dissatisfaction with information on certain strategic projects, on succession planning, on the Group's positioning relative to its competitors and on the execution of the Group's strategy.

Edgar Filing: Sanofi - Form 20-F

Failure to take into account certain conclusions and recommendations resulting from previous evaluations crystallized over the course of 2014 and led to the unanimous decision to remove Christopher Viehbacher from office as Chief Executive Officer on October 29, 2014.

Composition of the Board of Directors as of December 31, 2014

Positions held in listed companies are flagged by an asterisk. Each person's principal position is indicated in bold.

Table of Contents

Serge Weinberg 1,636 shares	Date of birth: Nationality: First elected: Last reappointment: Term expires:	February 10, 1951 French December 2009 May 2011 2015
---------------------------------------	--	--

Directorships and appointments of Serge Weinberg

Within the Sanofi Group

Current directorships and appointments

Outside the Sanofi Group

In French companies

Chairman of the Board and Chief Executive Officer of Sanofi*

Chairman of Weinberg Capital Partners

Chairman of the Strategy Committee of Sanofi

Chairman of Financière Piasa, Piasa Holding and Maremma

Member of the Appointments and Governance Committee of Sanofi

Manager of Alret

Chairman of the Supervisory Board of Financière Climater SAS

Vice Chairman and Director of Financière Sasa

Director of Madrigall

In foreign companies

None

None

Past directorships since 2010

In French companies

None

Director of Rasec (until 2010), Fnac (until 2010), Rothschild Concordia (until 2010), VL Holding (until 2010), Team Partners Group (until 2011) and Alliance Automotive Participations SAS (until 2014)

Member of the Supervisory Board of Rothschild & Cie (until 2010), Amplitude Group (until 2011), Alfina (until 2011), Financière BFSA (until 2013), Schneider Electric* (until 2014)

Member of the Board of Pharma Omnium International (until 2010)

Vice Chairman of the Supervisory Board of Schneider Electric* (until 2010)

Weinberg Capital Partners' permanent representative on the Board of Alliance Industrie (until 2011) and Sasa Industrie (until 2013)

Vice Chairman and Director of Financière Poincetié (until 2011)

In foreign companies

None

Member of the Supervisory Board of Gucci Group (Netherlands, until 2010)

Chairman of Corum (Switzerland, until 2013)

Education and business experience

Graduate in law, degree from the *Institut d'Etudes Politiques*

Graduate of ENA (*Ecole Nationale d'Administration*)

Since 2005 Chairman of Weinberg Capital Partners

1976-1982 *Sous-préfet* and then Chief of Staff of the French Budget Minister (1981)
1982-1987 Deputy General Manager of FR3 (French Television Channel) and then Chief Executive Officer of Havas Tourisme
1987-1990 Chief Executive Officer of Pallas Finance
1990-2005 Various positions at PPR* group including Chairman of the Management Board for 10 years
2006-2008 Director of Alliance Industrie
2007-2008 Director of Road Holding
2006-2009 Chairman of the Board of Accor*

Table of Contents

Laurent Attal	Date of birth:	February 11, 1958
1,000 shares	Nationality:	French
	First elected:	May 2012
	Term expires:	2016

Directorships and appointments of Laurent Attal

Within the Sanofi Group	Outside the Sanofi Group
<u>Current directorships and appointments</u>	

In French companies

Director of Sanofi*	Director of <i>Fondation d'Entreprise L'Oréal</i>
---------------------	---

Member of the Strategy Committee of Sanofi

None

In foreign companies

None

Past directorships since 2010

None

In French companies

None

None

In foreign companies

None

Education and business experience

Doctor in medicine, dermatologist

MBA from INSEAD (*Institut Européen d'Administration des Affaires*)

Since 1986 Various positions within the L'Oréal* Group notably within the active cosmetics division, and as President and Chief Executive Officer of L'Oréal USA (United States)

Since 2002 Member of L'Oréal* Executive Committee

Since 2010 **Vice President General Manager Research and Innovation at L'Oréal***

Table of Contents

Bonnie Bassler	Date of birth:	April 21, 1962
No shares	Nationality:	American
	First elected:	November 2014
	Term expires:	2015

Directorships and appointments of Bonnie Bassler

Within the Sanofi Group	Outside the Sanofi Group
<u>Current directorships and appointments</u>	

In French companies

None

Independent director of Sanofi*

None

In foreign companies

Member of the National Science Board (National Science Foundation)

Board of Director of the American Association for the Advancement of Science

Past directorships since 2010

None

In French companies

None

None

In foreign companies

None

Education and business experience

Graduated in biochemistry, University of California, Davis

Doctor in biochemistry, Johns Hopkins University

Since 2013	Squibb Professor and Chair at the Department of Molecular Biology, Princeton University
Since 2005	Investigator at the Howard Hughes Medical Institute
Since 2003	Professor at the Department of Molecular Biology, Princeton University
2002-2008	Director at the Molecular Biology Graduate Program
2010-2011	President of the American Society for Microbiology
2012	L'Oréal-UNESCO women in Science Award Winner
2011-2014	Chair of the Board of Governors of the American Academy of microbiology

Table of Contents

Uwe Bicker	Date of birth:	June 14, 1945
1,000 shares	Nationality:	German
	First elected:	May 2008
	Last reappointment:	May 2012
	Term expires:	2016

Directorships and appointments of Uwe Bicker

Within the Sanofi Group	Outside the Sanofi Group
<u>Current directorships and appointments</u>	

In French companies

None

Independent director of Sanofi*

Member of the Strategy Committee of Sanofi

None

In foreign companies

Trustee of the Aventis Foundation⁽¹⁾ (not-for-profit, Germany)

Chairman of the Board of Marburg University (Germany)

Member of the Advisory Board of Morgan Stanley (Germany)

Past directorships since 2010

None

In French companies

None

In French companies

None

Member of the Board of Trustees of Bertelsmann Stiftung
(Bertelsmann Foundation, Germany, until 2011)

Chairman of the Supervisory Board of Siemens Healthcare
Diagnostics Holding GmbH (Germany, until 2012)

Vice-Chairman of the Supervisory Board of Epigenomics AG (Germany) and of Definiens AG (Germany, until 2012)

Member of the Supervisory Board of Future Capital AG (Germany, until 2013)

Education and business experience

Doctorate in chemistry and in medicine

Honorary Doctorate, Klausenburg University

Honorary Senator, Heidelberg University

Since 1983 Professor at the Medical Faculty of Heidelberg (Germany)
Since 2011 **Dean at the Medical Faculty, Heidelberg University** (Germany)
1975-1994 Various positions at Boehringer Mannheim GmbH (later Roche AG) (Germany)
1994-2004 Various positions at Hoechst group (Germany)
1997-2007 Chairman of the Supervisory Board of Dade Behring GmbH (Germany)
2011-2013 Managing Director at the University Clinic of Mannheim (Germany)

(1)

No compensation is paid for this office. Appointments to the Board of Trustees of the Foundation are made independently of Sanofi.

Edgar Filing: Sanofi - Form 20-F

Table of Contents

Robert Castaigne	Date of birth:	April 27, 1946
1,000 shares	Nationality:	French
	First elected:	February 2000
	Last reappointment:	May 2014
	Term expires:	2018

Directorships and appointments of Robert Castaigne

Within the Sanofi Group	Outside the Sanofi Group
<u>Current directorships and appointments</u>	

In French companies

Independent director of Sanofi*

Société Générale*:

Member of the Audit Committee of Sanofi

Director

Member of the Audit and Internal Control Committee

Member of the Risk Committee

Vinci*:

Director

Member of the Audit Committee

Chairman of the Remuneration Committee

In foreign companies

None

None

Past directorships since 2010

Edgar Filing: Sanofi - Form 20-F

In French companies

None

None

In foreign companies

None

Director and member of the Audit Committee of *Compagnie Nationale à Portefeuille* (Belgium, until 2011)

Education and business experience

Degree from *Ecole Centrale de Lille* and *Ecole Nationale Supérieure du Pétrole et des Moteurs*

Doctorate in economics

1972-2008 Various positions at the Total* group, including Chief Financial Officer and member of the Executive Committee (1994-2008)

145

Edgar Filing: Sanofi - Form 20-F

Table of Contents

Jean-René Fourtou	Date of birth:	June 20, 1939
4,457 shares	Nationality:	French
	First elected:	August 2004
	Last reappointment:	May 2012
	Term expires:	2016

Directorships and appointments of Jean-René Fourtou

Within the Sanofi Group	Outside the Sanofi Group
<u>Current directorships and appointments</u>	

In French companies

Independent director of Sanofi*

Honorary Chairman of Vivendi*

President of the Appointments and Governance Committee of Sanofi

Member of the Compensation Committee of Sanofi

Member of the Strategy Committee of Sanofi

None

In foreign companies

Director of Generali* (Italy)

Past directorships since 2010

None

In French companies

Chairman of the Supervisory Board of Vivendi* (until 2014)

Chairman of the Supervisory Board of Canal+* Group (until 2011)

Axa*:

Vice President, then member of the Supervisory Board (until 2009)

Member of the Ethics and Governance Committee (until 2009)

Director of AXA Millésimes SAS (until 2011)

Director of Cap Gemini SA* (until 2010)

In foreign companies

None

Member of the Supervisory Board of Maroc Telecom* (Vivendi Group, Morocco, until 2014)

Director of NBC Universal Inc. (United States, until 2010)

Director and member of the Compensation Committee of Nestlé* (Switzerland, until 2012)

Education and business experience

Degree from *École Polytechnique*

1963-1986	Various positions at the Bossard group, including Chairman and Chief Executive Officer (1977-1986)
1986-1999	Chairman and Chief Executive Officer of Rhône-Poulenc*
1999-2004	Vice Chairman of the Management Board, then Vice Chairman of the Supervisory Board and member of the Strategy Committee of Aventis*
2002-2008	Vice Chairman, Chairman then Honorary Chairman of the International Chamber of Commerce
2002-2014	Chairman and Chief Executive Officer of Vivendi* (2002-2005) Chairman of the Supervisory Board of Vivendi* (2005-2014). He is Honorary Chairman of Vivendi*.

Edgar Filing: Sanofi - Form 20-F

Table of Contents

Claudie Haigneré 1,000 shares	Date of birth: Nationality: First elected: Last reappointment: Term expires:	May 13, 1957 French May 2008 May 2012 2016
---	--	--

Directorships and appointments of Claudie Haigneré

Within the Sanofi Group	Outside the Sanofi Group
<u>Current directorships and appointments</u>	

In French companies

Independent director of Sanofi*

Orange* (previously France Telecom):

Member of the Appointments and Governance Committee of Sanofi Director

Member of the Compensation Committee of Sanofi

Member of the Strategy Committee

Chairman of the Board of Directors of *La Géode*

Chairman of Universcience (*Cité des Sciences et de l'Industrie* and *Palais de la Découverte*)

Director of *Fondation de France*

Director of *Fondation C-Génial*

Edgar Filing: Sanofi - Form 20-F

Director of *Fondation d'Entreprise L'Oréal*

Director of *Fondation Lacoste*

Member of *Académie des Technologies*, of *Académie des Sports*, of *Académie Nationale de l'Air et de l'Espace*

Director of *Ecole Normale Supérieure (ENS), Campus Condorcet*, and *PRES HESAM (Pôle de Recherche et d'Enseignement Supérieur Hautes Etudes Sorbonne Arts et Métiers)*

In foreign companies

None

None

Past directorships since 2010

In French companies

None

Director of the *Aéro Club de France* (until 2011)

Vice President of the IAA (International Academy of Astronautics, until 2011)

In foreign companies

None

None

Education and business experience

Rheumatologist, doctorate in sciences majoring in neurosciences

Selected in 1985 by the CNES (French National Space Center) as an astronaut candidate

1984-1992	Rheumatologist, Cochin Hospital (Paris)
1996	Scientific space mission to the MIR space station (Cassiopee, Franco-Russian mission)
2001	Scientific and technical space mission to the International Space Station (Andromède mission)
2002-2004	Deputy Minister for Research and New Technologies in the French government
2004-2005	Deputy Minister for European Affairs in the French government
2005-2009	Counselor at the European Space Agency (ESA)

Table of Contents

Patrick Kron	Date of birth:	September 26, 1953
No shares	Nationality:	French
	First elected:	May 2014
	Term expires:	2018

Directorships and appointments of Patrick Kron

Within the Sanofi Group	Outside the Sanofi Group
<u>Current directorships and appointments</u>	

In French companies

Independent director of Sanofi*

Alstom*:

Chairman and Chief Executive Officer of Alstom

Chairman of Alstom Resources Management SAS

Bouygues*:

Director

Director of *Association Française des Entreprises Privées (AFEP)*

Vice President of the Vocal Group of the Association *Les Arts Florissants*

In Foreign Companies

None

None

Past directorships held since 2010

In French Companies

None

None

In Foreign Companies

None

Alstom*:

Director of Alstom UK Holdings Ltd. (until 2012)

Director and Managing Director of Alstom Asia Pte. Ltd. (until 2014)

Education and business experience

Degree from *Ecole Polytechnique* and *Ecole Nationale Supérieure des Mines de Paris*

- 1979-1984 Various positions at the French Ministry of Industry, including as project officer at the *Direction régionale de l'Industrie, de la Recherche et de l'Environnement (DRIRE)* and in the Ministry's general directorate
- 1984-1988 Operational responsibilities in one of the Pechiney Group's most important factories in Greece then manager of the Greek subsidiary
- 1988-1993 Various senior operational and financial positions within the Pechiney Group
- 1993 Member of the Executive Committee of the Pechiney Group
- 1993-1997 Chairman of the Board of the Carbone Lorraine Company
- 1995-1997 Manager of the Food and Health Care Packaging Sector of Pechiney and Chief Operating Officer of the American National Can Company in Chicago (United States)
- 1998-2002 Chief Executive Officer of Imerys
- Since 2003 **Chief Executive Officer then Chairman and Chief Executive Officer of Alstom***

Edgar Filing: Sanofi - Form 20-F

Table of Contents

Igor Landau	Date of birth:	July 13, 1944
1,000 shares	Nationality:	French
	First elected:	August 2004
	Last reappointment:	May 2011
	Term expires:	2015

Directorships and appointments of Igor Landau

Within the Sanofi Group	Outside the Sanofi Group
<u>Current directorships and appointments</u>	

In French companies

Director of Sanofi*

Director of INSEAD (*Institut Européen d'Administration des Affaires*)

Member of the Strategy Committee of Sanofi

In foreign companies

None

Chairman of the Supervisory Board of Adidas* (Germany)

Allianz SE* (formerly Allianz AG*, Germany):

Member of the Supervisory Board

Member of the Audit Committee

Past directorships since 2010

In French companies

None

Director of HSBC France (until 2012)

In foreign companies

None

Allianz AG* (later Allianz SE*, Germany, until 2012):

Edgar Filing: Sanofi - Form 20-F

Member of the Steering Committee

Member of the General Committee

Member of the Mediation Committee

Member of the Nomination Committee

Education and business experience

Degree from HEC (*Ecole des Hautes Etudes Commerciales*)

MBA from INSEAD (*Institut Européen d'Administration des Affaires*)

1968-1970	Chief Executive Officer of the German subsidiary of La Compagnie du Roneo (Germany)
1971-1975	Management consultant at McKinsey (France)
1975-2004	Various positions at the Rhône-Poulenc group, including member of the Management Board of Aventis (1999-2002), then Chairman of the Management Board of Aventis (2002-2004)
2001-2005	Director of Essilor*
2002-2005	Director of Thomson* (later Technicolor*)
2003-2006	Member of the Supervisory Board of Dresdner Bank (Germany)

149

Table of Contents

Fabienne Lecorvaisier	Date of birth:	August 27, 1962
1,000 shares	Nationality:	French
	First elected:	May 2013
	Term expires:	2017

Directorships and appointments of Fabienne Lecorvaisier

Within the Sanofi Group

Outside the Sanofi Group

Current directorships and appointments

In French companies

Independent director of Sanofi*

Air Liquide* Group:

Member of the Audit Committee of Sanofi

Director of Air Liquide International

Chairman and Chief Executive Officer of Air Liquide Finance

Director of Air Liquide France Industries

Director of Air Liquide Eastern Europe

Director of Aqualung International

In foreign companies

None

Air Liquide* Group:

Executive Vice-President of Air Liquide International Corporation

Edgar Filing: Sanofi - Form 20-F

Director of American Air Liquide Holdings, Inc.

Manager of Air Liquide US LLC

Director of SOAEO

Past directorships since 2010

None	In French companies	None
None	In foreign companies	

Air Liquide* Group:

Director of Air Liquide Japon (until 2013)

Education and business experience

Civil Engineer, graduate from *Ecole Nationale des Ponts et Chaussées*

Since 2008	Chief Financial Officer and Executive Committee Member of Air Liquide*
Since 2013	In charge of the diving activities of Air Liquide* (Aqualung)
1985-1989	Member of the Corporate Finance Department, then Mergers and Acquisitions Department of Société Générale*
1989-1990	Senior Banking Executive in charge of the LBO Department (Paris)/Corporate Finance Department (Paris and London) at Barclays
1990-1993	Assistant General Manager of Banque du Louvre, Taittinger Group
1993-2007	Various positions within Essilor* including Group Chief Financial Officer (2001-2007) and Chief Strategy and Acquisitions Officer (2007-2008)

Edgar Filing: Sanofi - Form 20-F

Table of Contents

Suet-Fern Lee 1,000 shares	Date of birth: Nationality: First elected: Term expires:	May 16, 1958 Singaporean May 2011 2015
--------------------------------------	---	---

Directorships and appointments of Suet-Fern Lee

Within the Sanofi Group	Outside the Sanofi Group
<u>Current directorships and appointments</u>	

In French companies

Independent director of Sanofi*

Axa*:

Director

Member of the Finance Committee

In foreign companies

None

Director of Macquarie International Infrastructure Fund Ltd*
(Bermuda)

Director of National Heritage Board (Singapore)

Director of Rickmers Trust Management Pte Ltd* (Singapore)

Director of Stamford Corporate Services Pte Ltd (Singapore)

Chairman of the Board of directors of the Asian Civilizations
Museum (Singapore)

Director of the World Justice Project (USA)

Past directorships since 2010

Edgar Filing: Sanofi - Form 20-F

In French companies

None

None

In foreign companies

None

Director of Transcu Group Limited* (Singapore, until 2010)

Director of Sembcorp Industries Ltd* (Singapore, until 2011)

Education and business experience

Law degree from Cambridge University (1980)

Admitted to London (1981) and Singapore (1982) Bars

Chairman & Senior Director of Stamford Law Corporation (Singapore)

Since 2006	Member of the Board of Trustees of Nanyang Technological University (Singapore) Member of the Accounting Advisory Board of National University of Singapore Business School (Singapore)
Since 2007	Member of the Advisory Committee of the Singapore Management University School of Law (Singapore)
Since 2014	Member of the Senate of the Singapore Academy of Law where she also chairs the Committee on Legal Education and Studies Chairman of the Expert Panel of Centre of Cross-Border Commercial Law in Asia of the Singapore Management University School of Law (Singapore)
2000-2007	Director of ECS Holdings Limited* (Singapore)
2004-2007	Director of International Capital Investment Limited (Singapore) Director of Media Asia Entertainment Group Limited (Hong Kong) Director of Transpac Industrial Holdings Limited* (Singapore)
2005-2008	Director of China Aviation Oil* (Singapore)
2006-2008	Director of Sincere Watch* (Hong Kong)
2005-2009	Director of Richina Pacific Limited* (Bermuda)
2010-2011	President of the Inter-Pacific Bar Association

Table of Contents

Christian Mulliez	Date of birth:	November 10, 1960
1,471 shares	Nationality:	French
	First elected:	June 2004
	Last reappointment:	May 2014
	Term expires:	2018

Directorships and appointments of Christian Mulliez

Within the Sanofi Group	Outside the Sanofi Group
<u>Current directorships and appointments</u>	

In French companies

Director of Sanofi*	Chairman of the Board of Directors of Regefi
---------------------	--

Member of the Audit Committee of Sanofi	Director of DG 17 Invest
---	--------------------------

Member of the Compensation Committee of Sanofi

None

In foreign companies

Director of L'Oréal USA Inc. (United States)

Director of The Body Shop International (United Kingdom)

Past directorships since 2010

None

In French companies

None

In foreign companies

None

Director of Galderma Pharma (Switzerland, until 2014)

Education and business experience

Degree from ESSEC (*Ecole Supérieure des Sciences Economiques et Commerciales*)

Since 2003	Vice President General Manager Administration and Finance at L'Oréal*
1984-2002	Various positions at Synthélabo and then at Sanofi-Synthélabo, including Vice President Finance

Edgar Filing: Sanofi - Form 20-F

Table of Contents

Carole Piwnica 1,000 shares	Date of birth: Nationality: First elected: Last reappointment: Term expires:	February 12, 1958 Belgian December 2010 May 2012 2016
---------------------------------------	--	---

Directorships and appointments of Carole Piwnica

Within the Sanofi Group	Outside the Sanofi Group
<u>Current directorships and appointments</u>	

In French companies

Independent director of Sanofi*

Eutelsat Communications*:

Member of the Audit Committee of Sanofi

Independent Director

Chairman of the Committee of Governance, Compensation and Appointment

Director of Paris Orléans*

In foreign companies

None

Director of Naxos UK Ltd (United Kingdom)

Director of Big Red (United States)

Director of Elevance (United States)

Director of i2O (United Kingdom)

Edgar Filing: Sanofi - Form 20-F

Director of RecyCoal Ltd. (United Kingdom)

Director of Amyris Inc.* (United States)

Past directorships since 2010

None	In French companies	None
None	In foreign companies	

Director of Toepfer GmbH (Germany, until 2010)

Director of Dairy Crest Plc.* (United Kingdom, until 2010)

Aviva Plc.* (United Kingdom, until 2011):

Director

Chairman of the Corporate Responsibility Committee

Member of the Compensation Committee

Director of Louis Delhaize* (Belgium, until 2013)

Education and business experience

Degree in law, *Université Libre de Bruxelles*

Edgar Filing: Sanofi - Form 20-F

Masters in law, New York University

Admitted to Paris and New York Bars

Since 2006 **Founder Director of Naxos UK Ltd** (United Kingdom)
1985-1991 Attorney at Proskauer, Rose (New York) and Shearman & Sterling (Paris) with practice in mergers and acquisitions
1991-1994 General Counsel of Gardini & Associés
1994-2000 Chief Executive Officer of Amylum France, then Chairman of Amylum Group
1998-2004 Director of Spadel (Belgium)
1996-2006 Director of Tate & Lyle Plc. (United Kingdom)
2000-2006 Director and Vice-Chairman of Tate & Lyle Plc. for Governmental Affairs (United Kingdom)
1996-2006 Chairman of the Liaison Committee and director of the *Confédération Européenne des Industries Agro-Alimentaires* (CIAA)
2000-2006 Chairman of the Export Commission and director of the *Association Nationale des Industries Alimentaires* (ANIA)
2006-2009 Member of the Ethical Committee of Monsanto* (United States)

153

Edgar Filing: Sanofi - Form 20-F

Table of Contents

Klaus Pohle 2,500 shares	Date of Birth: Nationality: First appointment: Last reappointment: Term expires:	November 3, 1937 German August 2004 May 2012 2016
------------------------------------	--	---

Directorships and appointments of Klaus Pohle

Within the Sanofi Group	Outside the Sanofi Group
<u>Current directorships and appointments</u>	

In French companies

None

Independent director of Sanofi*

Chairman of the Audit Committee of Sanofi

None

In foreign companies

Trustee of Aventis Foundation⁽¹⁾ (not-for-profit, Germany)

Past directorships since 2010

None

In French companies

None

In foreign companies

None

Director of Labelux Group GmbH* (Switzerland, until 2011)

Coty Inc.* New York (United States, until 2011):

Director

Chairman of the Audit Committee

Education and business experience

Doctorate in economics from Berlin University (Germany)

Doctorate in law from Frankfurt University (Germany)

LLM from Harvard University (United States)

Professor of Business Administration at the Berlin Institute of Technology (Germany)

1966-1980 Various positions at the BASF group (Germany)
1981-2003 Deputy Chief Executive Officer and Chief Financial Officer of Schering AG (Germany)
2003-2005 Chairman of the German Accounting Standards Board (Germany)
2004-2008 Various positions at Hypo Real Estate Holding AG*, Munich, including Chairman of the Supervisory Board (Germany)
2005-2009 Member of the Supervisory Board and Chairman of the Audit Committee at DWS Investment GmbH, Frankfurt (Germany)

(1)

No compensation is paid for this office. Appointments to the Board of Trustees of the Foundation are made independently of Sanofi.

Edgar Filing: Sanofi - Form 20-F

Table of Contents

Gérard Van Kemmel	Date of birth:	August 8, 1939
1,005 shares	Nationality:	French
	First elected:	May 2003
	Last reappointment:	May 2011
	Term expires:	2015

Directorships and appointments of Gérard Van Kemmel

Within the Sanofi Group	Outside the Sanofi Group
<u>Current directorships and appointments</u>	

In French companies

None

Independent director of Sanofi*

Chairman of the Compensation Committee of Sanofi

Member of the Audit Committee of Sanofi

Member of the Appointments and Governance Committee of Sanofi

In foreign companies

None

None

Past directorships since 2010

In French companies

None

Director of Groupe Eurotunnel* (until 2010)

Director of Europacorp* (until September 2012)

In foreign companies

None

Director of Eurotunnel NRS Holders Company Limited
(United Kingdom, until 2010)

Education and business experience

Graduate of HEC (*Ecole des Hautes Etudes Commerciales*)

Edgar Filing: Sanofi - Form 20-F

MBA from the Stanford Business School

- 1966-1995 Various positions including President of Arthur Andersen and Andersen Consulting in France (1976-1995) and Chairman of the Board of Arthur Andersen Worldwide (1989-1994)
- 1996-1997 Senior advisor to French Finance Minister
- 1997-2006 Various positions at Cambridge Technology Partners including Chief Operating Officer
- 2004-2006 Various positions at Novell* including EMEA Chairman then Europe Chairman

Changes in the Composition of the Board

The composition of the Board of Directors changed in 2014.

Patrick Kron was appointed as a Director of our Company at the Shareholders' General Meeting held on May 5, 2014. His appointment continued our policy of refreshing the Board and brought in additional industrial know-how and international awareness.

Three mandates were renewed in 2014: Christopher Viehbacher, Robert Castaigne and Christian Mulliez.

On October 23, 2014, Thierry Desmarest resigned from the office of Director of our Company in order to resume the chairmanship of Total's Board of Directors following Christophe de Margerie's death.

Following his removal from office as Chief Executive Officer on October 29, 2014, Christopher Viehbacher resigned as a director.

Table of Contents

During the meeting held on November 18, 2014, the Board of Directors co-opted Bonnie Bassler to replace Thierry Desmarest for the remaining part of his term. This appointment reinforces the scientific and pharmaceutical expertise within our Board and is in line with our policy of onboarding more women, and more international and younger directors. This decision is subject to ratification by the Shareholders' General Meeting to be held on May 4, 2015.

Following the enactment of the June 14, 2013 French Employment Protection Act, the Appointments and Governance Committee assessed its impact on Sanofi. The Board of Directors concluded that our Company does not fall within the scope of this Act because it has no obligation to set up a works council and indeed has set up none, the workforce of the parent company being less than 50.

Under current French legislation, given that employees own less than 3% of our share capital, the Board does not include a director representing employee shareholders.

Nevertheless, five Group employee representatives attend Board meetings without voting rights pursuant to the agreement implemented with the European Works Council signed on February 24, 2005. In addition, those French subsidiaries that fall within the scope of the new Act will appoint employee representatives to the Board.

Executive Committee

The Executive Committee is chaired by the Chief Executive Officer.

The Committee meets once a month, and as of the date of this annual report on Form 20-F, has the following permanent members:

Serge Weinberg, Chief Executive Officer;

Olivier Charmeil, Executive Vice President, Vaccines;

Jérôme Contamine, Executive Vice President, Chief Financial Officer;

David-Alexandre Gros, Executive Vice President, Chief Strategy Officer;

Peter Guenter, Executive Vice President, Global Commercial Operations;

Carsten Hellmann, Executive Vice President, Merial;

Karen Linehan, Executive Vice President, Legal Affairs and General Counsel;

Philippe Luscan, Executive Vice President, Global Industrial Affairs;

David P. Meeker, Executive Vice President & Chief Executive Officer Genzyme;

Roberto Pucci, Executive Vice President, Human Resources;

Pascale Witz, Executive Vice President, Global Divisions & Strategic Commercial Development; and

Edgar Filing: Sanofi - Form 20-F

Elias Zerhouni, President, Global Research and Development.

The name, business address, present principal occupation or employment and material occupations, positions, offices or employment for the past five years of each of the executive officers of Sanofi are set forth below. The business address and phone number of each such executive officer is c/o Sanofi, 54 rue La Boétie, 75008 Paris, France, +33 1 53 77 40 00.

Serge Weinberg

Chief Executive Officer

Chairman of the Executive Committee

Date of birth: February 10, 1951

Serge Weinberg was appointed as Chief Executive Officer on October 29, 2014, and is also Chairman of the Strategy Committee and a member of the Appointments and Governance Committee.

For additional information regarding his professional education and business experience see "Composition of the Board of Directors as of December 31, 2014" in "A. Directors and Senior Management" of this Item 6.

Serge Weinberg is a citizen of France.

Table of Contents

Olivier Charmeil

Executive Vice President, Vaccines

Date of birth: February 19, 1963

Olivier Charmeil is a graduate of HEC (*Ecole des Hautes Etudes Commerciales*) and of the *Institut d'Etudes Politiques* in Paris. From 1989 to 1994, he worked in the Mergers & Acquisitions department of Banque de l'Union Européenne. He joined Sanofi Pharma in 1994 as head of Business Development. Subsequently, he held various positions within the Group, including Chief Financial Officer (Asia) for Sanofi-Synthélabo in 1999 and *Attaché* to the Chairman, Jean-François Dehecq, in 2000, before being appointed as Vice President, Development within the Sanofi-Synthélabo International Operations Directorate, where he was responsible for China and support functions. In 2003, Olivier Charmeil was appointed Chairman and Chief Executive Officer of Sanofi-Synthélabo France, before taking the position of Senior Vice President, Business Management and Support within the Pharmaceutical Operations Directorate. In this role, he piloted the operational integration of Sanofi-Synthélabo and Aventis. He was appointed Senior Vice President Asia/Pacific, Pharmaceutical Operations in February 2006 and since January 1, 2008, Operations Japan have reported to him, as have Asia/Pacific and Japan Vaccines since February 2009. Since January 1, 2011, Olivier Charmeil has served as Executive Vice President Vaccines and as a member of the Executive Committee. He became the International Federation Pharmaceutical Manufacturers & Associations (IFPMA) representative on the GAVI Board on August 1, 2014 and as a result is also chairman of the CEO Steering Committee of IFPMA uniting the CEOs of the member companies (GSK, Merck, Johnson & Johnson, Pfizer, Takeda, Novartis and Daiichi Sankyo).

Olivier Charmeil is a citizen of France.

Jérôme Contamine

Executive Vice President, Chief Financial Officer

Date of birth: November 23, 1957

Jérôme Contamine is a Graduate of *École Polytechnique* (X), *ENSAE*, and *ENA (Ecole Nationale d'Administration)*. After four years at the "Cour des Comptes", as a Senior State General Auditor, he joined Elf Aquitaine in 1988, as advisor to the Chief Financial Officer, and became Group Finance and Treasury Director in 1991. He became the General Manager of Elf Petroleum Norway in 1995, after being named Deputy Vice President of Elf Upstream Division for Europe and the U.S. In 1999, he was appointed as a member of the taskforce for integration with Total, in charge of the reorganization of the merged entity, TotalFinaElf, and in 2000 became Vice President Europe and Central Asia, Upstream Division of Total. The same year, he joined Veolia Environnement as CFO and Deputy General Manager. In 2003, he was appointed Vice-President Senior Executive, Deputy Chief Executive Officer, Financial Director of Veolia Environnement. Since 2006 he has been a Director of Valeo. Jérôme Contamine joined Sanofi as Executive Vice President, Chief Financial Officer (CFO) in March 2009.

Jérôme Contamine is a citizen of France.

David-Alexandre Gros

Executive Vice President, Chief Strategy Officer

Date of birth: July 23, 1972

David-Alexandre Gros has a B.A. from Dartmouth College, an M.D. from Johns Hopkins University School of Medicine, and an M.B.A. from Harvard Business School. He did post-graduate training as a Resident Physician with the University of Pennsylvania Health System from 1999 to 2000. In 2002, he started his advisory career at McKinsey & Company as an Associate in the Pharmaceuticals & Medical Products practice, was promoted to Engagement Manager in 2004 and to Associate Principal in 2006. In late 2006, he was appointed Vice President at Merrill Lynch, serving healthcare clients on a wide range of strategic, corporate finance and merger & acquisitions issues. In 2009, he joined Centerview Partners as a Principal and founding member of the Healthcare Investment Banking practice. Dr. Gros joined Sanofi as Chief Strategy Officer in September 2011.

David-Alexandre Gros is a citizen of France.

Peter Guenter

Executive Vice President, Global Commercial Operations

Date of birth: September 2, 1962

Peter Guenter holds a Master's Degree in Physical Education at the Faculty of Medicine and Health Sciences, University of Ghent, Belgium. Peter started his career in Sales at SmithKline in 1986. He joined the Group in 1995 and

Table of Contents

held various positions in France, Europe and Global Marketing. In 2000, he was appointed General Manager Belgium and then Vice President for Eastern Europe and subsequently Northern Europe. In 2008, he took up the position of General Manager, Commercial Operations for Germany and in 2011, Peter became General Manager for the Multi-Country-Organisation for Germany, Switzerland and Austria. He was appointed Senior Vice President, Europe Global Operations in July 2011. He became a member of the Executive Committee and was appointed to his present position in July 2013.

Peter Guenter is a citizen of Belgium.

Carsten Hellmann

Executive Vice President, Merial

Date of birth: April 24, 1964

Carsten Hellmann undertook his first degree in Business Administration in Copenhagen in 1989 before completing an MSc in the UK in Information Management & Technology in 1990.

Carsten Hellmann began his career in 1990 at Radiometer Medical A/S as a product specialist before moving into a product manager role. He joined Novo Nordisk in 1993 and held different roles in marketing, business development, strategic alliances and business intelligence with increasing responsibilities. In 1996 he joined Synthelabo Scandinavia as Sales & Marketing Director and in 1997 Pronosco A/S, a diagnostics start up specialized in osteoporosis as Chief Operating Officer. In 2000 he was named Chief Executive Officer at Nunc Group where he oversaw the P&L and entire value chain of the company, from R&D to sales. Carsten Hellmann oversaw the integration processes during the acquisition of the Apogent Group (Nunc's owner) by Fisher Scientific and subsequently also became Group Vice President of Fisher. He joined Chr. Hansen Holding A/S in 2006 as Executive Vice President, Global Sales, and member of the executive management and board. He was appointed member of the Executive Committee of Sanofi and CEO of Merial in September 2013.

Carsten Hellmann is a citizen of Denmark.

Karen Linehan

Executive Vice President, Legal Affairs and General Counsel

Date of birth: January 21, 1959

Karen Linehan graduated from Georgetown University with Bachelor of Arts and Juris Doctorate degrees. Prior to practicing law, Ms. Linehan served on the congressional staff of the Speaker of the U.S. House of Representatives from September 1977 to August 1986. Until December 1990, she was an Associate in a mid-size law firm in New York. In January 1991, she joined Sanofi as Assistant General Counsel of its U.S. subsidiary. In July 1996, Ms. Linehan moved to Paris to work on international matters within the Group and she has held a number of positions within the Legal Department, most recently as Vice President Deputy Head of Legal Operations. She was appointed to her current position in March 2007.

Karen Linehan is a citizen of the United States of America and Ireland.

Philippe Luscan

Executive Vice President, Global Industrial Affairs

Date of birth: April 3, 1962

Philippe Luscan is a graduate of the *École Polytechnique* and the *École des Mines* in Biotechnology in Paris. He began his career in 1987 as a Production Manager at Danone. In 1990, he joined the Group as Director of the Sanofi Chimie plant at Sisteron, France, and subsequently served as Industrial Director of Sanofi in the United States, as Vice President Supply Chain and as Vice President Chemistry in September 2006. He was appointed to his present position in September 2008. Since January 1, 2015, Philippe Luscan is also President of Sanofi in France.

Philippe Luscan is a citizen of France.

Table of Contents

David P. Meeker

Executive Vice President & Chief Executive Officer Genzyme

Date of birth: October 4, 1954

Dr. Meeker received his M.D. from the University of Vermont Medical School. He completed an Internal Medicine residency at Beth Israel Hospital in Boston and a Pulmonary/Critical Care fellowship at Boston University. He completed the Advanced Management Program at Harvard Business School in 2000.

Prior to joining Genzyme, Dr. Meeker was the Director of the Pulmonary Critical Care Fellowship at the Cleveland Clinic and an assistant professor of medicine at Ohio State University. He is the author of more than 40 articles and multiple book chapters.

Dr. Meeker joined Genzyme in 1994 as Medical Director to work on the Gene Therapy and Cystic Fibrosis program. Subsequently, as Vice President, Medical Affairs, he was responsible for the development of therapeutic products, including treatments in the current rare genetic diseases portfolio.

He was promoted to Senior Vice President in 1998, and in 2000 became the Business Unit Leader for Genzyme's Lysosomal Storage Disease and Thyrogen programs in Europe. Dr. Meeker was promoted to President of the Global LSD business unit in 2003. In this role, he oversaw the global launches of Aldurazyme®, Fabrazyme® and Myozyme®. In 2008, he was promoted to Executive Vice President of Therapeutics, Biosurgery and Transplant. In 2009, he became Chief Operating Officer. In this role, he was responsible for Genzyme's commercial organization, overseeing the business units, country management organization and global market access functions. He became a member of the Executive Committee and was appointed to his present position on November 2011.

David P. Meeker is a citizen of the United States of America.

Roberto Pucci

Executive Vice President, Human Resources

Date of birth: December 19, 1963

Roberto Pucci has a law degree from the University of Lausanne, Switzerland. He started his career in 1985 at Coopers & Lybrand in Geneva, Switzerland as an external auditor. He then joined Hewlett-Packard (HP) in 1987, where he held various positions in Human Resources in Switzerland and Italy including HR Manager for the European Headquarters and Human Resources Director in Italy. In 1999, he became Director, Compensation & Benefits for Agilent Technologies, a spin off from HP, and was appointed Vice President Human Resources Europe in 2003. In 2005 he moved to the United States to join Case New Holland, a subsidiary of the Fiat Group, as Senior Vice President, Human Resources, and was appointed, in 2007, Executive Vice President, Human Resources for the Fiat Group in Torino, Italy. Roberto Pucci joined Sanofi as Senior Vice President Human Resources in October 2009.

Roberto Pucci is a citizen of Italy and Switzerland.

Pascale Witz

Executive Vice President, Global Divisions & Strategic Commercial Development

Date of birth: January 27, 1967

Pascale holds a Master's degree in life sciences / molecular biology from *Institut National des Sciences Appliquées Lyon* and an MBA from INSEAD. Pascale started her career in a research lab before moving to marketing at Becton Dickinson France in 1991. She joined GE Healthcare in 1996, where she had a successful career during 17 years. Throughout her successful career within GE Healthcare, Pascale Witz headed up a number of businesses, first in Europe, Middle East and Africa (EMEA): she was Vice President Six Sigma and Quality (2000-2001), Vice President Information Technology (2001-2002), General Manager, Nuclear Medicine & PET (2002-2004), Vice President Sales & Marketing Services (2005-2006), General Manager, Computed Tomography (2006-2007). She then became Vice President & General Manager of the Global Interventional Radiology and Interventional Cardiology Business (2008-2009), and in 2009 she was appointed President & CEO of the medical diagnostics business, a pharmaceutical business acquired by GE Healthcare (previously Amersham Health). She became a member of Sanofi's Executive Committee and was appointed to her present position in July 2013.

Pascale Witz is a citizen of France.

Table of Contents

Elias Zerhouni

President, Global Research and Development

Date of birth: April 12, 1951

Born in Algeria where he completed his initial medical training, Dr. Zerhouni continued his academic career at the Johns Hopkins University and Hospital (United States) in 1975 where he rose to the rank of professor of Radiology and Biomedical engineering. He served as Chair of the Russell H. Morgan Department of Radiology and Radiological Sciences, Vice Dean for Research and Executive Vice Dean of the School of Medicine from 1996 to 2002 before his appointment as Director of the National Institutes of Health of the United States of America from 2002 to 2008. Dr. Zerhouni was received as member of the U.S. National Academy of Sciences' Institute of Medicine in 2000. He was appointed as Chair of Innovation at the College de France, elected member of the French Academy of Medicine in 2010 and received the Transatlantic Innovation Leadership award in December 2011. He is the author of over 200 scientific publications and 8 patents. In February 2009, Sanofi named Dr. Zerhouni Scientific Advisor to the Chief Executive Officer and to the Senior Vice-President Research & Development. He was appointed President Global Research & Development and has served on the Executive Committee of Sanofi since January 2011. He was appointed as member of the U.S. National Academy of Engineering in 2013.

Dr. Zerhouni is a citizen of the United States of America.

As of December 31, 2014, none of the members of the Executive Committee had their principal business activities outside of Sanofi.

B. Compensation

Compensation and arrangements for corporate officers

The compensation policy for corporate officers is established by the Board of Directors upon the recommendation of the Compensation Committee.

The Board of Directors follows the AFEP-MEDEF Code when setting the compensation of our corporate officers.

The AFEP-MEDEF Code and the recommendations of the *Autorité des marchés financiers* (the French market regulator, hereafter referred to as "AMF"), require specific disclosures about the implementation of the recommendations and, if applicable, explanations of the reasons why any of them may not have been implemented. Currently, as reported under " C. Board Practices ", there is no divergence from the AFEP-MEDEF Code related to compensation.

Serge Weinberg

Serge Weinberg has held the office of Chairman of the Board of Directors since May 17, 2010. Since October 29, 2014, he has also been Chief Executive Officer. He was an outside appointment and has never had an employment contract with Sanofi distinct from his current office.

The Chairman of the Board also chairs the Strategy Committee and, in his capacity as Chief Executive Officer, the Executive Committee. In accordance with our Board Charter and in close collaboration with the Senior Management, the Chairman represents the Company in high-level dealings with governmental bodies and with the Group's key partners, both nationally and internationally, and participates in defining the major strategic choices of the Group especially as regards mergers, acquisitions and alliances. The Chairman and the Chief Executive Officer, when the two offices are separated, keep each other fully informed of their actions.

The compensation of the Chairman of the Board of Directors consists solely of fixed compensation and benefits in kind and excludes any variable compensation, any awards of stock options and performance shares and any directors' attendance fees.

The corporate officers do not receive directors' attendance fees in their capacity as directors. Consequently, Serge Weinberg does not receive directors' attendance fees in his capacity as Chairman of the Board, member of the Appointments and Governance Committee or chairman of the Strategy Committee.

Table of Contents**Compensation awarded to Serge Weinberg**

<i>(in euros)</i>	2014	2013	2012
Compensation payable for the year (details provided in the table below)	708,174	708,040	708,115
Value of stock subscription options awarded during the year	N/A	N/A	N/A
Value of performance shares awarded during the year	N/A	N/A	N/A
Total	708,174	708,040	708,115

Compensation payable and paid to Serge Weinberg

	2014		2013		2012	
<i>(in euros)</i>	Payable	Paid	Payable	Paid	Payable	Paid
Fixed compensation ⁽¹⁾	700,000	700,000	700,000	700,000	700,000	700,000
Annual variable compensation	N/A	N/A	N/A	N/A	N/A	N/A
Exceptional compensation	N/A	N/A	N/A	N/A	N/A	N/A
Attendance fees	N/A	N/A	N/A	N/A	N/A	N/A
Benefits in kind	8,174	8,174	8,040	8,040	8,115	8,115
Total	708,174	708,174	708,040	708,040	708,115	708,115

The amounts reported are gross amounts before taxes.

(1) Fixed compensation payable in respect of a given year is paid during that year.

On March 5, 2014, upon the recommendation of the Compensation Committee, the Board of Directors set the terms of the compensation of Serge Weinberg.

For 2014, his fixed compensation was maintained at an annual amount of €700,000, with no adjustment in consideration of his acting as Chief Executive Officer on a temporary basis. When the Board of Directors asked him to assume the office of Chief Executive Officer, it was decided at his request not to modify his compensation.

He did not receive any variable compensation, stock options, or performance shares during 2014, and nor did he receive director's attendance fees as a member of the Board of Directors.

The amount reported for benefits in kind relates mainly to a company car with a chauffeur.

Serge Weinberg does not benefit from the Sanofi top-up pension plan.

On March 3, 2015, upon the recommendation of the Compensation Committee, the Board of Directors set the terms of the compensation of Serge Weinberg. For 2015, his fixed compensation is maintained at an annual rate of €700,000. He will not receive any variable compensation, stock options, or performance shares. He will not receive attendance fees.

Compensation policy for the Chief Executive Officer

The compensation policy of the Chief Executive Officer follows the same structures and principles as the Group compensation policy described later in this section of the report.

The Sanofi compensation policy seeks to be consistent with market and industry practice in order to provide competitive levels of compensation, to create a strong link between company and individual performance, and to maintain a balance between short-term performance and mid-long-term performance.

The compensation of the Chief Executive Officer is set by the Board of Directors upon the recommendation of the Compensation Committee with reference to compensation paid to the chief executive officers of major global pharmaceutical companies and of major companies in the CAC 40 stock market index. Consistency with market practice is fundamental in order to attract and retain the talents necessary to the Group's success.

Sanofi compensation policy for the Chief Executive Officer aims at achieving a balance in the compensation structure between fixed compensation, short-term variable cash compensation, and medium-term variable equity

Table of Contents

compensation. The amounts of fixed and variable compensation are stable over time. Compensation adjustments based on performance and market practice are carried out through equity compensation, which is medium-term and aims at aligning the interests of the Chief Executive Officer with those of our shareholders and stakeholders.

Our overall compensation policy is designed to motivate and reward performance by ensuring that a significant portion of executive and employee compensation is contingent on the attainment of financial, operational and social criteria aligned with the corporate interest and creation of shareholder value. Variable cash compensation and equity compensation are the two principal levers for action. As an exception and upon his request, Serge Weinberg did not benefit from these elements of compensation for the transitional period during which he is acting as Chief Executive Officer.

Equity compensation is a critical tool for the worldwide attractiveness of Sanofi as an employer, and aims to align employee and shareholder interests and reinforce employees' ties to the Group.

Upon the recommendation of the Compensation Committee, the Board of Directors determines the performance conditions attached to equity compensation for all beneficiaries at Sanofi and its subsidiaries worldwide, favoring the attainment of goals based on the Group's consolidated results and balance sheet.

Since 2011 our equity compensation plan rules have been made available to our shareholders on the governance page of our website (www.sanofi.com) in the same form as that distributed to our employees.

Since 2011 the Board of Directors has substantially reworked our equity compensation policy to reinforce the link with long-term performance for all beneficiaries and to reduce potential dilution. As a result of very positive shareholder feedback collected through corporate governance roadshows, contacts with governance professionals and the results of the last three Annual General Meetings, the Board decided to maintain and reinforce this policy in 2013.

The current policy can generally be characterized by reduced dilution; diversified, multi-year performance conditions; increased transparency; and specific additional requirements for the Chief Executive Officer.

The policy requires that grants be primarily based on performance shares with only a limited number of high-level executives (members of the Global Leadership Team) continuing to receive stock options.

A greater reliance on performance shares allows the Board of Directors to maintain a comparable level of employee incentivization while reducing the dilutive effect for existing shareholders. However, the Board of Directors continues to believe that options remain an appropriate component of the compensation of senior managers, due to their multiplier effect.

The Board of Directors subject any grant of options to subscribe for shares and performance shares to several distinct performance criteria in order to ensure that Sanofi equity compensation incentivizes strong overall performance and does not encourage excessive risk taking. Failure to achieve these conditions over the entire performance period is sanctioned by a reduction or loss of the grant.

Grants are also contingent on the beneficiary's continued employment in the Sanofi Group (4 years for options, 3 to 4 years for performance shares).

The exercise price of options to subscribe for shares set by the Board never incorporates a discount, and must be at least equal to the average of the quoted market prices on the 20 trading sessions preceding the date of grant by the Board.

The Board is not allowed to reset prior grants, for instance with easier performance conditions or a lower strike price.

Each grant to the Chief Executive Officer takes into account previous grants and his global compensation.

Christopher Viehbacher

Christopher Viehbacher held the office of Chief Executive Officer of Sanofi from December 1, 2008 to October 29, 2014. He was an outside appointment and never had an employment contract with Sanofi distinct from his position as Chief Executive Officer.

Table of Contents

The compensation of Christopher Viehbacher which is hereafter reported corresponds to the period during which he was Chief Executive Officer, i.e. from January 1, until October 29, 2014.

The compensation of Christopher Viehbacher was made up of the following elements:

fixed compensation;

benefits in kind;

annual variable compensation subject to annual objectives;

equity compensation consisting of options to subscribe for shares and performance shares, subject to both internal and external conditions measured over three years and to stringent lock-up obligations.

In addition, Christopher Viehbacher benefited from:

a top-up defined benefit pension plan; and

a termination benefit contingent upon performance conditions and only payable if the departure is non-voluntary and linked to a change in control or strategy.

Compensation, options and shares awarded to Christopher Viehbacher

<i>(in euros)</i>	2014	2013	2012
Compensation payable for the year (details provided in the table below)	2,383,044	2,964,976	3,522,051
Value of stock subscription options awarded during the year ⁽¹⁾	3,026,400	2,884,800	2,020,800
Value of performance shares awarded during the year ⁽²⁾	2,846,700	2,798,550	1,938,300
Total	8,256,144	8,648,326	7,481,151

(1) *Valued at date of grant using the Black & Scholes method assuming fulfillment of the performance conditions.*

(2) *Valued at date of grant assuming fulfillment of the performance conditions. The value is the difference between the quoted market price of the share on the date of grant and the dividends to be paid over the next three years.*

Compensation payable and paid to Christopher Viehbacher

	2014		2013		2012	
<i>(in euros)</i>	Payable	Paid	Payable	Paid	Payable	Paid

Edgar Filing: Sanofi - Form 20-F

Fixed compensation ⁽¹⁾	1,040,870	1,040,870	1,260,000	1,260,000	1,250,000	1,250,000
Annual variable compensation ⁽²⁾	1,338,750	1,701,000	1,701,000	2,268,000	2,268,000	2,280,000
Exceptional compensation ⁽³⁾	0	0	0	0	0	0
Attendance fees	0	0	0	0	0	0
Benefits in kind	3,424	3,424	3,976	3,976	4,051	4,051
Total	2,383,044	2,745,294	2,964,976	3,531,976	3,522,051	3,534,051

The amounts reported are gross amounts before taxes.

(1) Fixed compensation payable in respect of a given year is paid during that year and prorated to reflect the period during which he held office in 2014.

(2) Variable compensation in respect of a given year is determined and paid at the start of the following year.

(3) Amounts payable in connection with his removal from office and the settlement agreement signed on January 22, 2015 are payable in 2015.

At its meeting on March 5, 2012, upon the recommendation of the Compensation Committee, the Board of Directors established the terms of the compensation package for Christopher Viehbacher for 2012. His fixed annual compensation was set at €1,260,000 as from March 5, 2012, i.e. the total fixed compensation for 2012 amounted to €1,250,000. This represented an increase of 5% compared to the level of fixed compensation set by the Board in 2008 at the time Christopher Viehbacher was recruited.

At its meeting of March 5, 2014, upon the recommendation of the Compensation Committee, the Board of Directors established the terms of the compensation package for Christopher Viehbacher for 2014. His fixed compensation was maintained at €1,260,000 for 2014.

Table of Contents

At its meeting of October 29, 2014, the Sanofi Board of Directors removed Christopher Viehbacher from office as Chief Executive Officer. As a result, his fixed compensation was prorated to €1,040,870 for 2014.

The amount reported for benefits in kind relates mainly to a company car with a chauffeur.

For 2014, the variable compensation of Christopher Viehbacher could have represented between 0% and 200% of his fixed compensation, with a target of 150%.

His variable compensation with respect to 2014 was established on the basis of quantitative and qualitative criteria. These criteria were as follows:

attainment of financial targets compared to our budget (45%) This objective included sales growth (15%) and growth in Business Net Income (30%);

improved performance in research and development (25%). This objective included new product registrations and submissions in the U.S. and in Europe and developments in the product portfolio;

organizational structure of the Group and succession planning for key posts in the Group (15%). This objective covered among others the implementation of a Group organizational structure suited to its strategy (in particular the rollout of the new commercial operations structure), and succession planning for key posts;

corporate social responsibility (15%). This objective covered four areas:

Patients: access to healthcare, patient safety;

Ethics: ethics in R&D, in business and in purchasing;

People: health and safety, diversity, people development;

Planet: power consumption, carbon footprint, water management and environment.

Objectives based on operations and research and development are quantitative criteria, whereas objectives based on the Group organizational structure and succession planning are of a qualitative nature. Corporate social responsibility criteria are partially quantitative and partially qualitative. Overall, quantitative objectives account for 77.5% and qualitative objectives account for 22.5%.

In general, the performance criteria apply not only to variable compensation but also to the vesting of stock options and performance shares in compliance with our targets, which are ambitious.

For reasons of confidentiality, the specific targets set for the quantitative and qualitative criteria, even though they have been properly established in a specific manner, cannot be publicly disclosed. In evaluating these criteria, the performance of the major global pharmaceutical companies was taken into account.

At its meeting on December 18, 2014, upon the recommendation of the Appointments and Governance Committee and of the Compensation Committee, the Board of Directors authorized the finalization and signing of a settlement agreement with Christopher Viehbacher with a view to putting an end to the ongoing dispute on the terms, conditions and consequences of his removal from office.

The settlement agreement was signed on January 22, 2015 and provides in particular for:

payment of €2,961,000, which corresponds to his fixed and variable compensation for one year;

payment of his 2014 variable compensation. At its meeting on March 3, 2015, the Board of Directors considered that the financial targets, R&D targets and corporate social responsibility targets had been fully attained, while the other criteria concerning organizational structure and succession planning had not been fully attained. Because he did not hold office for the whole of 2014, his variable compensation is due on a pro rata basis. Based on the above, the Board of Directors set his variable compensation for 2014 at 85.7% of his target, which prorated amounts to €1,338,750. Christopher Viehbacher's variable compensation for 2014 will be paid in 2015;

a non-compete undertaking valid until June 30, 2015 in exchange for a payment of €246,750 per month during that period;

an undertaking not to hire away previous employees of the Company and a confidentiality agreement, for 18 months and 24 months respectively;

an undertaking to cooperate in connection with legal procedures in which the Company may be involved.

Table of Contents

The undertaking to pay a termination benefit if the departure was forced, as described below and approved by the Shareholders' General Meeting held on April 17, 2009, was not implemented. See " Termination Arrangement" below.

Christopher Viehbacher's termination benefit could only have been activated in accordance with the AFEP-MEDEF Code, i.e. in the event of removal or resignation linked to a change in control or strategy.

Furthermore, pursuant to the plans' rules and applicable law, Christopher Viehbacher retains the ability to exercise the options to subscribe for shares that were already awarded to him and to vest the performance shares already awarded to him, in compliance with the terms and conditions of each plan, including performance conditions.

Stock options awarded to Christopher Viehbacher in 2014

Origin	Date of Board grant	Nature of options	Value (in €)	Number of options awarded in 2014	Exercise price (in €)	Exercise period
Sanofi	03/05/2014	Subscription options	3,026,400	240,000	73.48	03/06/2018 03/05/2024

On March 5, 2014, 240,000 share subscription options were awarded to Christopher Viehbacher. In compliance with the AFEP-MEDEF Code, the entire award is contingent upon both internal criteria based upon Business Net Income and Return on Assets ("ROA"), and an external criterion based on Total Shareholder Return ("TSR") in comparison to a reference set of pharmaceutical companies. These criteria were selected because they align medium-term equity-based compensation on the strategy adopted by the Company.

This award is broken down as follows:

The performance criterion based on Business Net Income covers 40% of the award and refers to the ratio, at constant exchange rates, between actual Business Net Income and the Business Net Income specified in the budget. If the ratio is less than 95%, the corresponding options will lapse. The Business Net Income target may not be lower than the lower range of the guidance published by the Company at the beginning of each year.

The ROA-based criterion covers 40% of the award. The schedule includes a target ROA, below which the performance will be penalized by the lapsing of some or all of the options.

The TSR-based criterion covers 20% of the award. The overall return to shareholders is evaluated both on the value of Sanofi shares (the increase in the share price) and the value distributed to shareholders (dividends), i.e. the two sources of a return on investment in Sanofi shares. Our TSR is compared with a reference set comprised of 11 companies, i.e. Sanofi, Astra Zeneca, Bayer, BMS, Eli Lilly, GSK, Johnson & Johnson, Merck, Novartis, Pfizer, and Roche. The number of options exercisable depends upon our position in comparison to the TSR for the other companies of this panel. Below the median, the corresponding options will lapse.

In addition to the three conditions set forth above, an implicit condition exists in the form of the exercise price, as well as the condition of continuing employment.

In order to bring equity-based compensation into line with medium-term performance, performance will be measured over three financial years.

Edgar Filing: Sanofi - Form 20-F

The Board regards these performance conditions as good indicators of the development of shareholder value in terms of: the quality of investment decisions in a period where external growth plays a greater role than in the past (ROA condition); a commitment to delivering challenging bottom-line results in a tough business environment (Business Net Income condition); and matching or exceeding our peer group as in terms of shareholder returns (TSR condition).

Although for reasons of confidentiality the quantitative measures for the internal criteria cannot be publicly disclosed, even though they have been properly established in a precise manner, the targets and the level of attainment for the internal criteria will be publicly disclosed at the end of the performance measurement period.

Using the Black & Scholes method, each option awarded on March 5, 2014 was valued at €12.61, valuing the total benefit at €3,026,400.

Table of Contents

The Board of Directors had decided to limit the number of options that could be awarded to Christopher Viehbacher to 15% of the total limit approved by the Shareholders' General Meeting held on May 3, 2013 (0.7% of our share capital). The number of options awarded to Christopher Viehbacher in 2014 represents 2.60% of the total limit approved by the Shareholders' General Meeting held on May 3, 2013 and 23.8% of the total award to all beneficiaries on March 5, 2014.

It is important to note that since 2011, options to subscribe for shares have been restricted to members of the Global Leadership Team and are no longer offered to all beneficiaries of equity compensation plans. This explains why the proportion of the option plans granted to Christopher Viehbacher is higher than in the past.

Stock options held by Christopher Viehbacher as of October 29, 2014

Origin	Date of Board grant	Nature of options	Value (in €)	Number of options awarded	Exercise price (in €)	Exercise period
sanofi-aventis	03/02/09	Subscription options	1,237,500	250,000	45.09	03/04/2013 03/01/2019
sanofi-aventis	03/01/10	Subscription options	2,499,750	275,000	54.12	03/03/2014 02/28/2020
sanofi-aventis	03/09/11	Subscription options	2,364,000	300,000	50.48	03/10/2015 03/09/2021
Sanofi	03/05/12	Subscription options	2,020,800	240,000	56.44	03/06/2016 03/05/2022
Sanofi	03/05/13	Subscription options	2,884,800	240,000	72.19	03/06/2017 03/05/2023
Sanofi	03/05/14	Subscription options	3,026,400	240,000	73.48	03/06/2018 03/05/2024

In 2011, as part of its commitment to transparency, Sanofi undertook to publish in its annual report the level of attainment determined by the Board of Directors for performance conditions applicable to future equity-based compensation plans awarded to the Chief Executive Officer and the other members of the Executive Committee. The Board believes that disclosing the level of attainment allows our shareholders to better understand the demanding nature of the performance conditions. The 2009 performance share plan and the 2011 stock option plan were the first plans for which the Board of Directors determined the level of fulfillment of the performance conditions.

On March 9, 2011, 300,000 subscription options were awarded to Christopher Viehbacher. In compliance with the AFEP-MEDEF Code, the entire award was contingent upon both internal criteria based on Business Net Income and Return on Assets ("ROA"), and external criteria based on Total Shareholder Return ("TSR") in comparison to a reference set of twelve pharmaceutical companies.

For the first period (consisting of fiscal years 2011 and 2012) which related to 50% of the March 9, 2011 grant, the performance was as follows:

The performance criterion based on Business Net Income (which covered 40% of the award) was fulfilled, reaching 106% of the target;

The ROA-based criterion (which covered 40% of the award) was fulfilled, being 1.7% above the target;

Edgar Filing: Sanofi - Form 20-F

The TSR-based criterion (which covered 20% of the award) was fulfilled, Sanofi ranking 5th among the panel of 12 peers.

The Board of Directors, in its meeting of February 6, 2013, determined that the global performance rate for the first period was greater than 100% and therefore, since the performance condition had been fulfilled, 50% of the stock subscription options granted would be exercisable at the end of the four-year vesting period subject to meeting the condition of continuing employment.

For the second period (consisting of fiscal years 2013 and 2014), the performance was as follows:

The performance criterion based on Business Net Income (which covered 40% of the award) was fulfilled, reaching 97.7% of the target;

Table of Contents

The ROA-based criterion (which covered 40% of the award) was fulfilled, being 0.2% above the target;

The TSR-based criterion (which covered 20% of the award) was fulfilled, reaching 78.6%, Sanofi ranking 8th among the panel of 11 peers.

The Board of Directors, in its meeting of March 3, 2015, determined that the global performance rate for the second period was 94.8% and therefore, since the performance condition had been partially fulfilled, 94.8% of the stock subscription options granted would be exercisable at the end of the four-year vesting period. The Board of Directors determined that the global performance rate for the March 9, 2011 option plan was 97.4% and therefore 292,200 options would be exercisable at the end of the 4-year vesting period.

On March 5, 2012, 240,000 subscription options were awarded to Christopher Viehbacher. In compliance with the AFEP-MEDEF Code, the entire award was contingent upon performance conditions for the period 2012-2014.

The Board of Directors, in its meeting of February 4, 2015, determined that:

The performance criterion based on Business Net Income (which covered 40% of the award) was fulfilled, reaching 84.4% of the target;

The ROA-based criterion (which covered 40% of the award) was fulfilled, being 0.5% above the target;

The TSR-based criterion (which covered 20% of the award) was fulfilled, reaching 57.6%, Sanofi ranking 9th among the panel of 11 peers.

The Board of Directors, in its meeting of February 4, 2015, determined that the global performance rate was 85.3% and therefore, since the performance condition had been partially fulfilled, 204,720 options would be exercisable at the end of the 4-year vesting period.

The total number of unexercised options held by Christopher Viehbacher as of October 29, 2014 represented 0.12% of the share capital as at December 31, 2014.

Performance shares awarded to Christopher Viehbacher in 2014

Origin	Date of Board award	Value (in €)	Number of performance shares awarded in 2014	Vesting date	Availability date
Sanofi	03/05/14	2,846,700	45,000	03/06/2017	03/06/2019

On March 5, 2014, 45,000 performance shares were awarded to Christopher Viehbacher. In compliance with the AFEP-MEDEF Code, the entire award is contingent upon both internal criteria based on Business Net Income and Return on Assets ("ROA"), and an external criterion based upon Total Shareholder Return ("TSR") in comparison to a reference set of pharmaceutical companies. These criteria were selected because they align medium-term equity-based compensation with the strategy adopted by the Company.

This award is broken down as follows:

Edgar Filing: Sanofi - Form 20-F

The performance criterion based on Business Net Income covers 40% of the award and refers to the ratio, at constant exchange rates, between actual Business Net Income and the Business Net Income specified in the budget. If the ratio is less than 95%, the corresponding performance shares will lapse. The Business Net Income target may not be lower than the lower range of the guidance published by the Company at the beginning of each year.

The ROA-based criterion covers 40% of the award. The schedule includes a target ROA, below which the performance will be penalized by the lapsing of part or all of the performance shares.

The TSR-based criterion covers 20% of the award. The overall return to shareholders is evaluated both on the value of Sanofi shares (the increase in the share price) and the value distributed to shareholders (dividends), i.e. the two sources of return on investment in Sanofi shares. Our TSR is compared with a reference set comprised of eleven companies, i.e. Sanofi, Astra Zeneca, Bayer, BMS, Eli Lilly, GSK, Johnson & Johnson, Merck, Novartis, Pfizer, and Roche. The number of shares vesting depends upon our position in comparison to the TSR for the other companies of this panel. Below the median, the corresponding performance shares will lapse.

Table of Contents

In order to bring equity-based compensation into line with medium-term performance, performance will be measured over three financial years.

The Board regards these performance conditions as good indicators of the development of shareholder value in terms of: the quality of investment decisions in a period where external growth plays a greater role than in the past (ROA condition); a commitment to delivering challenging bottom-line results in a tough business environment (Business Net Income condition); and matching or exceeding our peer group in terms of shareholder returns (TSR condition).

Although for reasons of confidentiality the quantitative measures for the internal criteria cannot be publicly disclosed, even though they have been properly established in a precise manner, the targets and the level of attainment for the internal criteria will be publicly disclosed at the end of the performance measurement period.

Each performance share awarded on March 5, 2014, was valued at €63.26, valuing the total benefit at €2,846,700.

The Board of Directors had decided to limit the number of performance shares that could be awarded to Christopher Viehbacher to 5% of the total limit approved by Shareholders' General Meeting held on May 4, 2012 (1.2% of our share capital). The number of shares awarded to Christopher Viehbacher in 2014 represents 0.28% of this total limit approved by the Shareholders' General Meeting held on May 4, 2012 and 3.5% of the total award to all beneficiaries on March 5, 2014.

Performance shares awarded to Christopher Viehbacher which became available in 2014

No performance shares became available.

Performance shares awarded to Christopher Viehbacher as of October 29, 2014

Origin	Date of Board award	Value (in €)	Number of performance shares awarded	Vesting date	Availability date
sanofi-aventis	03/02/09	2,221,700	65,000	03/03/2011	03/04/2013
sanofi-aventis	03/09/11	1,282,500	30,000	03/10/2013	03/10/2015
Sanofi	03/05/12	1,938,300	42,000	03/06/2015	03/06/2017
Sanofi	03/05/13	2,798,550	45,000	03/06/2016	03/06/2018
Sanofi	03/05/14	2,846,700	45,000	03/06/2017	03/06/2019

Under Share 2010, the Group's global restricted share plan benefiting each Group employee with at least three months' service, 20 restricted shares were awarded to Christopher Viehbacher on October 27, 2010. This award is not included in the schedule above as Christopher Viehbacher subsequently renounced this award.

On March 5, 2012, 42,000 performance shares were awarded to Christopher Viehbacher. In accordance with the AFEP-MEDEF Code, the entire award was contingent upon performance conditions for the period 2012-2014.

The Board of Directors, in its meeting of February 4, 2015, determined that:

The performance criterion based on Business Net Income (which covered 40% of the award) was fulfilled, reaching 84.4% of the target;

Edgar Filing: Sanofi - Form 20-F

The ROA-based criterion (which covered 40% of the award) was fulfilled, being 0.5% above the target;

The TSR-based criterion (which covered 20% of the award) was fulfilled, reaching 57.6%, Sanofi ranking 9th among the panel of 11 peers.

The Board of Directors, in its meeting of February 4, 2015, determined that the global performance rate was 85.3% and therefore, since the performance condition had been partially fulfilled, 35,826 shares would vest.

The total number of performance shares awarded to Christopher Viehbacher as of October 29, 2014 represented 0.017% of our share capital as of December 31, 2014.

Table of Contents

Olivier Brandicourt

The Board of Directors' meeting held on February 19, 2015 appointed Olivier Brandicourt as Chief Executive Officer and co-opted him as a Director of Sanofi with effect from April 2, 2015.

He is an outside appointment and has never had an employment contract with Sanofi distinct from his appointment as Chief Executive Officer.

Olivier Brandicourt has 28 years of global experience in the pharmaceutical industry, most recently as Chairman of the Board of Management of Bayer HealthCare AG and member of the Executive Council of Bayer AG. Previously, Olivier Brandicourt held numerous positions of increasing responsibility within major global pharmaceutical groups, such as Parke-Davis/Warner-Lambert and Pfizer. Notably, Olivier Brandicourt served as a member of Pfizer's global Executive Leadership Team from 2010-2013.

A physician by training, Olivier Brandicourt's career includes several senior positions in Europe, Canada and the United States. As the head of various key healthcare divisions, he has a broad range of expertise and knowledge of the pharmaceutical industry and has led the launch of numerous new medicines and the completion of strategic acquisitions and integrations.

Acting on the recommendation of the Compensation Committee, the Board authorized the financial conditions related to this appointment, which are summarized hereafter:

In compensation for benefits forfeited upon his departure from his previous employer, Oliver Brandicourt will receive:

A lump-sum indemnity of €2 million (gross), due upon his taking up office;

A lump-sum indemnity of €2 million (gross), payable in January 2016 and subject to a condition of continued employment;

A grant of 66,000 performance shares, subject to 3-year performance conditions. The vesting of these shares is contingent upon the average of the ratios of adjusted net income excluding selected items (a non-GAAP financial measure) to net sales for each financial year being at least 18% over the 3 years of the plan.

These elements are intended to indemnify him for the material benefits he is losing because of his departure from Bayer (variable compensation, equity-based compensation).

His annual compensation will be made up of the following elements:

Fixed annual compensation of €1,200,000 (gross);

Variable annual compensation with a target of 150% of his fixed annual compensation, subject to quantitative and qualitative performance conditions and capped at 250% of his fixed annual compensation.

His equity compensation will consist of an annual grant of 220,000 stock options and 45,000 performance shares.

Olivier Brandicourt will become a beneficiary of Sanofi's defined benefit top-up retirement plan, with an attribution of ten years' service as of the date of his taking up office. Ten years' service is a requirement for eligibility for the Sanofi retirement plan;

Edgar Filing: Sanofi - Form 20-F

In the event of removal or resignation from office as Chief Executive Officer linked to a change in control or strategy, Olivier Brandicourt will receive a termination benefit equivalent to 24 months of total compensation on the basis of his fixed compensation effective on the date he ceases to hold office and the last variable compensation received prior to that date.

Payment of the termination benefit will be contingent upon fulfillment of the following two performance criteria, assessed over the three financial years preceding his ceasing to hold office:

the average of the ratios of adjusted net income excluding selected items (a non-GAAP financial measure) to net sales for each financial year must be at least 15%;

the average of the ratios of operating cash flow before changes in working capital to net sales for each financial year must be at least 18%.

Table of Contents

The amount of this indemnity will be reduced by any amount received under the non-compete indemnity, such that the cumulative amount of these two indemnities may in no case exceed the equivalent of two years of total compensation.

In the event of his departure from the Company, Olivier Brandicourt undertakes for the 12-month period after his departure not to join a competitor of the Company as an employee or executive officer, or to provide services to or cooperate with such a competitor.

In return for his undertaking, he will receive an indemnity corresponding in total to one year's total compensation on the basis of his fixed compensation effective on the date he ceases to hold office and the last variable compensation received prior to that date. The indemnity will be payable in 12 instalments.

In the event of his departure from the Company, the Board reserves the unilateral right to cancel this 12-month non-compete agreement, either totally or partially. In such a case, this non-compete indemnity would not be due for the period of time waived by the Company.

At the annual general meeting scheduled for May 4, 2015, the Company's shareholders will vote on the statutory auditor's special report concerning retirement benefits and the termination and non-compete indemnity agreements.

Arrangements for corporate officers

Pension arrangements

During his term of office, Christopher Viehbacher was covered by the Sanofi top-up defined benefit pension plan. The plan is offered to all employees of Sanofi and its French subsidiaries who meet the eligibility criteria specified in the plan rules. This plan, which remains open, was set up on October 1, 2008 as the final stage in the process of harmonizing the status of personnel across the French subsidiaries.

Because he left the Company before the legal age of retirement, Christopher Viehbacher lost all rights under the pension arrangements described below.

This top-up defined-benefit pension plan is offered to executives (within the meaning of the AGIRC regime *Association Générale des Institutions de Retraite des Cadres*, a confederation of executive pension funds) of Sanofi and its French subsidiaries who meet the eligibility criteria specified in the plan rules; the benefit is contingent upon the plan member ending his or her career within the Group. The plan is reserved for executives with at least ten years of service whose annual base compensation has for ten years (not necessarily consecutive) exceeded four times the French social security ceiling, and is wholly funded by the Company.

Based on the assumptions used in the actuarial valuation of this plan, 560 executives were potentially eligible for this plan (11 retirees, 89 early retirees and 460 active employees) as of December 31, 2014.

The top-up pension, which may not exceed 37.50% (1.5% per year of service capped at 25 years) of the reference compensation, is in the form of a life annuity, and is transferable as a survivor's pension. The annuity is based on the arithmetical average of the three highest years' average annual gross compensation (fixed plus variable) paid during the five years (not necessarily consecutive) preceding final cessation of employment. This reference compensation is capped at 60 times the French social security ceiling ("PASS") applicable in the year in which the rights vest.

This annuity supplements the schemes to which the beneficiary may be eligible in France or abroad, subject to a cap on the total pension from all sources equal to 52% of the reference compensation. When the total amount of the annuities paid pursuant to the different schemes exceeds this 52% cap, the amount of the Sanofi top-up defined-benefit pension is reduced accordingly to respect this cap.

In order to receive this pension, Christopher Viehbacher had to be entitled to benefit from compulsory industry schemes, which means that because he was removed from office as Chief Executive Officer and consequently left the Company before the legal retirement age at which he would have been entitled to full pension rights, he lost the entire benefit of the Sanofi top-up defined-benefit pension.

The eligibility of Christopher Viehbacher for this plan had been approved by the Shareholders' General Meeting of April 17, 2009.

Table of Contents

Termination arrangement

Any activation of this termination benefit can only be carried out if the departure is forced, i.e. in the event of removal from office or resignation linked to a change in control or strategy. In practice, the non-renewal of the term of office of the Chief Executive Officer at its expiration date is not applicable as this office is held for an indefinite term.

Any activation of this termination benefit is excluded:

in the event of removal from office for gross or serious cause or misconduct ("*faute grave ou faute lourde*");

if he elects to leave the Company in order to hold another position;

if he is assigned to another position within the Group;

if he is able to benefit from pension rights in the near future.

The amount of this termination benefit is limited to 24 months of total compensation on the basis of the fixed compensation effective on the date he ceases to hold office and the last variable compensation received prior to that date, subject to the performance criteria described below.

In accordance with article L. 225-42-1 of the French Commercial Code and with the AFEP-MEDEF Code, payment of the termination benefit is contingent upon fulfillment of two of the three performance criteria listed below, assessed over the three financial years preceding his ceasing to hold office.

The three criteria are:

the average of the ratios of adjusted net income excluding selected items (a non-GAAP financial measure) to net sales for each financial year must be at least 15%;

the average of the ratios of operating cash flow before changes in working capital to net sales for each financial year must be at least 18%;

the average of the growth rates for the Group's activities, measured for each financial year in terms of net sales on a comparable basis, must be at least equal to the average of the growth rates of the Pharmaceutical and Vaccines activities of the top 12 global pharmaceutical companies, measured for each financial year in terms of net sales adjusted for the principal effects of exchange rates and changes in scope of consolidation.

On October 29, 2014, the Board of Directors removed Christopher Viehbacher from office. This undertaking could only be implemented in the event of his removal or resignation linked to a change in control or strategy of the Company. In order to put an end to the ongoing dispute on the terms, conditions and consequences of his removal from office, a settlement agreement was signed on January 22, 2015; this agreement is described above. See " Compensation payable and paid to Christopher Viehbacher" above.

Commitments for the benefit of the Chairman and Chief Executive Officer in office as of December 31, 2014

Contract of employment	Top-up pension plan	Compensation or benefits payable or potentially	Compensation payable under non-competition clause
-------------------------------	----------------------------	--	--

**payable on
termination
of office**

Serge Weinberg

None

None

None

None

Lock-up obligation for shares obtained on exercise of stock options or disposition of performance shares by the Chief Executive Officer

Until he ceases to hold office, the Chief Executive Officer will be required to retain, in the form of Sanofi shares, 50% of any capital gains (net of taxes and social contributions) obtained by the exercise of stock options or upon disposition of performance shares awarded by Sanofi. He must hold these shares in registered form until he ceases to hold office.

In compliance with the AFEP-MEDEF Code and our Board Charter, Christopher Viehbacher had undertaken to refrain from entering into speculative or hedging transactions, and, so far as Sanofi is aware, no such instruments had been contracted.

Table of Contents

Following his removal from office as Chief Executive Officer, Christopher Viehbacher is no longer bound either by his lock-up obligations or by his undertaking to refrain from entering into speculative or hedging transactions.

Compensation and pension payments for Directors other than the Chairman and the Chief Executive Officer

Attendance fees

The table below shows amounts paid to each member of the Sanofi Board of Directors in respect of 2013 and 2014, including those whose term of office ended during those years.

Attendance fees in respect of 2013, the payment timing schedule for which was determined at the Board meeting of July 31, 2013, and the amount of which was approved at the Board meeting of March 5, 2014 were partially paid in July 2013. The balance was paid in 2014.

Attendance fees in respect of 2014, the amount of which was approved at the Board meeting of March 3, 2015, were partially paid in July 2014. The balance will be paid in 2015.

For 2014, the basic annual attendance fee was set at €15,000, apportioned on a time basis for Directors who assumed or left office during the year.

For 2014, the variable portion of the fee is linked to actual attendance by Directors in accordance with the principles described below:

Directors resident in France receive €5,000 per Board or Committee meeting attended, except for Audit Committee meetings for which the fee is €7,500 per meeting;

Directors resident outside France but within Europe receive €7,000 per Board meeting attended, and €7,500 per Committee meeting attended;

Directors resident outside Europe receive €10,000 per Board meeting attended;

the chairman of the Compensation Committee receives €7,500 per Committee meeting;

the chairman of the Audit Committee, who is resident outside France, receives €10,000 per Committee meeting.

The attendance fee payable to a Director who participates by conference call or by videoconference is equivalent to half of the attendance fee received by a Director resident in France who attends in person.

As an exception, multiple meetings held on the same day give entitlement to a single attendance fee:

if on the day of a Shareholders' General Meeting, the Board of Directors meets both before and after the Meeting, only one attendance fee is paid for both;

if a Director participates in a meeting of the Compensation Committee and in a meeting of the Appointments and Governance Committee on the same day, only one attendance fee is paid for both.

Hence, in accordance with the AFEP-MEDEF Code, attendance fees are allocated predominantly on a variable basis.

The introduction of a separate attendance fee scale depending on whether or not the director is a European resident is intended to take into account the constraints associated with a significantly longer travel time to attend meetings in person.

Edgar Filing: Sanofi - Form 20-F

Table of Contents

The Shareholders' Annual General Meeting of May 6, 2011 approved a proposal to increase the maximum amount of annual attendance fees to €1,500,000. For 2014, as for 2009 and 2010, a reduction coefficient was applied to this scale in order to keep attendance fees within the total attendance fee entitlement.

Name	Attendance fees in respect of 2014		Pensions paid in 2014	Total Theoretical Compensation (6)	Total Actual Compensation (7)	Attendance fees in respect of 2013		Pensions paid in 2013	Total compensation
	fixed	variable				fixed	variable		
(in euros)									
Laurent Attal	15,000	75,000		90,000	79,662	15,000	50,000		65,000
Bonnie Bassler(1)	1,250	0		1,250	1,106				
Uwe Bicker	15,000	104,500		119,500	105,773	15,000	57,000		72,000
Robert Castaigne	15,000	95,000		110,000	97,365	15,000	105,000		120,000
Thierry Desmarest(2)	15,000	75,000		87,500	77,449	15,000	65,000		80,000
Lord Douro(3)	15,000	60,500		66,750	66,750	15,000	89,000		104,000
Jean-René Fourtou	15,000	120,000	1,720,829	1,855,829	1,840,322	15,000	55,000	1,704,213	1,774,213
Claudie Haigneré	15,000	110,000		125,000	110,641	15,000	55,000		70,000
Patrick Kron(4)	10,000	32,500		42,500	37,618				
Igor Landau	15,000	55,000	2,355,970	2,425,970	2,417,929	15,000	40,000	2,333,221	2,388,221
Fabienne Lecorvaisier(5)	15,000	95,000		110,000	97,365	10,000	30,000		40,000
Suet-Fern Lee	15,000	92,500		107,500	95,152	15,000	64,000		79,000
Christian Mulliez	15,000	142,500		157,500	139,408	15,000	87,500		102,500
Carole Piwnica	15,000	92,500		107,500	95,152	15,000	98,750		113,750
Klaus Pohle	15,000	136,000		151,000	133,655	15,000	144,000		159,000

Gérard Van Kemmel	15,000	190,000		205,000	181,452	15,000	127,500		142,500
Total	210,000	1,476,000	4,076,799	5,762,799	5,576,799	205,000	1,067,750	4,037,434	5,310,184
Total attendance fees (theoretical)	1,686,500						1,272,750		
Total attendance fees (actual)	1,500,000						1,272,750		

Amounts reported are gross amounts before taxes.

- (1) *Assumed office November 18, 2014.*
- (2) *Left office October 23, 2014.*
- (3) *Left office May 5, 2014.*
- (4) *Assumed office May 5, 2014.*
- (5) *Assumed office May 3, 2013.*
- (6) *Before reducing attendance fees pro rata by approximately 0.89%.*
- (7) *After reducing attendance fees pro rata by approximately 0.89%.*

Pensions

The amount recognized in 2014 in respect of corporate pension plans for directors with current or past executive responsibilities at Sanofi (or companies whose obligations have been assumed by Sanofi) was €3.9 million.

As retirees, Jean-René Fourtou and Igor Landau are covered by the "GRCD" top-up pension plan instituted in 1977 for senior executives of Rhône-Poulenc. This plan was amended in 1994, 1996, 1999 and 2003, and as of December 31, 2014 applied to 31 beneficiaries (one active executive, two early retirees and 28 retired executives, including three survivor's pensions). At its meeting of February 11, 2008, the Board of Directors decided to close this plan to new entrants. Christopher Viehbacher did not benefit from this top-up pension plan.

Compensation of Senior Management

The compensation of the other Executive Committee members is established upon the recommendation of the Compensation Committee taking into consideration the practices of major global pharmaceutical companies.

In addition to fixed compensation, they receive variable compensation. Variable compensation generally represents 70% to 100% of their fixed compensation. The amount of the individual variable compensation is set

Table of Contents

pursuant to market practice. It rewards the individual contribution of each Executive Committee member to the Group's performance as well as the performance of his/her organization.

For 2014, the variable compensation was composed of two elements:

meeting quantitative objectives (accounting for 60%), which are measured at Group level and at the level of the Executive Committee member's organization or function; and

meeting quantitative and qualitative objectives, both individually and collectively within the Executive Committee (accounting for 40%).

The objectives are intended particularly to reflect growth (growth in net sales, business net income, registration and submission of new products in the U.S. and in Europe, growth in net sales of new products); cash flow optimization; talent management and critical skills (including selected key recruitments in critical areas for the Group); talent retention; increase in the number of women in senior management positions; and promotion of high potential individuals.

In addition to cash compensation, Executive Committee members may be awarded share subscription or purchase options and/or performance shares (see "Item 6. Directors, Senior Management and Employees – E. Share Ownership" for details of the related plans).

With respect to 2014, the total gross compensation paid and accrued in respect of members of the Executive Committee (including the Chief Executive Officer) amounted to €17.9 million, including €7.6 million in fixed compensation.

The above-mentioned amounts do not take into account the amounts payable to Christopher Viehbacher in connection with his removal from office and the settlement agreement signed on January 22, 2015.

In 2011, the Board of Directors made significant changes to its equity compensation policy. In order to limit the dilutive effect on shareholders, the Board of Directors determined to primarily award performance shares, except for a limited group of senior managers who may continue to receive options. The members of the Executive Committee are included in this limited group. Furthermore, whoever the beneficiary is, any award of options or performance shares is now fully contingent upon the performance targets being achieved over several financial years, and upon the beneficiary still being an employee when the option is exercised or the performance share is delivered.

On March 5, 2014, 622,500 share subscription options were awarded to members of the Executive Committee (including 240,000 options awarded to Christopher Viehbacher). In compliance with the AFEP-MEDEF Code, the entire award is contingent upon internal criteria based upon Business Net Income and Return on Assets ("ROA"). These criteria were selected because they align medium-term equity-based compensation on the strategy adopted by the Company.

This award is broken down as follows:

The performance criterion based on Business Net Income covers 50% of the award and refers to the ratio, at constant exchange rates, between actual Business Net Income and the Business Net Income specified in the budget. If the ratio is less than 95%, the corresponding options will lapse. The Business Net Income target may not be lower than the lower range of the guidance published by the Company at the beginning of each year.

The ROA-based criterion covers 50% of the award. The schedule includes a target ROA, below which the performance will be penalized by the lapsing of some or all of the options.

In addition to the three conditions set forth above, an implicit condition exists in the form of the exercise price, as well as the condition of continuing employment.

In order to bring equity-based compensation into line with medium-term performance, performance will be measured over three financial years.

Edgar Filing: Sanofi - Form 20-F

The Board regards these performance conditions as good indicators of the development of shareholder value in terms of: the quality of investment decisions in a period where external growth plays a greater role than in the past (ROA condition), and a commitment to delivering challenging bottom-line results in a tough business environment (Business Net Income condition).

Table of Contents

Although for reasons of confidentiality the quantitative measures for the internal criteria cannot be publicly disclosed, even though they have been properly established in a specific manner, the targets and the extent to which the internal criteria are met will be publicly disclosed at the end of the performance measurement period.

As of December 31, 2014 a total of 4,040,500 options had been awarded to members of the Executive Committee (existing plans or plans ending in 2014). As of the same date, members of the Executive Committee held 3,052,841 unexercised options. These figures include the unexercised options awarded to Christopher Viehbacher, who was also a member of the Executive Committee at the time of the award.

During 2014, 150,346 share subscription options were exercised by individuals who were members of the Executive Committee when they exercised.

These exercises related to one option plan that pre-dates the creation of the Executive Committee (sanofi-aventis subscription option plan of May 31, 2005 with an exercise price of €70.38), and five others that post-date the creation of the Executive Committee (three on the sanofi-aventis subscription option plan of March 2, 2009 with an exercise price of €45.09 and two on the sanofi-aventis subscription option plan of March 1st, 2010 with an exercise price of €54.12).

The table below summarizes the options awarded to individuals who were members of the Executive Committee (including the Chief Executive Officer) at the time of the award. For more information on the characteristics of such options see the table " E. Share Ownership Existing Options Plans as of December 31, 2014" below.

Origin	Date of shareholder authorization	Date of Board grant	Grant to Executive Committee Members(1)	Start date of exercise period	Expiry date	Exercise price (in €)	Number exercised as of 12/31/2014	Number canceled as of 12/31/2014	Number outstanding
sanofi-aventis	05/31/07	12/13/07	520,000	12/14/11	12/13/17	62.33	475,000	0	45,000
sanofi-aventis	05/31/07	03/02/09	650,000	03/04/13	03/01/19	45.09	255,513	50,000	344,487
sanofi-aventis	04/17/09	03/01/10	805,000	03/03/14	02/28/20	54.12	157,146	50,000	597,854
sanofi-aventis	04/17/09	03/09/11	577,500	03/10/15	03/09/21	50.48	0	0	577,500
Sanofi	05/06/11	03/05/12	445,500	03/06/16	03/05/22	56.44	0	0	445,500
Sanofi	05/06/11	03/05/13	420,000	03/06/17	03/05/23	72.19	0	0	420,000
Sanofi	05/03/13	03/05/14	622,500	03/06/18	03/05/24	73.48	0	0	662,500

(1)

Members of the Executive Committee as of the date of grant. The number of shares is subject to performance conditions.

On March 9, 2011, 277,500 subscription options were awarded to members of the Executive Committee (on top of the 300,000 subscription options awarded to Christopher Viehbacher). In compliance with the AFEP-MEDEF Code, the entire award is contingent upon two internal criteria based on Business Net Income and Return on Assets ("ROA").

For the first period (consisting of fiscal years 2011 and 2012) which related to 50% of the March 9, 2011 grant, the performance was as follows:

Edgar Filing: Sanofi - Form 20-F

The performance criterion based on Business Net Income (which covered 50% of the award) was fulfilled, reaching 106% of the target;

The ROA-based criterion (which covered 50% of the award) was fulfilled, being 1.7% above the target;

The Board of Directors, in its meeting of February 6, 2013, determined that the global performance rate for the first period was greater than 100% and therefore, since the performance condition had been fulfilled, 50% of the stock subscription options granted would be exercisable at the end of the four-year vesting period subject to meeting the condition of continuing employment.

For the second period (consisting of fiscal years 2013 and 2014), the performance was as follows:

The performance criterion based on Business Net Income (which covered 50% of the award) was fulfilled, reaching 97.7% of the target;

The ROA-based criterion (which covered 50% of the award) was fulfilled, being 0.2% above the target;

Table of Contents

The Board of Directors, in its meeting of March 3, 2015, determined that the global performance rate for the second period was equal to 98.9% and therefore, since the performance condition had been partially fulfilled, 98.9% of the stock subscription options granted would be exercisable at the end of the four-year vesting period. The Board of Directors determined that the global performance rate for the March 9, 2011 option plan was 99.5% and therefore 276,133 options would be exercisable at the end of the 4-year vesting period.

On March 5, 2012, 205,500 subscription options were awarded to members of the Executive Committee (on top of the 240,000 subscription options awarded to Christopher Viehbacher). In compliance with the AFEP-MEDEF Code, the entire award was contingent upon performance conditions for the period 2012-2014.

The Board of Directors, in its meeting of February 4, 2015, determined that:

The performance criterion based on Business Net Income (which covered 50% of the award) was fulfilled, reaching 84.4% of the target;

The ROA-based criterion (which covered 50% of the award) was fulfilled, being 0.5% above the target.

The Board of Directors, in its meeting of February 4, 2015, determined that the global performance rate was 92.2% and therefore, since the performance condition had been partially fulfilled, 189,471 options would be exercisable at the end of the 4-year vesting period.

On March 5, 2014, 67,000 performance shares (including 45,000 performance shares awarded to Christopher Viehbacher) were awarded to members of the Executive Committee.

In compliance with the AFEP-MEDEF Code, the entire award is contingent upon both internal criteria based upon Business Net Income and Return on Assets ("ROA"). These criteria were selected because they align medium-term equity-based compensation on the strategy adopted by the Company.

This award is broken down as follows:

The performance criterion based on Business Net Income covers 50% of the award and refers to the ratio, at constant exchange rates, between actual Business Net Income and the Business Net Income specified in the budget. If the ratio is less than 95%, the corresponding performance shares will lapse. The Business Net Income target may not be lower than the lower range of the guidance published by the Company at the beginning of each year.

The ROA-based criterion covers 50% of the award. The schedule includes a target ROA, below which the performance will be penalized by the lapsing of some or all of the performance shares.

In order to bring equity-based compensation into line with medium-term performance, performance will be measured over three financial years.

The Board regards these performance conditions as good indicators of the development of shareholder value in terms of: the quality of investment decisions in a period where external growth plays a greater role than in the past (ROA condition), and a commitment to delivering challenging bottom-line results in a tough business environment (Business Net Income condition).

Although for reasons of confidentiality the quantitative measures for the internal criteria cannot be publicly disclosed, even though they have been properly established in a specific manner, the targets and the level of attainment for the internal criteria will be publicly disclosed at the end of the performance measurement period.

As of December 31, 2014, a total of 343,900 performance shares had been awarded to members of the Executive Committee (existing plans or plans ending in 2014). These figures include the performance shares awarded to Christopher Viehbacher, who was also a member of the Executive Committee at the date of grant.

Edgar Filing: Sanofi - Form 20-F

The table below summarizes the performance shares awarded to individuals who were members of the Executive Committee (including the Chief Executive Officer) at the time of the award. For more information on the

Edgar Filing: Sanofi - Form 20-F

Table of Contents

characteristics of such performance shares see the table " E. Share Ownership Existing Restricted Shares Plans as of December 31, 2012" below.

Origin	Date of shareholder authorization	Date of Board Decision	Grant to Executive Committee Members(1)	Date of award	Vesting date	Availability date	Number transferred as of 12/31/2014	Number of rights canceled as of 12/31/2014	Number outstanding
sanofi-aventis	5/31/07	03/02/09	65,000	03/02/09	03/03/11	03/04/13	65,000	0	0
sanofi-aventis	4/17/09	03/09/11	85,500	03/09/11	03/10/13	03/10/15	75,500	0	10,000
Sanofi	4/17/09	03/05/12	137,900	03/05/12	03/06/15	03/06/17	0	0	137,900
Sanofi	5/06/11	03/05/13	129,000	03/05/13	03/06/16	03/06/18	0	0	129,000
Sanofi	5/04/12	03/05/14	67,000	03/05/14	03/06/17	03/06/19	0	0	67,000

(1)

Members of the Executive Committee as of the date of grant. The number of shares is subject to performance conditions

In 2014, the Senior Management decided to put in place performance share units (hereafter "PSU") for beneficiaries (excluding the Chief Executive Officer) whose award exceeds a specified number of performance shares. The aim is to reduce the dilution resulting from share-based plans while conducting a compensation policy that is both attractive and comparable to major global companies.

These PSUs allow the beneficiaries to receive, subject to the fulfilment of performance conditions, cash compensation which is indexed to the value of the Sanofi share. Upon vesting, the amount received is equal to the number of PSUs (after applying the performance conditions) multiplied by the share value. The PSUs are subject to the same performance conditions as the performance shares, and to a 3-year continuing employment condition. Around 170 Group employees benefited from PSUs in 2014.

On March 5, 2012, 95,900 performance shares were awarded to members of the Executive Committee (in addition to the 42,000 performance shares awarded to Christopher Viehbacher). In compliance with the AFEP-MEDEF Code, the entire award was contingent upon performance conditions for the period 2012-2014.

The Board of Directors, in its meeting of February 4, 2015, determined that:

The performance criterion based on Business Net Income (which covered 50% of the award) was fulfilled, reaching 84.4% of the target;

The ROA-based criterion (which covered 50% of the award) was fulfilled, being 0.5% above the target.

The Board of Directors, in its meeting of February 4, 2015, determined that the global performance rate was 92.2% and therefore, since the performance condition had been partially fulfilled, 88,420 shares would vest.

Under French law, Directors may not receive options solely as compensation for service on our Board, and consequently our Company may grant options only to those Directors who are also our officers.

Edgar Filing: Sanofi - Form 20-F

Because some of our non-executive Directors were formerly officers or executive officers of our Company or its predecessor companies, some of our non-executive Directors hold Sanofi stock options.

We do not have separate profit-sharing plans for key executives. As employees, they are able to participate in our voluntary and statutory profit-sharing schemes on the same terms as our other employees. These plans are described below under " Employees Profit-sharing schemes."

The total amount accrued as of December 31, 2014 in respect of corporate pension plans for (i) directors with current or past executive responsibilities at Sanofi or at companies whose obligations have been assumed by Sanofi and (ii) members of the Executive Committee was €124 million, including €9.7 million recognized in the income statement for the year ended December 31, 2014.

This total amount accrued as of December 31, 2014 included €40.9 million for members of the Executive Committee collectively, including €7.3 million recognized in the income statement for the year ended December 31, 2014.

Table of Contents

C. Board Practices

Neither we nor our subsidiaries have entered into service contracts with members of our Board of Directors providing for benefits upon termination of employment. With respect to Christopher Viehbacher, see also " B. Compensation Compensation and arrangements for corporate officers" above.

Application of the AFEP-MEDEF Code

The AFEP-MEDEF Code requires us to specifically report on the application of its recommendations and, if applicable, explain why any of them have not been applied. Sanofi follows the guidelines contained in the AFEP-MEDEF Code as amended. Currently our departures from this Code are as follows:

The limitations on the powers of the Chief Executive Officer are not contained in our Board Charter but in a decision of our Board dated July 28, 2009 (see " A. Directors and senior management Limitations on the powers of the Chief Executive Officer set by the Board"). Because the publication and decision-making processes are the same, this departure is technical and has no practical repercussions.

The Committees do not each have their own charter separate from the Board Charter. The Board Charter, which has been adopted by the Board of Directors, gives a global vision of the functioning of the Board and of its committees. Indeed, combining the rules that apply to the Board of Directors and those that apply to its committees creates a single, coherent governing document approved by the entire Board.

The Board of Directors does not strictly apply the rule according to which being a Board member for more than 12 consecutive years is of itself sufficient to automatically disqualify a director from being regarded as independent. This is only one criterion that must be evaluated on a case by case basis, and not mechanically. It is only after reviewing all the factors that a director can be determined as being independent or non-independent. While length of service may in certain circumstances be associated with a loss of independence, in other circumstances it may enhance the capacity of a director to question senior management and give greater independence of mind.

The *Haut Comité de Gouvernement d'Entreprise* (the body in charge of overseeing the implementation of the AFEP-MEDEF Code) wrote a letter to our Company inviting us either to comply with this rule or to explain our departure therefrom.

The Board of Directors acknowledged this request. The Board noted that the AFEP-MEDEF Code itself provides that a board of directors may deem that a director is independent even though he or she does not fulfill all the independence criteria contained in the Code. This is precisely what our Board of Directors did upon the recommendation of its Appointments and Governance Committee. This committee is best placed to assess the behavior and hence the true independence of a director.

The Board of Directors takes the view that it is not favoring competence over independence but rather checking a director's willingness and ability to form an independent opinion, to ask for further details and question the decisions of Senior Management. Consequently, our Board of Directors provides explanations for the specific cases it reviews (see A. Directors and Senior Management Board Members Independence, below);

The annual assessment of the Board of Directors and of its committees covers their functioning as collective bodies and does not evaluate each director individually. The issue of competence and individual contribution to the activities of the Board and its committees is addressed on a continuous basis with a specific review when a director is up for reappointment as a board or committee member. Indeed, the Chairman of the Board continually assesses the involvement of each Board member. Moreover most of the annual assessments include one-on-one interviews with the Secretary to the Board.

During 2014, the Board of Directors met eleven times, with an overall attendance rate among Board members of over 92%. This attendance rate includes participation by conference call, though only a limited number of Directors participated in this way. The individual attendance rates varied between 70% and 100%.

Edgar Filing: Sanofi - Form 20-F

The following persons attended meetings of the Board of Directors in 2014:

the Directors;

the Secretary to the Board;

five employee representatives who attend Board meetings without voting rights, pursuant to the agreement implemented with the European Works Council signed on February 24, 2005;

and frequent attendance of: the Executive Vice President Chief Financial Officer, the Executive Vice President Chief Strategy Officer, the Executive Vice President Global Commercial Operations, the Executive Vice President Global Divisions & Strategic Commercial Development and the President, Global Research & Development.

Edgar Filing: Sanofi - Form 20-F

Table of Contents

The agenda for each meeting of the Board is prepared by the Secretary after consultation with the Chairman, taking account of the agendas for the meetings of the specialist Committees and the suggestions of the directors.

Approximately one week prior to each meeting of the Board of Directors, the Directors each receive a file containing the agenda, the minutes for the prior meeting, and documentation relating to the agenda.

The minutes for each meeting are expressly approved at the next meeting of the Board of Directors.

In compliance with our Board Charter, certain issues are examined in advance by the various Committees according to their areas of competence in order for them to make a recommendation; these issues are then submitted for a decision by the Board of Directors.

In 2014, the main activities of the Board of Directors related to the following issues:

the review of the individual company and consolidated financial statements for the 2013 financial year, the review of the individual company and consolidated financial statements for the first half of 2014 and the consolidated financial statements for the first three quarters of 2014, as well as the review of the draft press releases and presentations to analysts with respect to the publication of such financial statements;

the examination of documents relating to management forecasts and the financial arrangements adopted with respect to Group subsidiaries over the 2013 financial year, the full-year forecasts for 2014 and the budget for 2015;

the delegation of authority to the Chief Executive Officer to issue bonds and to issue guarantees, and the renewal of the share repurchase program;

reviews of the Board of Directors' Management Report, the Chairman's Report and the reports of the statutory auditors;

the recording of the amount of the share capital, the reduction in share capital through cancellation of treasury shares and the corresponding amendments to the Articles of Association;

the determination of the 2013 variable compensation for the Chief Executive Officer, the determination of the 2014 fixed and variable compensation for the Chief Executive Officer, the determination of the 2014 fixed compensation of the Chairman of the Board and an update of the 2013 and 2014 fixed and variable compensation of the members of the Executive Committee. During the presentation of the report of the Compensation Committee on the compensation of corporate officers, the Board of Directors deliberated in their absence: the Board of Directors in the first place discussed the compensation of the Chairman in his absence, and then discussed the compensation of the Chief Executive Officer with the Chairman present but with the Chief Executive Officer still absent;

the allocation of Directors' attendance fees for 2013, the principles of allocation for the year 2014 and the allocation of attendance fees for the first half of 2014, the expenses of Directors and executive officers;

the adoption of equity-based compensation plans, consisting of share subscription option plans and restricted share awards, in respect of 2014 and the recording of the fulfillment of the performance conditions of previous share-based plans;

the composition of the Board, the proposed reappointment of Directors at the Shareholders' General Meeting in 2014, the independence of the Directors, the appointment of a new Director, the review of the composition of the Committees in view of the new composition of the Board, the coopting of a new director;

Edgar Filing: Sanofi - Form 20-F

the removal from office of the Chief Executive Officer, the temporary combination of the offices of Chairman and Executive Officer, the appointment of the Chairman of the Board as Chief Executive Officer;

a presentation on the French R&D platform, on the Diabetes activity, PCSK9 and the Animal Health activity;

the review of significant proposed alliances and acquisitions, and strategic opportunities;

Company policy on equal pay and opportunities;

the notice of meeting for the General Meeting of Shareholders and of Holders of Participating Shares (Series issued in 1983, 1984 and 1987 and Series A participating shares issued in 1989), the adoption of the draft resolutions, the report of the Board of Directors on the resolutions, and the special reports on the share subscription options and on the restricted shares awarded;

the evaluation of the functioning of the Board and its Committees.

Table of Contents

Board Committees

Since 1999, our Board of Directors has been assisted in its deliberations and decisions by specialist committees. Chairmen and members of these committees are chosen by the Board from among its members, based on their experience.

The Committees are responsible for the preparation of certain items on the agenda of the Board of Directors. The decisions of the Committees are adopted by a simple majority with the chairman of the Committee having a casting vote. Minutes are established and approved by the Committee members.

The chairman of each specialist Committee reports to the Board on the work of the Committee in question, so that the Board is fully informed whenever it adopts a decision.

Audit Committee

At December 31, 2014, this Committee was composed of:

Klaus Pohle, Chairman;

Robert Castaigne;

Fabienne Lecorvaisier;

Christian Mulliez;

Carole Piwnica;

Gérard Van Kemmel.

Five members of the Audit Committee are classified as independent pursuant to the criteria adopted by the Board of Directors, i.e. Robert Castaigne, Fabienne Lecorvaisier, Carole Piwnica, Klaus Pohle and Gérard Van Kemmel. In addition, all of the members, including Christian Mulliez, fulfill the conditions required to be classified as independent under the Sarbanes-Oxley Act.

All six members of the Committee have financial or accounting expertise as a consequence of their education and professional experience as reflected in their biographies. Furthermore, Robert Castaigne, Fabienne Lecorvaisier, Christian Mulliez, Klaus Pohle and Gérard Van Kemmel are deemed to be financial experts pursuant to the definition in the Sarbanes-Oxley Act and the definition in Article L. 823-19 of the French Commercial Code. See "Item 16A. Audit Committee Financial Expert".

On March 3, 2015, Robert Castaigne was appointed to succeed Klaus Pohle as Chairman of the Audit Committee.

The Audit Committee met six times in 2014, including prior to the meetings of the Board of Directors during which the financial statements were approved. In addition to the statutory auditors, the principal financial officers, the Senior Vice President Group Internal Audit and other members of senior management of the Group attended meetings of the Audit Committee, in particular concerning risk exposure and off-balance-sheet commitments.

The meetings of the Audit Committee take place at least two days prior to any meetings of the Board of Directors during which the annual or interim financial statements are to be examined.

The members of the Audit Committee have a good attendance record for meetings, with an overall attendance rate among members of more than 97%. Individual attendance rates varied between over 83% and 100%.

Edgar Filing: Sanofi - Form 20-F

The statutory auditors attended all of the meetings of the Audit Committee; they presented their opinions on the annual and half yearly financial statements at the Committee meetings of February 3 and July 28, 2014, respectively.

In 2014, the main activities of the Audit Committee related to:

the preliminary review of the individual company and consolidated financial statements for the 2013 financial year, the review of the individual company and consolidated financial statements for the first half of 2014 and of the consolidated financial statements for the first three quarters of 2014, as well as a review of the press releases and analysts presentations relating to the publication of such financial statements;

the financial position of the Group, its indebtedness and liquidity;

Table of Contents

investigation and evaluation of internal control for 2013, as certified by the statutory auditors pursuant to Section 404 of the Sarbanes-Oxley Act, and an examination of the 2013 Annual Report on Form 20-F;

reporting on guarantees;

the review of the draft resolutions to the May 5, 2014 Shareholders' General Meeting;

the principal risks facing the Company, including an update on the compliance program, impairment testing of goodwill, the management of health, safety and environmental (HSE) risks, management of market risks, update on retirement funds and actuarial assumptions, review of tax risks and deferred tax assets, the review of litigation and of environmental risks (meetings of March 4, April 24, July 28, October 23, and December 17, 2013);

the conclusions of Group management as to internal control procedures, the 2013 Board of Directors' Management Report, the 2013 Report under the French Financial Security Act, and the 2013 Chairman's Report, including the description of risk factors contained in the French *Document de Référence*;

reporting on the implementation of shared services in France and in Europe, on capital expenditure, progress reports on acquisitions (Chattem), report of the Risk Committee, reporting on internal audit activities and computer services;

application of the equity method of accounting to our investment in Regeneron, and progress reports of this investment;

the budget for audit-related services and non-audit services and the 2014 audit plan, statutory auditors' report and fees;

presentation of the 2015 budget.

The Committee did not have recourse to external consultants in 2014.

Compensation Committee

At December 31, 2014, this Committee was composed of:

Gérard Van Kemmel, Chairman;

Jean-René Fourtou;

Claudie Haigneré;

Christian Mulliez.

Of the four members of the Compensation Committee, three are deemed to be independent.

The Compensation Committee met twelve times in 2014.

Edgar Filing: Sanofi - Form 20-F

The members of the Compensation Committee have a very good attendance record for meetings, with an overall attendance rate among members of 98%. Individual attendance rates varied between over 85% and 100%.

When the Committee discusses the compensation policy for members of senior management who are not corporate officers, i.e. the members of the Executive Committee, the Committee invites the members of senior management who are corporate officers to attend.

In 2014, the main activities of the Compensation Committee related to:

the fixed and variable compensation of corporate officers and senior management;

the establishment of the amount of Directors' attendance fees for 2013, the review of the expenses of Directors and corporate officers for 2013, the principles of allocation of Directors attendance fees for 2014;

the review of the governance chapter of the 2013 *Document de Référence*, which contains disclosures about compensation;

the implementation of the policy for equity-based compensation, including both share subscription options and performance shares, which was discussed at several meetings;

the review of draft resolutions to be presented to the shareholders in 2014, in particular the Say on Pay;

Table of Contents

an update on the 2013 and 2014 fixed and variable compensation of the members of the Executive Committee, including performance share units;

the conditions of the Chief Executive Officer's removal from office, and the compensation of the Chairman and Chief Executive Officer;

the review of draft resolutions to be presented to the shareholders in 2015 requesting the renewal of the delegation of authority granted to the Board to allocate performance shares and the delegation related to the share capital increase reserved for employees;

a compensation structure for the next Chief Executive Officer.

The Committee did not have recourse to external consultants in 2014.

Appointments and Governance Committee

At December 31, 2014, this Committee was composed of:

Jean René Fourtou, Chairman (since November 18, 2014);

Serge Weinberg;

Claudie Haigneré;

Gérard Van Kemmel.

Of the four members of the Appointments and Governance Committee, three are deemed to be independent.

The Appointments and Governance Committee met eleven times in 2014.

The members of the Appointments and Governance Committee have a very good attendance record for meetings, with an overall attendance rate among members of 98%. Individual attendance rates varied between over 85% and 100%.

In 2014, the main activities of the Appointments and Governance Committee related to:

the results of the evaluation of the Board and its Committees;

the review of the Board of Directors Management Report, Chairman's Report, and the chapter of the 2013 *Document de Référence* containing disclosures about governance;

update on the composition of the Board, the independence of Directors, proposals about the reappointment and appointment of Directors, the review of the independence of the proposed new Director, update on the composition of the Committees after the May 5, 2014 Shareholders' General Meeting;

Edgar Filing: Sanofi - Form 20-F

whether the Chief Executive Officer should remain in office, and review of the conditions for the removal of the Chief Executive Officer from office;

the appointment of the Chairman as Chief Executive Officer, change to the Appointments and Governance Committee chairmanship, search for a new Chief Executive Officer; and

the coopting of a new director.

The Committee did not have recourse to external consultants in 2014.

Strategy Committee

At December 31, 2014, this Committee was composed of:

Serge Weinberg, Chairman;

Laurent Attal;

Uwe Bicker;

Jean-René Fourtou;

Igor Landau (since May 5, 2014).

Table of Contents

Of the five members of the Strategy Committee, two are deemed to be independent.

In 2014, the Strategy Committee met seven times, including twice in expanded sessions to welcome other directors.

The members of the Strategy Committee have a very good attendance record for meetings, with an overall attendance rate among members of over 87%. Individual attendance rates varied between 80% and 100%.

The work of the Committee covered, in particular an overview of Diabetes, Oncology, digital, Generics, Biosurgery, an update on R&D and its financing, strategic opportunities, resource allocation, and several proposed acquisitions and partnership opportunities.

The Committee did not have recourse to external consultants in 2014.

D. Employees

Number of Employees

In 2014, Sanofi employed 113,496 people worldwide, 1,368 more than in 2013. The tables below give a breakdown of employees by geographic area and function for the years ended December 31, 2014, 2013 and 2012.

Employees by geographic area

As of December 31,

	2014	%	2013	%	2012	%
Europe	53,341	47.0%	53,880	48.0%	56,265	50.2%
North America	18,627	16.4%	18,795	16.8%	18,994	17.0%
Other countries	41,528	36.6%	39,453	35.2%	36,715	32.8%
Total	113,496	100%	112,128	100%	111,974	100%

Employees by function

As of December 31,

	2014	%	2013	%	2012	%
Sales	34,118	30.1%	33,509	29.9%	32,270	28.8%
Research and Development	16,257	14.3%	16,688	14.9%	17,066	15.2%
Production	44,366	39.1%	44,031	39.3%	45,035	40.2%
Marketing and Support Functions	18,755	16.5%	17,900	16.0%	17,603	15.7%
Total	113,496	100%	112,128	100%	111,974	100%

Industrial Relations

In all countries where Sanofi operates, we strive to combine economic and social performance which we believe are inseparable.

Edgar Filing: Sanofi - Form 20-F

Sanofi's social responsibility is based on the basic principles of the Group's Social Charter, which outlines the rights and duties of all Group employees. The Social Charter addresses Sanofi's key commitments towards its workforce: equal opportunity for all people without discrimination, the right to health and safety, respect for privacy, the right to information and professional training, social protection for employees and their families, freedom of association and the right to collective bargaining, and respect for the principles contained in the Global Compact on labor relations and ILO treaties governing the physical and emotional well-being and safety of children.

The Group's labor relations are based on respect and dialogue. In this spirit, the Company's management and employee representatives meet regularly to exchange views, negotiate, sign agreements and ensure that agreements are being implemented.

Table of Contents

Employee dialogue takes place in different ways from one country to the next, as dictated by specific local circumstances. Depending on the circumstances, employee dialogue relating to information, consultation and negotiation processes may take place at the national, regional or company level. It may be organized on an interprofessional or sectoral basis, or both. Employee dialogue may be informal or implemented through a specific formal body, or a combination of both methods. Whatever the situation, Sanofi encourages employees to voice their opinions, help create a stimulating work environment and take part in decisions aiming to improve the way we work. These efforts reflect one of the principles of the Social Charter whereby the improvement of working conditions and the Group's necessary adaptation to its environment go hand-in-hand.

Profit-sharing Schemes, Employee Savings Schemes and Employee Share Ownership

Profit-sharing Schemes

All employees of our French companies belong to voluntary and statutory profit-sharing schemes.

Voluntary Scheme (*Intéressement des salariés*)

These are collective schemes that are optional for the employer and contingent upon performance. The aim is to give employees an interest in the growth of the business and improvements in its performance.

The amount distributed by our French companies during 2014 in respect of voluntary profit-sharing for the year ended December 31, 2013 represented 3.20% of total payroll.

In June 2011, Sanofi entered into a three-year Group-wide agreement, effective from the 2011 financial year, and applicable to all French companies more than 50% owned by Sanofi. Under the agreement, payments under the Group voluntary profit-sharing scheme were contingent on the more favorable of two criteria: year-on-year growth in the net sales of our growth platforms (at constant exchange rates and on a constant structure basis) and the level of business net income. For each criterion, a matrix was used to determine the percentage of total payroll to be distributed.

In June 2014, Sanofi entered into a three-year Group-wide agreement, effective from the 2014 financial year, and applicable to all French companies more than 50% owned by Sanofi. Under the agreement, payments under the Group voluntary profit-sharing scheme are contingent on the more favorable of two criteria: the Group net sales growth (at constant exchange rates and on a constant structure basis) and the level of business net income. For each criterion, a matrix is used to determine the percentage of total payroll to be distributed.

Statutory Scheme (*Participation des salariés aux résultats de l'entreprise*)

The scheme is a French legal obligation for companies with more than 50 employees that made a profit in the previous financial year.

The amount distributed by our French companies during 2014 in respect of the statutory scheme for the year ended December 31, 2013 represented 5.94% of total payroll.

In November 2007, Sanofi entered into a new Group-wide agreement for an indefinite period, covering all the employees of our French companies.

An amendment to this agreement was signed in April 2009, primarily to align the agreement on a change in French legislation (Law 2008-1258 of December 3, 2008) in order to protect against erosion in purchasing power, under which each qualifying employee can elect to receive some or all of his or her profit-sharing bonus without regard to the normally applicable mandatory lock-up period.

Distribution Formula

In order to favor lower-paid employees, the voluntary and statutory profit-sharing agreements entered into since 2005 split the benefit between those entitled as follows:

60% on the basis of presence during the year; and

Edgar Filing: Sanofi - Form 20-F

40% on the basis of annual salary, up to a limit of three times the Social Security ceiling.

Table of Contents

Employee Savings Schemes and Collective Retirement Savings Plan

The employee savings arrangements operated by Sanofi are based on a Group savings scheme (*Plan Epargne Groupe*) and a collective retirement savings plan (*Plan Epargne pour la Retraite Collectif*). These schemes reinvest the sums derived from the statutory and voluntary profit-sharing schemes (compulsory investments), and voluntary contributions by employees.

In June 2014, more than 86% of the employees who benefited from the profit-sharing schemes had opted to invest in the collective retirement savings plan.

In 2014, €117.5 million and €61.1 million were invested in the Group savings scheme and the collective retirement savings plan respectively through the voluntary and statutory schemes for 2013, and through top-up contributions.

Employee Share Ownership

At December 31, 2014, shares held by employees of Sanofi and of related companies and by former employees under Group employee savings schemes amounted to 1.31% of the share capital.

E. Share Ownership

Senior Management

Members of the Executive Committee hold shares of our Company amounting in the aggregate to less than 1% of our share capital.

At December 31, 2014, a total of 4,040,500 options had been granted to the members of the Executive Committee (plans existing or closed in 2014) and 3,052,841 unexercised options to subscribe for or to purchase Sanofi shares were held by the members of the Executive Committee.

In 2014, 150,346 options were exercised by individuals who were members of the Executive Committee when they exercised.

These exercises related to one option plan that pre-dates the creation of the Executive Committee (sanofi-aventis subscription option plan of May 31, 2005 with an exercise price of €70.38), and five others that post-date the creation of the Executive Committee (three on the sanofi-aventis subscription option plan of March 2, 2009 with an exercise price of €45.09 and two on the sanofi-aventis subscription option plan of March 1st, 2010 with an exercise price of €54.12).

At December 31, 2014, a total of 343,900 performance shares have been awarded to the members of the Executive Committee (plans existing or closed in 2014).

These figures include the options granted to Christopher Viehbacher, who was a member of the Executive Committee until October 29, 2014. The terms of these options and performance shares are summarized in the tables below.

Existing Option Plans as of December 31, 2014

As of December 31, 2014, a total of 25,602,256 options were outstanding, including 193,331 options to purchase Sanofi shares and 25,408,925 options to subscribe for Sanofi shares. Out of this total, 22,225,731 were immediately exercisable, including 193,331 options to purchase shares and 22,032,400 options to subscribe for shares.

Equity-based compensation, consisting of share subscription option plans and performance share plans, aims to align the employees' objectives on those of the shareholders and to reinforce the link between employees and the Group. Under French law, this falls within the powers of the Board of Directors. Stock options (which may be options to subscribe for shares or options to purchase shares) are granted to employees and the Chief Executive Officer by the Board of Directors on the basis of recommendations from the Compensation Committee.

Granting options is a way of recognizing the beneficiary's contribution to the Group's development, and also of securing his or her future commitment to the Group.

Table of Contents

For each plan, the Compensation Committee and the Board of Directors assess whether it should take the form of options to subscribe for shares or options to purchase shares, based on criteria that are primarily financial.

A list of beneficiaries is proposed by the Senior Management to the Compensation Committee, which reviews the list and then submits it to the Board of Directors, which decides to grant the options. The Board of Directors also sets the terms for the exercise of the options (including the exercise price) and the lock-up period. The exercise price never incorporates a discount, and must be at least equal to the average of the quoted market prices on the 20 trading days preceding the date of grant by the Board. Stock option plans generally specify a vesting period of four years and a total duration of ten years.

In 2011, the Board of Directors made significant changes to its equity-based compensation policy. In order to limit the dilutive effect on shareholders, the Board of Directors determined to primarily award performance shares, except for a limited group of senior managers who may continue to receive options. Furthermore, whoever the beneficiary is, any award of options or performance shares is now fully contingent upon the performance targets being met over three financial years.

On March 5, 2014, 769,250 share subscription options were awarded to 59 beneficiaries (excluding 240,000 options awarded to Christopher Viehbacher). Each option entitles the grantee to subscribe for one share, in the aggregate representing 0.08% of our share capital before dilution.

The entire award was contingent upon the same criteria based on Business Net Income and Return on Assets as the award to members of the Executive Committee, each criterion representing 50% of the grant. The quantitative measures of performance are the same as for the award to members of the Executive Committee.

The percentage of options awarded to Christopher Viehbacher in 2014 represents 2.60% of the total limit approved by the Shareholders' General Meeting held on May 3, 2013 (0.7% of our share capital) and 23.8% of the total award to all beneficiaries on March 5, 2014.

Not all employees are able to benefit from awards of performance shares, but a new agreement on the voluntary scheme (*intéressement des salariés*) was concluded in June 2014 to ensure that all employees have an interest in the performance of the business.

In addition, pursuant to the French Law of July 28, 2011, all employees in France of the French subsidiaries of the Group benefited from a profit-sharing bonus amounting to €350 gross in June 2014. In total, Sanofi paid out €11.4 million in this regard (including social contributions).

Share Purchase Option Plans

Date of shareholder authorization	Date of Board grant	Number of options initially granted	- to corporate officers(1)	- to the 10 employees		Start date of exercise period	Expiry date	Purchase price (in €)	Number exercised as of 12/31/2014	Number canceled as of 12/31/2014	out
				- to	granted the most options(2)						
6/28/1990	10/18/1994	330,200	0	200,200	10/18/1999	10/18/2014	6.01	330,200	0		
6/28/1990	1/12/1996	208,000	0	52,000	1/12/2001	1/12/2016	8.56	204,330	0		
6/28/1990	4/05/1996	228,800	0	67,600	4/05/2001	4/05/2016	10.85	218,200	0		
6/28/1990	10/14/1997	262,080	0	165,360	10/14/2002	10/14/2017	19.73	244,400	5,200		
6/28/1990	6/25/1998	296,400	148,200	117,000	6/26/2003	6/25/2018	28.38	296,400	0		
6/23/1998	3/30/1999	716,040	0	176,800	3/31/2004	3/30/2019	38.08	543,739	5,720		

(1)

Includes the Chairman and Chief Executive Officer, the Chief Executive Officer or equivalent officers as of the date of grant.

(2)

Employed as of the date of grant.

Table of Contents**Share Subscription Option Plans**

Date of shareholder authorization	Date of grant	Number of options initially granted	- to corporate officers(1)	- to the 10 employees granted the most options(2)	Start date of exercise period	Expiry date	Subscription price (in €)	Number exercised as of 12/31/2014	Number canceled as of 12/31/2014
5/31/2005	5/31/2005	15,228,505	400,000	550,000	6/01/2009	5/31/2015	70.38	8,343,048	2,168,675
5/31/2005	12/14/2006	11,772,050	450,000	585,000	12/15/2010	12/14/2016	66.91	5,675,515	1,176,690
5/31/2007	12/13/2007	11,988,975	325,000	625,000	12/14/2011	12/13/2017	62.33	6,221,169	1,069,820
5/31/2007	3/02/2009	7,736,480	250,000	655,000	03/04/2013	3/01/2019	45.09	4,203,003	615,395
4/17/2009	3/01/2010	7,316,355	0	665,000	3/03/2014	02/28/2020	54.12	2,512,109	629,500
4/17/2009	3/01/2010	805,000	275,000	805,000	3/03/2014	02/28/2020	54.12	157,146	50,000
4/17/2009	3/09/2011	574,500	0	395,000	3/10/2015	3/09/2021	50.48	0	30,000
4/17/2009	3/09/2011	300,000	300,000	0	3/10/2015	3/09/2021	50.48	0	0
5/06/2011	3/05/2012	574,050	0	274,500	3/06/2016	3/05/2022	56.44	0	31,000
5/06/2011	3/05/2012	240,000	240,000	0	3/06/2016	3/05/2022	56.44	0	0
5/06/2011	3/05/2013	548,725	0	261,000	3/06/2017	3/05/2023	72.19	0	31,750
5/06/2011	3/05/2013	240,000	240,000	0	3/06/2017	3/05/2023	72.19	0	0
5/03/2013	3/05/2014	769,250	0	364,500	3/06/2018	3/05/2024	73.48	0	17,250
5/03/2013	3/05/2014	240,000	240,000	0	3/06/2018	3/05/2024	73.48	0	0

(1)

Includes the Chairman and Chief Executive Officer, the Chief Executive Officer, or equivalent officers as of the date of grant.

(2)

Employed as of the date of grant.

The main characteristics of our stock options are also described in Note D.15.8 to our consolidated financial statements, included in Item 18 of this annual report.

Existing Restricted Share Plans as of December 31, 2014

Edgar Filing: Sanofi - Form 20-F

Since 2009, the Board of Directors has awarded restricted shares to certain employees in order to give them a direct stake in the Company's future and performances via trends in the share price, as a partial substitute for the granting of stock options.

Restricted shares are awarded to employees on the basis of a list submitted to the Compensation Committee. This Committee then submits this list to the Board of Directors, which decides to award the shares. The Board of Directors sets the vesting conditions for the award, and any lock-up conditions for the shares.

In 2011, the Board of Directors made significant changes to its equity-based compensation policy. In order to limit the dilutive effect on shareholders, the Board of Directors determined to primarily award performance shares, except for a limited group of senior managers who may continue to receive options. Furthermore, whoever the beneficiary is, any award of options or performance shares is now fully contingent upon the performance targets being attained over three financial years.

On March 5, 2014, the Board of Directors set up two plans in addition to the award made to the Chief Executive Officer:

a French plan awarding 1,257,620 performance shares to 2,546 beneficiaries, subject to a vesting period of three years followed by a lock-up period of two years; and

an international plan awarding 2,605,515 restricted shares to 5,204 beneficiaries, subject to a vesting period of four years.

The entire award was contingent upon the same criteria based on Business Net Income and Return on Assets as the award of members of the Executive Committee, each criterion representing 50% of the grant. The quantitative measures of performance are the same as for the award of members of the Executive Committee.

The 2014 awards represent a dilution of 0.30% of our share capital before dilution as of December 31, 2014.

Not all employees are able to benefit from awards of performance shares, but a new agreement on the voluntary scheme (*intéressement des salariés*) was concluded in June 2014 to ensure that all employees have an interest in the performance of the business.

In addition, pursuant to the French Act of July 28, 2011, all employees in France of the French subsidiaries of the Group benefited from a profit-sharing bonus amounting to €350 gross in June 2014. In total, Sanofi paid out €11.4 million in this regard (including social contributions).

Table of Contents**Restricted Share Plans**

	Date of shareholder authorization	Date of award	Number of shares initially awarded	- to corporate officers(1)	- to the 10 employees awarded the most shares(2)	Date of award(3)	Vesting date	Availability date	Number transferred as of 12/31/2014	Number of rights canceled as of 12/31/2014	outs
ntis	4/17/09	3/01/10	531,725	0	12,600	3/01/10	3/02/12	3/03/14	523,767	7,958	
ntis	4/17/09	3/01/10	699,524	0	16,530	3/01/10	3/02/14	3/03/14	614,371	85,153	
ntis	4/17/09	10/27/10	556,480	20	200	10/27/10	10/27/12	10/28/14	533,200	23,280	
ntis	4/17/09	10/27/10	1,544,860	0	200	10/27/10	10/27/14	10/28/14	1,242,220	304,040	
ntis	4/17/09	3/09/11	1,366,040	0	71,000	3/09/11	3/10/13	3/10/15	1,346,090	19,950	
ntis	4/17/09	3/09/11	1,934,610	0	103,300	3/09/11	3/10/15	3/10/15	18,950	215,140	1
ntis	4/17/09	3/09/11	30,000	30,000	0	3/09/11	3/10/13	3/10/15	30,000	0	
	4/17/09	3/05/12	1,519,430	0	126,700	3/05/2012	3/06/15	3/06/17	400	25,490	1
	4/17/09	3/05/12	3,132,830	0	96,300	3/05/2012	3/06/16	3/06/16	4,300	317,750	2
	4/17/09	3/05/12	42,000	42,000	0	3/05/2012	3/06/15	3/06/17	0	0	
	5/04/12	3/05/13	1,410,360	0	97,300	3/05/2013	3/06/16	3/06/18	400	16,500	1
	5/04/12	3/05/13	2,840,345	0	85,100	3/05/2013	3/06/17	3/06/17	3,350	151,405	2
	5/04/12	3/05/13	45,000	45,000	0	3/05/2013	3/06/16	3/06/18	0	0	
	5/04/12	3/05/14	1,257,620	0	28,060	3/05/2014	3/06/17	3/06/19	0	4,900	1
	5/04/12	3/05/14	2,605,515	0	35,400	3/05/2014	3/06/18	3/06/18	900	47,320	2
	5/04/12	3/05/14	45,000	45,000	0	3/05/2014	3/06/17	3/06/19	0	0	

(1) *Includes the Chief Executive Officer as of the date of grant.*

(2) *Employed as of the date of grant.*

(3) *Subject to vesting conditions.*

Edgar Filing: Sanofi - Form 20-F

As of December 31, 2014, a total of 14,025,905 restricted shares were outstanding.

Shares Owned by Members of the Board of Directors

As of December 31, 2014, members of our Board of Directors held in the aggregate 19,069 shares, or under 1% of the share capital and of the voting rights, excluding the beneficial ownership of 118,227,307 shares held by L'Oréal as of such date which may be attributed to Laurent Attal or Christian Mulliez (who disclaim beneficial ownership of such shares).

Transactions in Shares by Members of the Board of Directors and equivalent persons in 2014

On March 20, 2014, Peter Guenter, Executive Vice President Global Commercial Operations, sold 1,190 shares at a price of €72.27 per share;

On May 26, 2014, Jérôme Contamine, Executive Vice President Chief Financial Officer, exercised 38,000 options to subscribe for shares at a price of €54.12 per share and sold the resulting 38,000 shares at a price of €77.75 per share (sanofi-aventis subscription option plan of March 1, 2010);

On June 6, 2014, Jérôme Contamine, Executive Vice President Chief Financial Officer, exercised 9,146 options to subscribe for shares at a price of €54.12 per share (sanofi-aventis subscription option plan of March 1, 2010);

On June 25, 2014, Philippe Luscan, Senior Vice President Industrial and Global Affairs, exercised 6,200 options to subscribe for shares at a price of €45.09 per share (sanofi-aventis subscription option plan of March 2, 2009);

On August 4, 2014, Karen Linehan, Executive Vice President Legal Affairs and General Counsel, exercised 12,000 options to subscribe for shares at a price of €70.38 per share and sold the resulting 12,000 shares at a price of €79.50 per share (sanofi-aventis subscription option plan of May 31, 2005);

On September 2, 2014, Roberto Pucci, Executive Vice President Human Resources, exercised 43,000 options to subscribe for shares at a price of €54.12 per share and sold the resulting 43,000 shares at a price of €83.53 per share (sanofi-aventis subscription option plan of March 1, 2010);

On September 16, 2014, Roberto Pucci, Executive Vice President Human Resources, exercised 7,000 options to subscribe for shares at a price of €54.12 per share (sanofi-aventis subscription option plan of March 1, 2010);

On December 15, 2014, Olivier Charmeil, Executive Vice President Vaccines, exercised 20,000 options to subscribe for shares at a price of €45.09 per share (sanofi-aventis subscription option plan of March 2, 2009);

On December 19, 2014, Olivier Charmeil, Executive Vice President Vaccines, exercised 15,000 options to subscribe for shares at a price of €45.09 per share (sanofi-aventis subscription option plan of March 2, 2009).

Table of Contents**Item 7. Major Shareholders and Related Party Transactions***A. Major Shareholders*

The table below shows the ownership of our shares as of January 31, 2015, indicating the beneficial owners of our shares. To the best of our knowledge and on the basis of the notifications received as disclosed below, except for L'Oréal, no other shareholder currently holds more than 5% of our share capital or voting rights.

	Total number of issued shares		Number of actual voting rights (excluding treasury shares)(3)		Theoretical number of voting rights (including treasury shares)(4)	
	Number	%	Number	%	Number	%
	L'Oréal	118,227,307	8.96	236,454,614	16.31	236,454,614
Treasury shares⁽¹⁾	12,190,839	0.92			12,190,839	0.84
Employees⁽²⁾	17,075,788	1.29	32,787,982	2.26	32,787,982	2.24
Public	1,172,161,659	88.83	1,180,547,664	81.43	1,180,547,664	80.75
Total	1,319,655,593	100	1,449,790,260	100	1,461,981,099	100

(1) *Includes net position of share repurchases under the Group's liquidity contract which amounted to 7,500 shares as of January 31, 2015. Amounts held under this contract vary over time.*

(2) *Shares held via the Sanofi Group Employee Savings Plan.*

(3) *Based on the total number of voting rights as of January 31, 2015.*

(4) *Based on the total number of voting rights as of January 31, 2015 as published in accordance with article 223-11 and seq. of the General Regulations of the Autorité des Marchés Financiers (i.e., calculated including suspension of the voting rights of treasury shares).*

Our *statuts* (Articles of Association) provide for double voting rights for shares held in registered form for at least two years. All of our shareholders may benefit from double voting rights if these conditions are met, and no shareholder benefits from specific voting rights. For more information relating to our shares, see "Item 10. Additional Information – B. Memorandum and Articles of Association."

L'Oréal is the only entity known to hold more than 5% of the outstanding Sanofi ordinary shares.

For the year ended December 31, 2014, we did not receive any share ownership declaration informing us that any legal threshold had been passed.

Edgar Filing: Sanofi - Form 20-F

In accordance with our Articles of Association, shareholders must notify us once they have passed the threshold of 1% of our share capital or our voting rights and each time they cross an incremental 1% threshold (see "Item 10. Additional Information B. Memorandum and Articles of Association Requirements for Holdings Exceeding Certain Percentages").

For the year ended December 31, 2014, in accordance with our Articles of Association, we were informed that the following share ownership declaration thresholds had been passed:

Amundi Asset Management declared that, through its mutual funds, it had successively passed below (declaration of March 13, 2014), above (declaration of March 24, 2014), and finally below (declaration of April 8, 2014) the threshold of 3% of our voting rights, and as of its last declaration held 2.99% of our voting rights (declaration of April 8, 2014);

Dodge & Cox declared that it held 3.004% of our share capital and 2.720% of our voting rights (declaration of March 11, 2014);

Franklin Resources Inc. declared that it had passed above the threshold of 2% of our share capital (declaration of April 8, 2014), and above and then below the threshold of 2% of our voting rights (declaration of May 6, 2014 and June 30, 2014) and as of its last declaration held 2.203% of our share capital and 1.989% of our voting rights (declaration of June 30, 2014);

Natixis Asset Management declared that it had passed above the threshold of 2% of our voting rights (declaration of January 9, 2014) and then below the threshold of 1% of our voting rights (declaration of June 3, 2014) and below the threshold of 1% of our share capital (declaration of October 16, 2014) and as of its last declaration held 0.994% of our share capital and 0.996% of our voting rights (declaration of October 16, 2014);

Table of Contents

State Street, acting on behalf of several funds and portfolios managed by its group, declared that it had passed above the threshold of 1% and 2% of our capital and 1% of our voting rights and as of its last declaration held 2.28% of our share capital and 1.38% of our voting rights (declaration of January 8, 2014).

UBS declared that it held 0.95% of our share capital and 0.86% of our voting rights (declaration of May 22, 2014).

As of December 31, 2014, individual shareholders (including employees of Sanofi and its subsidiaries, as well as retired employees holding shares via the Sanofi Group Employee Savings Plan) held approximately 7.5% of our share capital. Institutional shareholders (excluding L'Oréal) held approximately 77.3% of our share capital. Such shareholders are primarily American (29.1%), French (13.7%) and British (12.9%). German institutions held 3.4% of our share capital, Swiss institutions held 2.6%, institutions from other European countries held 7.8% and Canadian institutions held 1.6% of our share capital. Other international institutional investors (excluding those from Europe and North America) held approximately 6.2% of our share capital. In France, our home country, we have 27,794 identified shareholders of record. In the United States, our host country, we have 51 identified shareholders of record and 20,042 identified ADS holders of record.

(source: a survey conducted by Euroclear France as of December 31, 2014, and internal information).

Shareholders' Agreement

We are unaware of any shareholders' agreement currently in force.

B. Related Party Transactions

See Note D.33 to our consolidated financial statements included at Item 18 of this annual report.

C. Interests of Experts and Counsel

N/A

Table of Contents**Item 8. Financial Information***A. Consolidated Financial Statements and Other Financial Information*

Our consolidated financial statements as of and for the years ended December 31, 2014, 2013, and 2012 are included in this annual report at "Item 18. Financial Statements."

Dividends on Ordinary Shares

We paid annual dividends for the years ended December 31, 2010, 2011, 2012 and 2013 and our shareholders will be asked to approve the payment of an annual dividend of €2.85 per share for the 2014 fiscal year at our next annual shareholders' meeting. If approved, this dividend will be paid on May 13, 2015.

We expect that we will continue to pay regular dividends based on our financial condition and results of operations. The proposed 2014 dividend equates to a distribution of 55% of our business earnings per share. For information on the non-GAAP financial measure, "business earnings per share", see "Item 5. Operating and Financial Review and Prospects – Business Net Income." The proposed dividend distribution will subject Sanofi to a 3% additional corporate tax charge on the amount distributed.

The following table sets forth information with respect to the dividends paid by our Company in respect of the 2010, 2011, 2012 and 2013 fiscal years and the dividend that will be proposed for approval by our shareholders in respect of the 2014 fiscal year at our May 4, 2015 shareholders' meeting.

	2014(1)	2013	2012	2011	2010
Dividend per Share (in €)	2.85	2.80	2.77	2.65	2.50
Dividend per Share (in \$) ⁽²⁾	3.46	3.86	3.65	3.43	3.34

(1)

Proposal, subject to shareholder approval.

(2)

Based on the relevant year-end exchange rate.

The declaration, amount and payment of any future dividends will be determined by majority vote of the holders of our shares at an ordinary general meeting, following the recommendation of our Board of Directors. Any declaration will depend on our results of operations, financial condition, cash requirements, future prospects and other factors deemed relevant by our shareholders. Accordingly, we cannot assure you that we will pay dividends in the future on a continuous and regular basis. Under French law, we are required to pay dividends approved by an ordinary general meeting of shareholders within nine months following the meeting at which they are approved.

Disclosure pursuant to Section 219 of the Iran Threat Reduction & Syria Human Rights Act (ITRA)

Sanofi conducts limited business relating to human and animal health products with Iran contributing well under 1% of the Group's consolidated net sales in 2014. Although these activities are compliant with applicable law and not financially material to the Group, the Iran Threat Reduction and Syria Human Rights Act of 2012 (the "Act") requires us to include the following disclosures in this report. Sales consisted of bulk and branded pharmaceuticals, vaccines, and animal health supplies. U.S. affiliates, or foreign affiliates controlled by U.S. affiliates, are either not involved in these activities or operate under humanitarian licenses issued by the U.S. Treasury Department's Office of Foreign Assets Control, and the Group has not knowingly conducted a transaction or dealing with a person or entity designated in U.S. Executive Orders No. 13224 and 13382. Limited business amounting to approximately €11.6 million in gross revenues has been conducted by foreign subsidiaries not requiring an OFAC license with entities such as public hospitals or distributors tied to the Ministry of Health or Ministry of Agriculture. It is

estimated that this activity contributed no more than €4.9 million to net profits. A representative office in Tehran incurs incidental expenses from state-owned utilities. Otherwise, no business has been transacted with the Government of Iran as defined in the Act. The Group does not believe any of its activities to be sanctionable under the Iran Sanctions Act or the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010. In light of the nature of the products concerned, Sanofi does not currently intend to cease its commercial operations in Iran.

Information on Legal or Arbitration Proceedings

This Item 8 incorporates by reference the disclosures found at Note D.22 to the consolidated financial statements found at Item 18 of this annual report; material updates thereto as of the date of this annual report are found below under the heading " Updates to Note D.22".

Table of Contents

Sanofi and its subsidiaries are involved in litigation, arbitration and other legal proceedings. These proceedings typically are related to product liability claims, intellectual property rights (particularly claims against generic companies seeking to limit the patent protection of Sanofi products), competition law and trade practices, commercial claims, employment and wrongful discharge claims, tax assessment claims, waste disposal and pollution claims, and claims under warranties or indemnification arrangements relating to business divestitures. As a result, the Group may become subject to substantial liabilities that may not be covered by insurance and could affect our business and reputation. While we do not currently believe that any of these legal proceedings will have a material adverse effect on our financial position, litigation is inherently unpredictable. As a consequence, we may in the future incur judgments or enter into settlements of claims that could have a material adverse effect on results of operations, cash flows and/or our reputation.

Patents*Plavix® Patent Litigation (Canada)*

On April 22, 2009, Apotex filed an impeachment action against Sanofi in the Federal Court of Canada alleging the invalidity of Sanofi's Canadian Patent No. 1,336,777 (the '777 Patent) claiming clopidogrel bisulfate. On June 8, 2009, Sanofi filed its defense to the impeachment action and filed a suit against Apotex for infringement of the '777 Patent. The actions were combined and the trial was completed in June 2011. In December 2011, the Federal Court issued a decision that the '777 Patent is invalid, and subsequently generic companies entered the market with generic clopidogrel products. Sanofi filed an appeal with the Federal Court of Appeal in January 2012. On July 24, 2013, the Federal Court of Appeal issued its decision reversing the Federal Court's decision and upholding the validity of the '777 Patent and returned the case to the lower Court for a determination of damages owed by Apotex to Sanofi for marketing clopidogrel prior to the proper expiration of the '777 patent. In October 2013, Apotex appealed this decision to the Supreme Court of Canada.

On December 5, 2013, new infringement actions were initiated in the Federal Court of Canada (a) against Apotex, seeking recovery of damages arising from exports that Apotex made from Canada to a number of other countries, and (b) against nine other generic companies seeking recovery of damages arising from their sales of generic clopidogrel within Canada.

In January 2014, the Supreme Court of Canada granted leave to hear Apotex's appeal. The appeal was withdrawn and action terminated as part of a global settlement between parties encompassing co-pending action in Australia (see Note D.22). The case is now closed.

Apotex Settlement Claim

On November 13, 2008, Apotex filed a complaint before a state court in New Jersey against Sanofi and Bristol-Myers Squibb (BMS) claiming the payment of a U.S.\$60 million break-up fee, pursuant to the terms of the initial settlement agreement of March 2006 relating to the U.S. Plavix® patent litigation. On April 8, 2011, the New Jersey State Court granted Sanofi and BMS a motion for summary judgment that was reversed in November 2012. On July 12, 2013, Sanofi, BMS and Apotex executed an arbitration agreement moving the case to an arbitration setting. On June 4, 2014, the arbitral panel decided in Sanofi-BMS's favor, rejecting Apotex's Breach of Contract claim against Sanofi-BMS. As a consequence, the underlying NJ court case was dismissed with prejudice in June. The case is closed.

In January 2011, Apotex filed a lawsuit in Florida State Court, Broward County, alleging breach of contract relating to the parties' March 2006 proposed settlement agreement. Sanofi was granted a motion for summary judgment in 2012, removing Sanofi from the case. BMS's summary judgment motion was denied. In December 2012, Apotex appealed the summary judgment as to Sanofi. In March 2013, the court ruled in favor of BMS. In July 2013, as part of the agreement to move the New Jersey action to arbitration, Apotex discontinued the appeal of the summary judgment ruling of 2012 in favor of Sanofi, voluntarily dismissing the Florida action against Sanofi with prejudice. The case is closed.

Allegra® Patent Litigation (Japan)

In August 2012, Elmed Eisai Co., Ltd. ("Eisai"), Kobayashi Kako Co., Ltd. ("Kobayashi"), and Taisho Pharm. Ind., Ltd. ("Taisho") obtained approvals to manufacture and market generic fexofenadine hydrochloride products in Japan, despite the existence and validity of the two fexofenadine hydrochloride patents. In August and September 2012, patent invalidation actions against those two patents were filed at the Japan Patent Office ("JPO")

Table of Contents

by Eisai, Daiko Pharmaceutical Co. Ltd., Kyorin Rimedio Co. Ltd., Nihon Generic Co., Ltd., Nihon Pharmaceutical Industry Co. Ltd., Nippon Chemiphar Co., Ltd., Nissin Pharmaceutical Co., Ltd., Shiono Chemical Co. Ltd., Teva Pharma Japan Inc., and Yoshindo Inc. On October 22, 2013, JPO issued a pre-decision notice finding the patents invalid.

In October 2012, Sanofi filed patent infringement lawsuits against Eisai, Taisho and Kobayashi. In December 2012, the previously approved generic fexofenadine hydrochloride products of Eisai and Kobayashi were added to Japan's National Health Insurance (NHI) price list. Since February 2013, Allegra® as a prescription medicine has been subject to generic competition in this country.

These cases were settled in March 2014 with all the counterparties withdrawing their JPO invalidation trials and Sanofi withdrawing the pending infringement lawsuits with the parties bearing their own costs. The cases are now closed.

Co-Aprovel® Patent Infringement Actions in Europe

Sanofi has been involved since early 2012 in a number of legal proceedings involving generic companies that attempted to launch or launched generic versions of Sanofi's Co-Aprovel® in several European countries including United Kingdom, Belgium, France, Germany, the Netherlands, Italy and Norway. Sanofi filed for and was granted preliminary injunctions (PI) against several generic companies based on Sanofi's Supplemental Protection Certificate (SPC) covering Co-Aprovel® until October 15, 2013. The U.K. Court referred the question on the validity of the Co-Aprovel® SPC to the Court of Justice of the European Union (CJEU) in October 2012.

Following the CJEU decision on December 12, 2013, deciding the invalidity of Co-Aprovel® SPC, generic companies (which were withdrawn from the market due to national preliminary injunction or cross undertaking) have filed damages claims in several countries against Sanofi. The cases are currently pending.

Lantus® and Lantus® SoloStar® Patent Litigation (United States, France and Japan)

In mid-December 2013 and late January 2014, Sanofi received notifications from Eli Lilly and Company (Lilly), stating that it had filed an NDA (505(b)(2) New Drug Application) with the FDA for an insulin glargine drug product. Lilly also stated that its NDA included Paragraph IV certifications directed to six of the eight Sanofi patents listed in the FDA Orange Book for Sanofi's Lantus® and Lantus® SoloStar® products. On January 30, 2014, Sanofi filed a patent infringement suit against Lilly in the United States District Court for the District of Delaware, alleging infringement of two device patents and two formulation patents. Sanofi added a third device patent to this lawsuit in May 2014. This suit resulted in a stay during which the FDA cannot approve Lilly's NDA. The stay is expected to expire on the earlier of (i) a court decision favorable to Lilly or (ii) June 20, 2016.

In May 2014, Sanofi received notifications from Lilly stating that it had filed a second NDA (505(b)(2) New Drug Application) with the FDA. This NDA is directed to a 3 ml cartridge of insulin glargine and included Paragraph IV certifications challenging three of the eight Sanofi patents listed in the FDA Orange Book for Sanofi's Lantus® product. On July 7, 2014, Sanofi filed a new patent infringement suit against Lilly in the United States District Court for the District of Delaware, alleging infringement of seven patents covering Lantus® and Lantus® SoloStar® (two formulation patents and five device patents). This suit resulted in a stay during which the FDA cannot approve Lilly's NDA. The stay is expected to expire on the earlier of (i) a court decision favorable to Lilly or (ii) November 27, 2016.

In August 2014, Sanofi filed patent infringement law suits against Lilly in France, based on different patents (protecting the insulin glargine, a manufacturing process and a device). In September 2014, Sanofi further requested a preliminary injunction against Lilly based on the insulin glargine compound patent; in its decision rendered in December 2014, the court accepted and recorded Lilly's undertaking not to commit any infringing acts in France (including import or export of insulin glargine) before the May 5, 2015 expiration of the pediatric extension of the insulin glargine compound patent in Europe. The law suit based on the compound SPC and process patent is adjourned and a hearing is set for June 2015. The lawsuit on basis of the device patent is pending.

On December 8, 2014, Sanofi filed a petition for a preliminary injunction against Lilly's insulin glargine biosimilar pre-loaded in its MirioPen® with the Tokyo District Court based on a Japanese device patent. This action is proceeding. In January 2015, Lilly filed an invalidation action concerning this Sanofi Japanese device patent with the Japanese Patent Office.

Table of Contents

Humalog® MirioPen® and Humulin® MirioPen® Patent Litigation (Japan)

On October 7, 2014, Sanofi filed a patent infringement lawsuit against Lilly Japan at the Tokyo District Court claiming that Lilly's Humalog® MirioPen® and Humulin® MirioPen® products infringe a Japanese device patent. Sanofi seeks damages from Lilly. This action is proceeding.

Multaq® Patent Litigation (United States)

From January 2014 to November 2014, several generic manufacturers notified Sanofi that they had filed Abbreviated New Drug Applications (ANDAs) seeking FDA approval to market generic versions of Multaq® (dronedarone hydrochloride) in the U.S. The notices challenged some, but not all, of the patents listed by Sanofi in the FDA's Orange Book in connection with Multaq®. None of the ANDA filers challenged the patent directed to the active ingredient in Multaq®, US Patent No. 5,223,510 (the '510 patent).

From February 2014 to November 2014, Sanofi brought suit against all of the ANDA filers in the United States District Court for the District of Delaware for patent infringement. Depending on the contents of the particular Paragraph IV Certification, Sanofi has brought suit for infringement of at least three and sometimes four of its Orange Book listed patents. In all but one case the 30-month stay expires on the earlier of (1) January 1, 2017 or (2) a court decision in favor of one or more of the defendants on all patents that support the stay. In the Sandoz case the 30 month stay expires on the earlier of (1) May 14, 2017 or (2) a court decision in favor of one or more of the defendants on all patents that support the stay.

Government Investigations

From time to time, subsidiaries of Sanofi are subject to governmental investigations and information requests from regulatory authorities inquiring as to the practices of Sanofi with respect to the sales, marketing, and promotion of its products. For example, Sanofi is cooperating with the U.S. Department of Justice in its respective investigations into the promotion of Septrafilm® and Plavix®.

In December 2013, Genzyme entered into a settlement agreement to resolve civil claims arising out of the investigation into promotional practices of Septrafilm® and paid in that respect approximately U.S.\$23 million. Discussions with the U.S. Government are ongoing to resolve the matter completely, including any potential criminal resolution. As part of this settlement, and as part of the settlement entered into by Sanofi U.S. in December 2012 relating to civil claims arising out of an investigation into sampling of its former product Hyalgan® for which Sanofi U.S. paid U.S.\$109 million, the companies expect to enter into a Corporate Integrity Agreement with the Office of the Inspector General of the United States Department of Health and Human Services.

In June 2012, Sanofi U.S. became aware that the U.S. Department of Justice is investigating disclosures to the FDA regarding the variability of response to Plavix®. Sanofi U.S. is cooperating with the U.S. Department of Justice in this matter.

In France, in the claim concerning allegations that Sanofi's communication and promotional practices inhibited the entry on the market of generics of clopidogrel (the active ingredient of Plavix®), the French Antitrust Authority issued its decision on May 14, 2013, imposing on Sanofi a fine of €40.6 million. In December 2014, the Paris Court of Appeal rejected Sanofi's appeal and confirmed in totality the decision. Sanofi filed a "pourvoi" with the French Supreme Court (*Cour de Cassation*) in January 2015. As a consequence to the May 2013 ruling, claims were filed respectively by Sandoz in August 2014 and by Teva in September 2014 before the Commercial Court of Paris for compensation of their alleged damages: loss of margin and other ancillary damages (legal fees to external counsels, image and reputation).

Sanofi is engaged in discussions with the U.S. Department of Justice and the U.S. Securities and Exchange Commission regarding allegations that certain subsidiaries outside the United States made improper payments in connection with the sale of pharmaceutical products and whether those payments, if made, fall within the U.S. Foreign Corrupt Practices Act. Sanofi also received anonymous allegations of wrongdoing related to improper payments to healthcare professionals in connection with the sale of pharmaceutical products that may have occurred between 2007 and 2013 in certain parts of the Middle East and Africa. Sanofi proactively notified the U.S. Department of Justice and the U.S. Securities and Exchange Commission of all of the allegations. The Company has voluntarily provided and will continue to provide information to the DOJ and SEC, and will cooperate with the agencies' reviews of these matters.

Table of Contents

Glossary of Terminology

A number of technical terms which may be used above in Item 8 are defined below for the convenience of the reader.

Summary judgment: A judgment granted on a claim or defense about which there is no genuine issue of material fact and upon which the movant is entitled to prevail as a matter of law. This procedural device allows the speedy disposition of a controversy without the need for trial.

Updates to Note D.22

CVR Class Action

On February 20, 2015, the lead plaintiff Deerhaven Capital filed a notice of appeal concerning the U.S. district court's dismissal of the purported CVR class action. Subsequently, on February 27, 2015, the individual plaintiffs also filed a notice of appeal.

B. Significant Changes

N/A

Table of Contents**Item 9. The Offer and Listing***A. Offer and Listing Details*

We have one class of shares. Each American Depositary Share, or ADS, represents one-half of one share. The ADSs are evidenced by American Depositary Receipts, or ADRs, which are issued by JPMorgan Chase Bank, N.A..

Our shares trade on Compartment A of the regulated market of Euronext Paris, and our ADSs trade on the New York Stock Exchange, or NYSE.

In April 2011, in connection with our acquisition of Genzyme, we issued contingent value rights ("CVRs") under a CVR agreement entered into by and between us and the American Stock Transfer & Trust Company, LLC, as trustee (see Item 10.C. Material Contracts – The Contingent Value Rights Agreement). Our CVRs trade on the NASDAQ Global Market.

Trading History

The table below sets forth, for the periods indicated, the reported high and low market prices of our shares on Euronext Paris and our ADSs on the NYSE (source: Bloomberg).

Calendar period	Shares, as traded on Euronext Paris		ADSs, as traded on the NYSE	
	High	Low	High	Low
	(price per share in €)		(price per ADS in \$)	
Monthly				
February 2015	89.17	80.42	50.62	46.00
January 2015	84.36	72.94	47.36	43.57
December 2014	78.87	69.77	48.98	44.24
November 2014	77.89	71.60	48.58	45.01
October 2014	89.74	69.58	56.39	44.50
September 2014	89.95	82.88	57.42	54.68
2014				
First quarter	77.70	68.29	52.76	47.06
Second quarter	80.42	73.86	54.64	50.84
Third quarter	89.95	75.40	57.42	50.74
Fourth quarter	89.74	69.58	56.39	44.24

Edgar Filing: Sanofi - Form 20-F

Full Year	89.95	68.29	57.42	44.24
2013				
First quarter	79.46	65.91	51.29	44.50
Second quarter	87.03	75.33	55.94	49.33
Third quarter	81.15	71.50	53.53	46.95
Fourth quarter	80.74	71.68	54.49	48.43
Full Year	87.03	65.91	55.94	44.50
2012				
Full Year	72.38	53.20	47.97	33.03
2011				
Full Year	56.82	42.85	40.75	30.98
2010				
Full Year	58.90	44.01	41.59	28.01

Fluctuations in the exchange rate between the euro and the U.S. dollar will affect any comparisons of euro share prices and U.S. ADS prices.

Table of Contents

B. Plan of Distribution

N/A

C. Markets

Shares and ADSs

Our shares are listed on Euronext Paris under the symbol "SAN" and our ADSs are listed on the NYSE under the symbol "SNY".

As of the date of this annual report, our shares are included in a large number of indices, including the "CAC 40 Index", the principal French index published by Euronext Paris. This index contains 40 stocks selected among the top 100 companies based on free-float capitalization and the most active stocks listed on the Euronext Paris market. The CAC 40 Index indicates trends in the French stock market as a whole and is one of the most widely followed stock price indices in France. Our shares are also included in the S&P Global 100 Index, the Dow Jones Euro STOXX 50, the Dow Jones STOXX 50, the FTS Eurofirst 100, the FTS Eurofirst 80 and the MSCI Pan-Euro Index, among other indices.

CVRs

Our CVRs trade on the NASDAQ Global Market under the symbol "GCVRZ".

Trading by Sanofi in our own Shares

Under French law, a company may not issue shares to itself, but it may purchase its own shares in the limited cases described at "Item 10. Additional Information B. Memorandum and Articles of Association Trading in Our Own Shares."

D. Selling Shareholders

N/A

E. Dilution

N/A

F. Expenses of the Issue

N/A

Table of Contents

Item 10. Additional Information

A. Share Capital

N/A

B. Memorandum and Articles of Association

General

Our Company is a *société anonyme*, a form of limited liability company, organized under the laws of France.

In this section, we summarize material information concerning our share capital, together with material provisions of applicable French law and our Articles of Association (*statuts*), an English translation of which has been filed as an exhibit to this annual report. For a description of certain provisions of our Articles of Association relating to our Board of Directors and statutory auditors, see "Item 6. Directors, Senior Management and Employees." You may obtain copies of our Articles of Association in French from the *greffe* (Clerk) of the *Registre du Commerce et des Sociétés de Paris* (Registry of Commerce and Companies of Paris, France, registration number: 395 030 844). Please refer to that full document for additional details.

Our Articles of Association specify that our corporate affairs are governed by:

applicable laws and regulations (in particular, Title II of the French Commercial Code); and

the Articles of Association themselves.

Article 3 of our Articles of Association specifies that the Company's corporate purpose, in France and abroad, is:

acquiring interests and holdings, in any form whatsoever, in any company or enterprise, in existence or to be created, connected directly or indirectly with the health and fine chemistry sectors, human and animal therapeutics, nutrition and bio-industry;

in the following areas:

purchase and sale of all raw materials and products necessary for these activities;

research, study and development of new products, techniques and processes;

manufacture and sale of all chemical, biological, dietary and hygiene products;

obtaining or acquiring all intellectual property rights related to results obtained and, in particular, filing all patents, trademarks and models, processes or inventions;

Edgar Filing: Sanofi - Form 20-F

operating directly or indirectly, purchasing, and transferring for free or for consideration pledging or securing all intellectual property rights, particularly all patents, trademarks and models, processes or inventions;

obtaining, operating, holding and granting all licenses;

within the framework of a group-wide policy and subject to compliance with the relevant legislation, participating in treasury management transactions, whether as lead company or otherwise, in the form of centralized currency risk management or intra-group netting, or any other form permitted under the relevant laws and regulations;

and, more generally:

all commercial, industrial, real or personal property, financial or other transactions, connected directly or indirectly, totally or partially, with the activities described above and with all similar or related activities or having any other purposes likely to encourage or develop the Company's activities.

Directors

Transactions in Which Directors Are Materially Interested

Under French law, any agreement entered into (directly or through an intermediary) between our Company and any one of the members of the Board of Directors that is not entered into (i) in the ordinary course of our business and (ii) under normal conditions is subject to the prior authorization of the disinterested members of the Board of

Table of Contents

Directors. The same provision applies to agreements between our Company and another company if one of the members of the Board of Directors is the owner, general partner, manager, director, general manager or member of the executive or supervisory board of the other company, as well as to agreements in which one of the members of the Board of Directors has an indirect interest.

The Board of Directors must also authorize any undertaking taken by our Company for the benefit of our Chairman, Chief Executive Officer (*directeur général*) or his delegates (*directeurs généraux délégués*) pursuant to which such persons will or may be granted compensation, benefit or any other advantage as a result of the termination of or a change in their offices or following such termination or change.

In addition, except with respect to any non-compete indemnity or certain pension benefits, any such termination package: (i) must be authorized by our shareholders through the adoption of a separate general shareholders meeting resolution for each such beneficiary, which authorization must be renewed at each renewal of such beneficiary's mandate, and (ii) cannot be paid to such beneficiary unless (a) the Board of Directors decides that such beneficiary has satisfied certain conditions, linked to such beneficiary's performance measured by our Company's performance, that must have been defined by the Board of Directors when granting such package, and (b) such decision is publicly disclosed.

Directors' Compensation

The aggregate amount of attendance fees (*jetons de présence*) of the Board of Directors is determined at the Shareholders' Ordinary General Meeting. The Board of Directors then divides this aggregate amount among its members by a simple majority vote. In addition, the Board of Directors may grant exceptional compensation (*rémunérations exceptionnelles*) to individual directors on a case-by-case basis for special assignments following the procedures described above at " Transactions in Which Directors Are Materially Interested." The Board of Directors may also authorize the reimbursement of travel and accommodation expenses, as well as other expenses incurred by Directors in the corporate interest. See also "Item 6. Directors, Senior Management and Employees."

Board of Directors' Borrowing Powers

All loans or borrowings on behalf of the Company may be decided by the Board of Directors within the limits, if any, imposed by the Shareholders' General Meeting. There are currently no limits imposed on the amounts of loans or borrowings that the Board of Directors may approve.

Directors' Age Limits

For a description of the provisions of our Articles of Association relating to age limits applicable to our Directors, see "Item 6. Directors, Senior Management and Employees."

Directors' Share Ownership Requirements

Pursuant to the Board Charter, our Directors are required to hold at least 1,000 shares during the term of their appointment.

Share Capital

As of December 31, 2014, our share capital amounted to €2,638,734,990, divided into 1,319,367,445 outstanding shares with a par value of €2 per share. All of our outstanding shares are of the same class and are fully paid. Of these shares, we or entities controlled by us held 9,456,234 shares (or 0.72% of our outstanding share capital), as treasury shares as of such date. As of December 31, 2014, the carrying amount of such shares was €695 million.

At an extraordinary general meeting held on May 3, 2013, our shareholders authorized our Board of Directors to increase our share capital, through the issuance of shares or other securities giving access to the share capital with or without preemptive rights, by an aggregate maximum nominal amount of €1.3 billion. See " Changes in Share Capital Increases in Share Capital," below.

The maximum total number of authorized but unissued shares as of December 31, 2014 was 299 million, reflecting the unused part of the May 4, 2012 and May 3, 2013 shareholder authorizations to issue shares without preemptive rights, outstanding options to subscribe for shares, and awards of shares.

Table of Contents

Stock Options

Types of Stock Options

We have two types of stock options outstanding: options to subscribe for shares (*options de souscription d'actions*) and options to purchase shares (*options d'achat d'actions*). Upon exercise of an option to subscribe for shares, we issue new shares, whereas upon exercise of an option to purchase shares, the option holder receives existing shares. We purchase our shares on the market prior to the vesting of the options to purchase in order to provide the option holder with shares upon exercise.

Because the exercise of options to purchase shares will be satisfied with existing shares repurchased on the market or held in treasury, the exercise of options to purchase shares has no impact on the amount of our share capital.

Stock Option Plans

Our combined general meeting held on May 3, 2013 authorized our Board of Directors for a period of 38 months to grant, on one or more occasions, options to subscribe for shares and options to purchase shares in favor of persons to be chosen by the Board of Directors from among the salaried employees and corporate officers of our Company or of companies or groupings of economic interest of the Group in accordance with Article L. 225-180 of the French Commercial Code.

The aggregate number of options to subscribe for shares and options to purchase shares that may be granted under this authorization may not give entitlement to a total number of shares exceeding 0.7% of the share capital as of the date of the decision by the Board of Directors to grant such options.

The Board of Directors sets the exercise price of options to subscribe for shares and options to purchase shares. However, the exercise price never incorporates a discount and must be at least equal to the average of the quoted market prices on the 20 trading sessions preceding the date of grant by the Board of Directors.

Stock option plans generally provide for a lock-up period of four years and have a duration of ten years.

Under such authorization the shareholders expressly waive, in favor of the grantees of options to subscribe for shares, their preemptive rights in respect of shares that are to be issued as and when options are exercised.

The Board of Directors is granted full power to implement this authorization and to set the terms and conditions on which options are granted and the arrangements with respect to the dividend entitlement of the shares.

See "Item 6. Directors, Senior Management and Employees E. Share Ownership" for a description of our option plans currently in force.

Awards of Shares

Our combined general meeting held on May 4, 2012 authorized our Board of Directors for a period of 38 months to allot, on one or more occasions, existing or new restricted shares in favor of persons to be chosen by the Board of Directors from among the salaried employees and corporate officers of our Company or of companies or economic interest groupings of the Group in accordance with Articles L. 225-197-1 *et seq.* of the French Commercial Code.

The existing or new shares allotted under this authorization may not represent more than 1.2% of the share capital as of the date of the decision by the Board of Directors to allot such shares.

The authorization provides that allotment of shares to the allottees will become irrevocable either (i) at the end of a minimum vesting period of three years, in which case the allottees will also be required to retain their shares for a minimum period of two years from the irrevocable allotment thereof, or (ii) after a minimum vesting period of four years, in which case allottees may not be subject to any minimum retention period.

Our combined general meeting held on May 3, 2013 authorized our Board of Directors for a period of 26 months to allot, on one or more occasions, existing or new restricted shares in favor of persons to be chosen by the Board of Directors from among the salaried employees and corporate officers of our Company or of companies or economic interest groupings of the Group in accordance with Articles L. 225-197-1 *et seq.* of the French Commercial Code.

Table of Contents

The existing or new shares allotted under this authorization may not represent more than 0.2% of the share capital as of the date of the decision by the Board of Directors to allot such shares.

The authorization provides that allotment of shares to the allottees will become irrevocable either (i) at the end of a minimum vesting period of three years, in which case the allottees will also be required to retain their shares for a minimum period of two years from the irrevocable allotment thereof, or (ii) after a minimum vesting period of four years, in which case allottees may not be subject to any minimum retention period.

The allotment of shares is subject to the subscription by the allottees to a share capital increase reserved for employees decided by the Board of Directors in accordance with articles L.3332-18 and *seq.* of the French Employment Code and with the 11th resolution of the aforementioned general meeting.

In the case of newly issued shares, the authorization entails the express waiver by the shareholders, in favor of the allottees of restricted shares, of their preemptive rights in respect of shares that are to be issued as and when restricted shares vest.

The Board of Directors sets the terms on which restricted shares are granted and the arrangements with respect to the dividend entitlement of the shares.

See "Item 6. Directors, Senior Management and Employees E. Share Ownership" for a description of our restricted shares plans currently in force.

Changes in Share Capital in 2014

See Note D.15.1. to our consolidated financial statements included at Item 18 of this annual report.

Voting Rights

In general, each shareholder is entitled to one vote per share at any shareholders' general meeting. Our Articles of Association do not provide for cumulative voting rights. However, our Articles of Association provide that any fully paid-up shares that have been held in registered form under the name of the same shareholder for at least two years acquire double voting rights. The double voting rights cease automatically for any share converted into bearer form or transferred from one owner to another, subject to certain exceptions permitted by law.

As of December 31, 2014, there were 142,364,896 shares that were entitled to double voting rights, representing 10.79% of our total share capital, approximately 9.80% of our voting rights held by holders other than us and our subsidiaries, and 9.74% of our total voting rights.

Double voting rights are not taken into account in determining whether a quorum exists.

Under the French Commercial Code, treasury shares or shares held by entities controlled by that company are not entitled to voting rights and do not count for quorum purposes.

Our Articles of Association allow us to obtain from Euroclear France the name, nationality, address and number of shares held by holders of our securities that have, or may in the future have, voting rights. If we have reason to believe that a person on any list provided by Euroclear France holds securities on behalf of another person, our Articles of Association allow us to request information regarding beneficial ownership directly from such person. See " B. Memorandum and Articles of Association Form, Holding and Transfer of Shares," below.

Our Articles of Association provide that Board members are elected on a rolling basis for a maximum tenure of four years.

Shareholders' Agreement

We are not aware of any shareholder's agreement currently in force concerning our shares.

Table of Contents

Shareholders' Meetings

General

In accordance with the provisions of the French Commercial Code, there are three types of shareholders' meetings: ordinary, extraordinary and special.

Ordinary general meetings of shareholders are required for matters such as:

electing, replacing and removing directors;

appointing independent auditors;

approving the annual financial statements;

declaring dividends or authorizing dividends to be paid in shares, provided the Articles of Association contain a provision to that effect; and

approving share repurchase programs.

Extraordinary general meetings of shareholders are required for approval of matters such as amendments to our Articles of Association, including any amendment required in connection with extraordinary corporate actions. Extraordinary corporate actions include:

changing our Company's name or corporate purpose;

increasing or decreasing our share capital;

creating a new class of equity securities;

authorizing the issuance of:

shares giving access to our share capital or giving the right to receive debt instruments, or

other securities giving access to our share capital;

establishing any other rights to equity securities;

selling or transferring substantially all of our assets; and

the voluntary liquidation of our Company.

Edgar Filing: Sanofi - Form 20-F

Special meetings of shareholders of a certain category of shares or shares with certain specific rights (such as shares with double voting rights) are required for any modification of the rights derived from that category of shares. The resolutions of the shareholders' general meeting affecting these rights are effective only after approval by the relevant special meeting.

Annual Ordinary Meetings

The French Commercial Code requires the Board of Directors to convene an annual ordinary general shareholders' meeting to approve the annual financial statements. This meeting must be held within six months of the end of each fiscal year. This period may be extended by an order of the President of the Commercial Court. The Board of Directors may also convene an ordinary or extraordinary general shareholders' meeting upon proper notice at any time during the year. If the Board of Directors fails to convene a shareholders' meeting, our independent auditors may call the meeting. In case of bankruptcy, the liquidator or court-appointed agent may also call a shareholders' meeting in some instances. In addition, any of the following may request the court to appoint an agent for the purpose of calling a shareholders' meeting:

one or several shareholders holding at least 5% of our share capital;

duly qualified associations of shareholders who have held their shares in registered form for at least two years and who together hold at least 1% of our voting rights;

the works council in cases of urgency; or

any interested party in cases of urgency.

Table of Contents

Notice of Shareholders' Meetings

All prior notice periods provided for below are minimum periods required by French law and cannot be shortened, except in case of a public tender offer for our shares.

We must announce general meetings at least thirty-five days in advance by means of a preliminary notice (*avis de réunion*), which is published in the *Bulletin des Annonces Légales Obligatoires*, or *BALO*. The preliminary notice must first be sent to the French Financial markets authority (*Autorité des marchés financiers*, the "AMF"), with an indication of the date on which it will be published in the *BALO*. It must be published on our website at least twenty-one days prior to the general meeting. The preliminary notice must contain, among other things, the agenda, a draft of the resolutions to be submitted to the shareholders for consideration at the general meeting and a detailed description of the voting procedures (proxy voting, electronic voting or voting by mail), the procedures permitting shareholders to submit additional resolutions or items to the agenda and to ask written questions to the Board of Directors. The AMF also recommends that, prior to or simultaneously with the publication of the preliminary notice, we publish a summary of the notice indicating the date, time and place of the meeting in a newspaper of national circulation in France and on our website.

At least fifteen days prior to the date set for a first convening, and at least ten days prior to any second convening, we must send a final notice (*avis de convocation*) containing the final agenda, the date, time and place of the meeting and other information related to the meeting. Such final notice must be sent by mail to all registered shareholders who have held shares in registered form for more than one month prior to the date of the final notice and by registered mail, if shareholders have asked for it and paid the corresponding charges. The final notice must also be published in a newspaper authorized to publish legal announcements in the local administrative department (*département*) in which our Company is registered as well as in the *BALO*, with prior notice having been given to the AMF for informational purposes. Even if there are no proposals for new resolutions or items to be submitted to the shareholders at the meeting, we must publish a final notice in a newspaper authorized to publish legal announcements in the local administrative department (*département*) in which our Company is registered as well as in the *BALO*.

Other issues

In general, shareholders can only take action at shareholders' meetings on matters listed on the agenda. As an exception to this rule, shareholders may take action with respect to the appointment and dismissal of directors even if this action has not been included on the agenda.

Additional resolutions to be submitted for approval by the shareholders at the shareholders' meeting may be proposed to the Board of Directors, for recommendation to the shareholders at any time from the publication of the preliminary notice in the *BALO* until twenty-five days prior to the general meeting and in any case no later than twenty days following the publication of the preliminary notice in the *BALO* by:

one or several shareholders together holding a specified percentage of shares;

a duly qualified association of shareholders who have held their shares in registered form for at least two years and who together hold at least 1% of our voting rights; or

the works council.

Within the same period, the shareholders may also propose additional items (*points*) to be submitted and discussed during the shareholders' meeting, without a shareholders' vote. The shareholders must substantiate the reasons for proposing their proposals of additional items.

The resolutions and the list of items added to the agenda of the shareholders' meeting must be promptly published on our website.

The Board of Directors must submit the resolutions to a vote of the shareholders after having made a recommendation thereon. The Board of Directors may also comment on the items that are submitted to the shareholders' meeting.

Following the date on which documents must be made available to the shareholders (including documents to be submitted to the shareholders' meeting and resolutions proposed by the Board of Directors, which must be published on our website at least twenty-one days prior to the general meeting), shareholders may submit written questions to the Board of Directors relating to the agenda for the meeting until the fourth business day prior to the general meeting. The Board of Directors must respond to these questions during the meeting or may refer to a

Edgar Filing: Sanofi - Form 20-F

Q&A section located on our website in which the question submitted by a shareholder has already been answered.

Table of Contents

Attendance at Shareholders' Meetings; Proxies and Votes by Mail

In general, all shareholders may participate in general meetings either in person or by proxy. Shareholders may vote in person, by proxy or by mail.

The right of shareholders to participate in general meetings is subject to the recording (*inscription en compte*) of their shares on the second business day, zero hour (Paris time), preceding the general meeting:

for holders of registered shares: in the registered shareholder account held by the Company or on its behalf by an agent appointed by it; and

for holders of bearer shares: in the bearer shareholder account held by the accredited financial intermediary with whom such holders have deposited their shares; such financial intermediaries shall deliver to holders of bearer shares a shareholding certificate (*attestation de participation*) enabling them to participate in the general meeting.

Attendance in Person

Any shareholder may attend ordinary general meetings and extraordinary general meetings and exercise its voting rights subject to the conditions specified in the French Commercial Code and our Articles of Association.

Proxies and Votes by Mail

Proxies are sent to any shareholder upon a request received between the publication of the final notice of meeting and six days before the general meeting and must be made available on our website at least twenty-one days before the general meeting. In order to be counted, such proxies must be received at our registered office, or at any other address indicated on the notice of the meeting or by any electronic mail indicated on the notice of the meeting, prior to the date of the meeting (in practice, we request that shareholders return proxies at least three business days prior to the meeting; electronic proxies must be returned before 3 p.m. Paris time, on the day prior to the general meeting). A shareholder may grant proxies to any natural person or legal entity. The agent may be required to disclose certain information to the shareholder or to the public.

Alternatively, the shareholder may send us a blank proxy without nominating any representative. In this case, the chairman of the meeting will vote the blank proxies in favor of all resolutions proposed or approved by the Board of Directors and against all others.

With respect to votes by mail, we must send shareholders a voting form upon request or must make available a voting form on our website at least twenty- one days before the general meeting. The completed form must be returned to us at least three days prior to the date of the shareholders' meeting. For holders of registered shares, in addition to traditional voting by mail, instructions may also be given via the internet.

Quorum

The French Commercial Code requires that shareholders holding in the aggregate at least 20% of the shares entitled to vote must be present in person, or vote by mail or by proxy, in order to fulfill the quorum requirement for:

an ordinary general meeting; and

an extraordinary general meeting where the only resolutions pertain to either (a) a proposed increase in our share capital through incorporation of reserves, profits or share premium, or (b) the potential issuance of free share warrants in the event of a public tender offer for our shares (article L. 233- 32 of the French Commercial Code).

For any other extraordinary general meeting the quorum requirement is at least 25% of the shares entitled to vote, held by shareholders present in person, voting by mail or by proxy.

Edgar Filing: Sanofi - Form 20-F

For a special meeting of holders of a certain category of shares, the quorum requirement is one third of the shares entitled to vote in that category, held by shareholders present in person, voting by mail or by proxy.

If a quorum is not present at a meeting, the meeting is adjourned. However, only questions that were on the agenda of the adjourned meeting may be discussed and voted upon once the meeting resumes.

Table of Contents

When an adjourned meeting is resumed, there is no quorum requirement for meetings cited in the first paragraph of this "*Quorum*" section. In the case of any other reconvened extraordinary general meeting or special meeting, the quorum requirement is 20% of the shares entitled to vote (or voting shares belonging to the relevant category for special meetings of holders of shares of such specific category), held by shareholders present in person or voting by mail or by proxy. If a quorum is not met, the reconvened meeting may be adjourned for a maximum of two months with the same quorum requirement. No deliberation or action by the shareholders may take place without a quorum.

Votes Required for Shareholder Action

The affirmative vote of a simple majority of the votes cast may pass a resolution at either an ordinary general meeting or an extraordinary general meeting where the only resolution(s) pertain to either (a) a proposed increase in our share capital through incorporation of reserves, profits or share premium, or (b) the potential issuance of free share warrants in the event of a public tender offer for our shares (article L. 233-32 of the French Commercial Code). At any other extraordinary general shareholders' meeting and at any special meeting of holders of a specific category of shares, the affirmative vote of two-thirds of the votes cast is required.

Abstention from voting by those present or those represented by proxy or voting by mail is counted as a vote against the resolution submitted to a shareholder vote.

Changes to Shareholders' Rights

Under French law, the affirmative vote of two-thirds of the votes cast at an extraordinary shareholders' meeting is required to change our Articles of Association, which set out the rights attached to our shares, except for capital increases through incorporation of reserves, profits or share premium, or through the issuance of free share warrants in the event of a public tender offer for our shares (article L. 233-32 of the French Commercial Code).

The rights of a class of shareholders can be amended only after a special meeting of the class of shareholders affected has taken place. The voting requirements applicable to this type of special meeting are the same as those applicable to an extraordinary general shareholders' meeting. The quorum requirements for a special meeting are one-third of the voting shares, or 20% upon resumption of an adjourned meeting.

A unanimous shareholders' vote is required to increase the liabilities of shareholders.

Financial Statements and Other Communications with Shareholders

In connection with any shareholders' meeting, we must provide a set of documents which includes our annual report.

We must also provide on our website at least twenty-one days before a shareholders' meeting certain information and a set of documents that includes the preliminary notice, the proxies and voting forms, the resolutions proposed by the Board of Directors, and the documents to be submitted to the shareholders' meeting pursuant to articles L. 225-115 and R. 225-83 of the French Commercial Code, etc. The resolutions and the list of items added to the agenda of the shareholders' meeting must be promptly published on our website.

Dividends

We may only distribute dividends out of our "distributable profits," plus any amounts held in our reserves that the shareholders decide to make available for distribution, other than those reserves that are specifically required by law or our Articles of Association. "Distributable profits" consist of our unconsolidated net profit in each fiscal year, as increased or reduced by any profit or loss carried forward from prior years, less any contributions to the reserve accounts pursuant to law or our Articles of Association.

Legal Reserve

The French Commercial Code requires us to allocate 5% of our unconsolidated net profit for each year to our legal reserve fund before dividends may be paid with respect to that year. Funds must be allocated until the amount in the legal reserve is equal to 10% of the aggregate par value of the issued and outstanding share capital. This restriction on the payment of dividends also applies to each of our French subsidiaries on an unconsolidated basis. At December 31, 2014, our legal reserve amounted to €282,280,863, representing 10.70% of the aggregate par value of our issued and outstanding share capital as of that date. The legal reserve of any company subject to this requirement

Table of Contents

may serve to allocate losses that may not be allocated to other reserves, or may be distributed to shareholders upon liquidation of the company.

Approval of Dividends

According to the French Commercial Code, our Board of Directors may propose a dividend for approval by shareholders at the annual general shareholders' meeting. If we have earned distributable profits since the end of the preceding fiscal year, as reflected in an interim income statement certified by our independent auditors, our Board of Directors may distribute interim dividends to the extent of the distributable profits for the period covered by the interim income statement. Our Board of Directors exercises this authority subject to French law and regulations and may do so without obtaining shareholder approval.

Distribution of Dividends

Dividends are distributed to shareholders *pro rata* according to their respective holdings of shares. In the case of interim dividends, distributions are made to shareholders on the date set by our Board of Directors during the meeting in which the distribution of interim dividends is approved. The actual dividend payment date is decided by the shareholders at an ordinary general shareholders' meeting or by our Board of Directors in the absence of such a decision by the shareholders. Shareholders that own shares on the actual payment date are entitled to the dividend.

Dividends may be paid in cash or, if the shareholders' meeting so decides, in kind, provided that all shareholders receive a whole number of assets of the same nature paid in lieu of cash. Our Articles of Association provide that, subject to a decision of the shareholders' meeting taken by ordinary resolution, each shareholder may be given the choice to receive his dividend in cash or in shares.

Timing of Payment

According to the French Commercial Code, we must pay any existing dividends within nine months of the end of our fiscal year, unless otherwise authorized by court order. Dividends on shares that are not claimed within five years of the date of declared payment revert to the French State.

Changes in Share Capital

Increases in Share Capital

As provided for by the French Commercial Code, our share capital may be increased only with shareholders' approval at an extraordinary general shareholders' meeting following the recommendation of our Board of Directors. The shareholders may delegate to our Board of Directors either the authority (*délégation de compétence*) or the power (*délégation de pouvoir*) to carry out any increase in share capital. Our Board of Directors may further delegate this power to our Chief Executive Officer or, subject to our Chief Executive Officer's approval, to his delegates (*directeurs généraux délégués*).

Increases in our share capital may be effected by:

issuing additional shares;

increasing the par value of existing shares;

creating a new class of equity securities; or

exercising the rights attached to securities giving access to the share capital.

Increases in share capital by issuing additional securities may be effected through one or a combination of the following:

in consideration for cash;

in consideration for assets contributed in kind;

through an exchange offer;

by conversion of previously issued debt instruments;

by capitalization of profits, reserves or share premium; or

Table of Contents

subject to various conditions, in satisfaction of debt incurred by our Company.

Decisions to increase the share capital through the capitalization of reserves, profits and/or share premium or through the issuance of free share warrants in the event of a public tender offer for our shares (article L. 233-32 of the French Commercial Code) require shareholders' approval at an extraordinary general shareholders' meeting, acting under the quorum and majority requirements applicable to ordinary shareholders' meetings. Increases effected by an increase in the par value of shares require unanimous approval of the shareholders, unless effected by capitalization of reserves, profits or share premium. All other capital increases require shareholders' approval at an extraordinary general shareholders' meeting acting under the regular quorum and majority requirements for such meetings. See " Quorum" and " Votes Required for Shareholder Action" above.

On May 3, 2013, our shareholders approved various resolutions delegating to the Board of Directors the authority to increase our share capital through the issuance of shares or securities giving access to the share capital, subject to an overall cap set at €1.3 billion. This cap applies to all the resolutions whereby the extraordinary shareholders' meeting delegated to the Board of Directors the authority to increase the share capital, it being also specified that:

the maximum aggregate par value of capital increases that may be carried out with preemptive rights maintained was set at €1.3 billion;

the maximum aggregate par value of capital increases that may be carried out by public offering without preemptive rights was set at € 520 million;

the maximum aggregate par value of capital increases that may be carried out by capitalization of share premium, reserves, profits or other items was set at €500 million; and

capital increases resulting in the issuance of securities to members of employee savings plans are limited to 1% of the share capital as computed on the date of the Board of Directors' decision to issue such securities, and such issuances may be made at a discount of 20% (or 30%) if certain French law restrictions on resales were to apply, i.e. a lock up period of five years (or 10 years).

On May 3, 2013, our shareholders also approved resolutions delegating to the Board of Directors the authority to increase the share capital by granting options to our employees and/or corporate officers, subject to the overall cap mentioned above and under the following terms and conditions:

the authorization is valid for a period of 38 months, and any options granted may not give entitlement to a total number of shares exceeding 0.7% of the share capital as computed on the date of the decision of the Board of Directors to grant such options; see " Stock Options" above;

On May 4, 2012, our shareholders approved resolutions delegating to the Board of Directors the authority to increase the share capital by granting existing or new restricted shares to our employees and/or corporate officers, subject to the overall cap mentioned above and under the following terms and conditions:

the authorization is valid for a period of 38 months, and is subject to a limit of 1.2% of the share capital as computed on the date of the decision of the Board of Directors to allot such shares; see " Awards of Shares" above.

See also "Item 6. Directors, Senior Management and Employees E. Share Ownership".

On May 3, 2013, our shareholders approved resolutions delegating to the Board of Directors the authority to increase the share capital by granting existing or new restricted shares to our employees and/or corporate officers, subject to the overall cap mentioned above and under the following terms and conditions:

the authorization is valid for a period of 26 months, and is subject to a limit of 0.2% of the share capital as computed on the date of the decision of the Board of Directors to allot such shares; see " Awards of Shares" above. The allotment of these shares is subject to the subscription by the allottees to a share capital increase decided by the Board of Directors as above described.

Decreases in Share Capital

In accordance with the provisions of the French Commercial Code, any decrease in our share capital requires approval by the shareholders entitled to vote at an extraordinary general meeting. The share capital may be reduced either by decreasing the par value of the outstanding shares or by reducing the number of outstanding shares. The number of outstanding shares may be reduced either by an exchange of shares or by the repurchase and cancellation

Table of Contents

of shares. Holders of each class of shares must be treated equally unless each affected shareholder agrees otherwise.

In addition, specific rules exist to permit the cancellation of treasury shares, by which the shareholders' meeting may authorize the cancellation of up to a maximum of 10% of a company's share capital within any 24-month period. On May 3, 2013, our shareholders delegated to our Board of Directors for 26 months the right to reduce our share capital by canceling our own shares.

Preemptive Rights

According to the French Commercial Code, if we issue additional securities to be paid in cash, current shareholders will have preemptive rights to these securities on a *pro rata* basis. These preemptive rights require us to give priority treatment to current shareholders. The rights entitle the individual or entity that holds them to subscribe to the issuance of any securities that may increase the share capital of our Company by means of a cash payment or a set-off of cash debts. Preemptive rights are transferable during the subscription period relating to a particular offering. These rights may also be listed on Euronext Paris Stock Exchange.

Preemptive rights with respect to any particular offering may be waived by the affirmative vote of shareholders holding two-thirds of the shares entitled to vote at an extraordinary general meeting. Our Board of Directors and our independent auditors are required by French law to present reports that specifically address any proposal to waive preemptive rights. In the event of a waiver, the issue of securities must be completed within the period prescribed by law. Shareholders may also notify us that they wish to waive their own preemptive rights with respect to any particular offering if they so choose.

The shareholders may decide at extraordinary general meetings to give the existing shareholders a non-transferable priority right to subscribe to the new securities, for a limited period of time.

In the event of a capital increase without preemptive rights to existing shareholders, French law requires that the capital increase be made at a price equal to or exceeding the weighted average market prices of the shares for the last three trading days on Euronext Paris Stock Exchange prior to the determination of the subscription price of the capital increase less 5%.

Form, Holding and Transfer of Shares

Form of Shares

Our Articles of Association provide that the shares may be held in either bearer form or registered form at the option of the holder.

Holding of Shares

In accordance with French law relating to the dematerialization of securities, shareholders' ownership rights are represented by book entries instead of share certificates. We maintain a share account with Euroclear France (a French clearing system, which holds securities for its participants) for all shares in registered form, which is administered by BNP Paribas Securities Services. In addition, we maintain separate accounts in the name of each shareholder either directly or, at a shareholder's request, through the shareholder's accredited intermediary. Each shareholder account shows the name of the holder and the number of shares held. BNP Paribas Securities Services issues confirmations (*attestations d'inscription en compte*) to each registered shareholder as to shares registered in the shareholder's account, but these confirmations are not documents of title.

Shares of a listed company may also be issued in bearer form. Shares held in bearer form are held and registered on the shareholder's behalf in an account maintained by an accredited financial intermediary and are credited to an account at Euroclear France maintained by such intermediary. Each accredited financial intermediary maintains a record of shares held through it and provides the account holder with a securities account statement. Transfers of shares held in bearer form may only be made through accredited financial intermediaries and Euroclear France.

Shares held by persons who are not domiciled in France may be registered in the name of intermediaries who act on behalf of one or more investors. When shares are so held, we are entitled to request from such intermediaries the names of the investors. Also, we may request any legal entity (*personne morale*) which holds more than 2.5% of our shares or voting rights to disclose the name of any person who owns, directly or indirectly, more than one-third of its

Table of Contents

share capital or of its voting rights. A person not providing the complete requested information in time, or who provides incomplete or false information, will be deprived of its voting rights at shareholders' meetings and will have its payment of dividends withheld until it has provided the requested information in strict compliance with French law. If such person acted willfully, the person may be deprived by a French court of either its voting rights or its dividends or both for a period of up to five years.

Transfer of Shares

Our Articles of Association do not contain any restrictions relating to the transfer of shares.

Registered shares must be converted into bearer form before being transferred on the Euronext Paris Stock Exchange on the shareholders' behalf and, accordingly, must be registered in an account maintained by an accredited financial intermediary on the shareholders' behalf. A shareholder may initiate a transfer by giving instructions to the relevant accredited financial intermediary.

A fee or commission is payable to the broker involved in the transaction, regardless of whether the transaction occurs within or outside France. Registration duty is currently payable in France if a written deed of sale and purchase (*acte*) is executed in France or outside France with respect to the shares of the Company.

Redemption of Shares

Under French law, our Board of Directors is entitled to redeem a set number of shares as authorized by the extraordinary shareholders' meeting. In the case of such an authorization, the shares redeemed must be cancelled within one month after the end of the offer to purchase such shares from shareholders. However, shares redeemed on the open market do not need to be cancelled if the company redeeming the shares grants options on or awards those shares to its employees within one year following the acquisition. See also " Trading in Our Own Shares" below.

Sinking Fund Provisions

Our Articles of Association do not provide for any sinking fund provisions.

Liability to Further Capital Calls

Shareholders are liable for corporate liabilities only up to the par value of the shares they hold; they are not liable to further capital calls.

Liquidation Rights

If we are liquidated, any assets remaining after payment of our debts, liquidation expenses and all of our remaining obligations will first be distributed to repay in full the par value of our shares. Any surplus will be distributed *pro rata* among shareholders in proportion to the par value of their shareholdings.

Requirements for Holdings Exceeding Certain Percentages

The French Commercial Code provides that any individual or entity, acting alone or in concert with others, that becomes the owner, directly or indirectly, of more than 5%, 10%, 15%, 20%, 25%, 30%, 33¹/₃%, 50%, 66²/₃%, 90% or 95% of the outstanding shares or voting rights of a listed company in France, such as our Company, or that increases or decreases its shareholding or voting rights above or below any of those percentages, must notify the company, before the end of the fourth trading day following the date it crosses the threshold, of the number of shares it holds and their voting rights. The individual or entity must also notify the AMF before the end of the fourth trading day following the date it crosses any such threshold. The AMF makes the notice public.

Table of Contents

Pursuant to the French Commercial Code and the AMF General Regulation, the participation thresholds shall be calculated on the basis of the shares and voting rights owned, and shall take into account the shares and voting rights which are deemed to be shares and voting rights owned, even if the individual or entity does not itself hold shares or voting rights. In accordance with this deemed ownership principle, the individual or entity must take into account specific situations where shares and voting rights are deemed to be shares and voting rights owned when calculating the number of shares owned to be disclosed in the notifications to the Company and to the AMF. It includes among others situations where an individual or entity is entitled to acquire issued shares at its own initiative, immediately or at the end of a maturity period, under an agreement or a financial instrument, without set-off against the number of shares that this individual or entity is entitled to sell under another agreement or financial instrument. The individual or entity required to make such notification shall also take into account issued shares covered by an agreement or cash-settled financial instrument and having an economic effect for said individual or entity that is equivalent to owning such shares. In the cases of deemed ownership described above, the notification shall mention the type of deemed ownership and include a description of the main characteristics of the financial instrument or agreement with specific details required by the AMF General Regulation.

The AMF General Regulation provides that shares and voting rights subject to multiple cases of deemed ownership shall only be counted once.

When an individual or entity modifies the allocation between the shares it owns and its financial instruments or agreements deemed to be owned shares, it must disclose that change in a new notification. However, the change must only be disclosed if the acquisition of owned shares due to the settlement of the financial instruments or agreements causes the investor to cross a threshold.

Subject to certain limited exceptions, French law and AMF regulations impose additional reporting requirements on persons who acquire more than 10%, 15%, 20%, or 25% of the outstanding shares or voting rights of a company listed in France. These persons must file a report with the company and the AMF before the end of the fifth trading day following the date they cross any such threshold.

In the report, the acquirer will have to specify its intentions for the following six months including:

whether it acts alone or in concert with others;

the means of financing of the acquisition (the notifier shall indicate in particular whether the acquisition is being financed with equity or debt, the main features of that debt, and, where applicable, the main guarantees given or received by the notifier. The notifier shall also indicate what portion of its holding, if any, it obtained through securities loans);

whether or not it intends to continue its purchases;

whether or not it intends to acquire control of the company in question;

the strategy it contemplates *vis-à-vis* the issuer;

the way it intends to implement its strategy, including: (i) any plans for a merger, reorganization, liquidation, or partial transfer of a substantial part of the assets of the issuer or of any other entity it controls within the meaning of article L. 233-3 of the French Commercial Code, (ii) any plans to modify the business of the issuer, (iii) any plans to modify articles of association of the issuer, (iv) any plans to delist a category of the issuer's financial instruments, and (v) any plans to issue the issuer's financial instruments;

any agreement for the temporary transfer of shares or voting rights of the issuer;

the way it intends to settle its agreements or instruments on the shares or voting rights of the issuer mentioned in Article L. 233- 9,4° and 4° bis of the French Commercial Code; and

Edgar Filing: Sanofi - Form 20-F

whether it seeks representation on the Board of Directors.

The AMF makes the report public. Upon any change of intention within the six-month period following the filing of the report, it will have to file a new report for the following six-month period.

In order to enable shareholders to give the required notice, we must each month publish on our website and send the AMF a written notice setting forth the total number of our shares and voting rights (including treasury shares) whenever they vary from the figures previously published.

If any shareholder fails to comply with an applicable legal notification requirement, the shares in excess of the relevant threshold will be deprived of voting rights for all shareholders' meetings until the end of a two-year period

Table of Contents

following the date on which the owner complies with the notification requirements. In addition, any shareholder who fails to comply with these requirements may have all or part of its voting rights suspended for up to five years by the Commercial Court at the request of our Chairman, any shareholder or the AMF, and may be subject to criminal fines.

Under AMF regulations, and subject to limited exemptions granted by the AMF, any person or entity, acting alone or in concert, that crosses the threshold of 30% of the share capital or voting rights of a French listed company must initiate a public tender offer for the balance of the shares and securities giving access to the share capital or voting rights of such company. Cash-settled derivative instruments or agreements mentioned in Article L. 233-9, 4° bis of the French Commercial Code are not included in the calculation of the number of shares related to the mandatory public tender offer.

In addition, our Articles of Association provide that any person or entity, acting alone or in concert with others, who becomes the owner of 1%, or any multiple of 1% of our share capital or our voting rights, even beyond the minimum declaration limits permitted by the legal and regulatory provisions, must notify us by certified mail, return receipt requested, within five trading days, of the total number of shares and securities giving access to our share capital and voting rights that such person then owns. The same provisions of our Articles of Association apply whenever such owner increases or decreases its ownership of our share capital or our voting rights to such extent that it goes above or below one of the thresholds described in the preceding sentence. Any person or entity that fails to comply with such notification requirement will, upon the request of one or more shareholders holding at least 5% of our share capital or of our voting rights made at the general shareholders' meeting, be deprived of voting rights with respect to the shares in excess of the relevant threshold for all shareholders' meetings until the end of a two-year period following the date on which such person or entity complies with the notification requirements.

Change in Control/Anti-takeover

There are no provisions in our Articles of Association that would have the effect of delaying, deferring or preventing a change in control of our Company or that would operate only with respect to a merger, acquisition or corporate restructuring involving our Company or any of our subsidiaries. Further, there are no provisions in our Articles of Association that allow the issuance of preferred stock upon the occurrence of a takeover attempt or the addition of other "anti-takeover" measures without a shareholder vote.

Our Articles of Association do not include any provisions discriminating against any existing or prospective holder of our securities as a result of such shareholder owning a substantial number of shares.

Trading in Our Own Shares

Under French law, Sanofi may not issue shares to itself. However, we may, either directly or through a financial intermediary acting on our behalf, acquire up to 10% of our issued share capital within a maximum period of 18 months, provided our shares are listed on a regulated market. Prior to acquiring our shares, we must publish a description of the share repurchase program (*descriptif du programme de rachat d'actions*).

We may not cancel more than 10% of our issued share capital over any 24-month period. Our repurchase of shares must not result in our Company holding, directly or through a person acting on our behalf, more than 10% of our issued share capital. We must hold any shares that we repurchase in registered form. These shares must be fully paid up. Shares repurchased by us continue to be deemed "issued" under French law but are not entitled to dividends or voting rights so long as we hold them directly or indirectly, and we may not exercise the preemptive rights attached to them.

The shareholders, at an extraordinary general shareholders meeting, may decide not to take these shares into account in determining the preemptive rights attached to the other shares. However, if the shareholders decide to take them into account, we must either sell the rights attached to the shares we hold on the market before the end of the subscription period or distribute them to the other shareholders on a *pro rata* basis.

On May 5, 2014, our shareholders approved a resolution authorizing us to repurchase up to 10% of our shares over an 18-month period. Under this authorization, the purchase price for each Sanofi ordinary share may not be greater than €100.00 and the maximum amount that Sanofi may pay for the repurchases is €12,883,098,900. This authorization was granted for a period of 18 months from May 5, 2014 and cancelled and replaced the authorization granted to the Board of Directors by the general meeting held on May 3, 2013. A description of this share repurchase program as adopted by the Board of Directors on May 5, 2014, (*descriptif du programme de rachat d'actions*) was published on March 7, 2014.

Table of Contents

Purposes of Share Repurchase Programs

Under the European regulation 2273/2003, dated December 22, 2003 (which we refer to in this section as the "Regulation"), in application of European directive 2003/6/EC, dated January 28, 2003, known as the "Market Abuse Directive", an issuer will benefit from a safe harbor for share transactions that comply with certain conditions relating in particular to the pricing, volume and timing of transactions (see below) and that are made in connection with a share repurchase program the purpose of which is:

to reduce the share capital through the cancellation of treasury shares; and/or

to meet obligations arising from debt instruments exchangeable into equity instruments and/or the implementation of employee share option programs or other employee share allocation plans.

Safe harbor transactions will by definition not be considered market abuses under the Regulation. Transactions that are carried out for other purposes than those mentioned above do not qualify for the safe harbor. However, as permitted by the Directive, which provides for the continuation of existing practices that do not constitute market manipulation and that conform with certain criteria set forth in European directive 2004/72, dated April 29, 2004, the AMF published exceptions on March 22, 2005, October 1, 2008, March 21, 2011, March 10, 2012, and April 24, 2013 to permit the following existing market practices:

transactions pursuant to a liquidity agreement entered into with a financial services intermediary that complies with the ethical code (*charte de déontologie*) approved by the AMF; and

the purchase of shares that are subsequently used as acquisition currency in a business combination transaction.

The AMF confirmed that all transactions directed at maintaining the liquidity of an issuer's shares must be conducted pursuant to a liquidity agreement with a financial services intermediary acting independently.

Pricing, Volume and Other Restrictions

In order to qualify for the safe harbor, the issuer must generally comply with the following pricing and volume restrictions:

a share purchase must not be made at a price higher than the higher of the price of the last independent trade and the highest current independent bid on the trading venues where the purchase is carried out;

subject to certain exceptions for illiquid securities, the issuer must not purchase more than 25% of the average daily volume of the shares in any one day on the regulated market on which the purchase is carried out. The average daily volume figure must be based on the average daily volume traded in the month preceding the month of public disclosure of the share repurchase program and fixed on that basis for the authorized period of that program. If the program does not make reference to this volume, the average daily volume figure must be based on the average daily volume traded in the 20 trading days preceding the date of purchase.

In addition, an issuer must not:

sell treasury shares during the period of the repurchase program (without prejudice to the right of the issuer to meet its obligations under employee share option programs or other employee share allocation plans or to use shares as acquisition currency as mentioned above); it being further specified that such prohibition is not applicable in the event of off-market block trades or if the share repurchase program is implemented by a financial services intermediary pursuant to a liquidity agreement as mentioned above; and

Edgar Filing: Sanofi - Form 20-F

effect any transaction during a "blackout period" imposed by the applicable law of the Member State in which the transaction occurs (*i.e.*, under French law, during the period between the date on which the company has knowledge of insider information and the date on which such information is made public and during the 30-day period preceding the date of publication of annual and half-year financial statements and the 15-day period preceding the date of publication of quarterly financial information), without prejudice to transactions carried out pursuant to a liquidity agreement as mentioned above; or

effect any transaction in securities with respect to which the issuer has decided to defer disclosure of any material, non-public information.

Table of Contents

Use of Share Repurchase Programs

Pursuant to the AMF rules, issuers must immediately allocate the repurchased shares to one of the purposes provided for in the Regulation and must not subsequently use the shares for a different purpose. As an exception to the foregoing, shares repurchased with a view to covering stock option plans may, if no longer needed for this purpose, be re-allocated for cancellation or sold in compliance with AMF requirements relating in particular to blackout periods. Shares repurchased in connection with one of the market practices authorized by the AMF (see above) may also be re-allocated to one of the purposes contemplated by the Regulation or sold in compliance with AMF requirements. Shares repurchased with a view to their cancellation must be cancelled within 24 months following their acquisition.

During the year ended December 31, 2014, we used the authority delegated by our shareholders to repurchase our shares on the stock market.

Pursuant to our share repurchase programs authorized by our shareholders on May 3, 2013 and on May 5, 2014, we repurchased 23,670,039 of our shares for a weighted average price of €75.93, i.e. a total cost of €1,797 million. Brokerage fees and financial transaction taxes (net of income taxes) amounted to €3 million.

On April 28, 2014, the Board of Directors cancelled 8,136,828 treasury shares repurchased between December 2013 and the end of March 2014 pursuant to the share repurchase program of the Company.

On October 27, 2014, the Board of Directors cancelled 9,648,226 treasury shares repurchased between April and July 2014 pursuant to the share repurchase program of the Company.

During 2014, pursuant to the liquidity contract, Exane BNP Paribas purchased 3,397,431 of our shares at an average weighted price of €77.18 for a total amount of €262,200,258 and sold 3,397,431 of our shares at an average weighted price of €77.27 for a total amount of €262,521,490.

In 2014, of the 223,181 shares allocated to stock purchase option plans outstanding at December 31, 2013, 29,850 shares were transferred to grantees of options.

As a result, as of December 31, 2014, out of the 9,456,234 treasury shares, representing 0.72% of our share capital, 193,331 were allocated to outstanding stock purchase option plans and 9,262,903 were allocated to the purpose of cancellation. At the same date, none of the shares was allocated to the liquidity account, even though the liquidity contract was outstanding.

As of December 31, 2014, we directly owned 9,456,234 Sanofi shares with a par value of €2 representing around 0.72% of our share capital and with an estimated value of €704,756,543, based on the share price at the time of purchase.

Reporting Obligations

Pursuant to the AMF Regulation and the French Commercial Code, issuers trading in their own shares are subject to the following reporting obligations:

issuers must report all transactions in their own shares on their web site within seven trading days of the transaction in a prescribed format, unless such transactions are carried out pursuant to a liquidity agreement that complies with the ethical code approved by the AMF; and

issuers must declare to the AMF on a monthly basis all transactions completed under the share repurchase program unless they provide the same information on a weekly basis.

Ownership of Shares by Non-French Persons

The French Commercial Code and our Articles of Association currently do not limit the right of non-residents of France or non-French persons to own or, where applicable, to vote our securities. However, non-residents of France must file an administrative notice with the French authorities in connection with certain direct and indirect investments in us, including the acquisition of a controlling interest in our Company. Under existing administrative rulings, ownership of 33¹/₃% or more of our share capital or voting rights is regarded as a controlling interest, but a lower percentage might be held to be a controlling interest in certain circumstances depending upon factors such as:

the acquiring party's intentions;

Table of Contents

the acquiring party's ability to elect directors; or

financial reliance by the company on the acquiring party.

Moreover, certain foreign investments in companies incorporated under French laws are subject to the prior authorization from the French Minister of the Economy, where all or part of the target's business and activity relate to a strategic sector, such as energy, transportation, public health, telecommunications, etc.

Enforceability of Civil Liabilities

We are a limited liability company (*société anonyme*) organized under the laws of France, and most of our officers and directors reside outside the United States. In addition, a substantial portion of our assets is located in France.

As a result, investors may find it difficult or be unable to effect service of process within the United States upon or obtain jurisdiction over our Company or our officers and directors in U.S. courts in actions predicated on the civil liability provisions of U.S. securities law. It may also be difficult to enforce against them, either inside or outside the United States, judgments obtained against them in U.S. courts, or to enforce in U.S. courts, judgments obtained against them in courts in jurisdictions outside the United States, in any action based on civil liabilities under the U.S. federal securities laws. There is doubt as to the enforceability against such persons in France, whether in original actions or in actions to enforce judgments of U.S. courts, of liabilities based solely on the U.S. federal securities laws. In addition, actions in the United States under the U.S. federal securities laws could be affected under certain circumstances by the French law No. 80-538 of July 16, 1980, which may preclude or restrict the obtaining of evidence in France or from French persons in connection with such actions. Additionally, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in France.

C. Material Contracts

The Contingent Value Rights Agreement

In connection with its acquisition of Genzyme Corporation, now a wholly-owned subsidiary of Sanofi, Sanofi issued one CVR per Genzyme share. On March 30, 2011, Sanofi and the American Stock Transfer & Trust Company, LLC, as trustee, entered into a Contingent Value Rights agreement governed by the laws of the State of New York and subject to the jurisdiction of the courts of the State of New York (the "CVR Agreement") governing the terms of the CVRs.

Pursuant to the terms of the CVR Agreement, a holder of a CVR is entitled to cash payments upon the achievement of contractually defined milestones.

The two first milestones (related, respectively, to manufacturing of Cerezyme® and Fabrazyme® and U.S. regulatory approval on or before March 31, 2014 of Lemtrada® for the treatment of MS (the "Approval Milestone")) were not met and therefore lapsed.

The remaining milestone payments are triggered on achievement of certain aggregate Lemtrada® sales thresholds within defined periods ("Product Sales Milestones"), as summarized below:

Product Sales Milestone #1 Payment. \$2 per CVR if Lemtrada® net sales post launch exceed an aggregate of \$400 million within specified periods and territories.

Product Sales Milestone #2 Payment. \$3 per CVR upon the first instance in which global Lemtrada® net sales for a four calendar quarter period are equal to or in excess of \$1.8 billion. However, given that the Approval Milestone was not achieved, the milestone payment amount would be \$4 per CVR.

Product Sales Milestone #3 Payment. \$4 per CVR upon the first instance in which global Lemtrada® net sales for a four calendar quarter period are equal to or in excess of \$2.3 billion (however, no quarter in which global Lemtrada® net sales were used to determine the achievement of Product Sales Milestone #1 or #2 shall be included in the calculation of sales for

Edgar Filing: Sanofi - Form 20-F

determining whether Product Sales Milestone #3 has been achieved).

Product Sales Milestone #4 Payment. \$3 per CVR upon the first instance in which global Lemtrada® net sales for a four calendar quarter period are equal to or in excess of \$2.8 billion (however, no quarter in which global Lemtrada® net sales were used to determine the achievement of Product Sales Milestone #1, #2 or #3 shall be included in the calculation of sales for determining whether Product Sales Milestone #4 has been achieved).

Table of Contents

The CVRs will expire and no payments will be due under the CVR Agreement on the earlier of (a) December 31, 2020 and (b) the date that Product Sales Milestone #4 is paid.

Sanofi has agreed to use diligent efforts (as defined in the CVR Agreement), until the CVR Agreement is terminated, to achieve each of the remaining milestones. However, we are not required to take all possible actions to achieve these goals. There can be no assurance that the Product Sales Milestone #1 or the other sales milestones will be achieved. Sanofi has also agreed to use its commercially reasonable efforts to maintain a listing for trading of the CVRs on the NASDAQ market.

For more information on Lemtrada® see "Item 4.B Business Overview Pharmaceutical Products Multiple Sclerosis".

The CVR Agreement does not prohibit Sanofi or any of its subsidiaries or affiliates from acquiring the CVRs, whether in open market transactions, private transactions or otherwise. Sanofi has certain disclosure obligations in connection with such acquisitions under the CVR Agreement. On or after April 1st, 2017, Sanofi may also, subject to certain terms and conditions as set forth in the CVR Agreement, optionally purchase and cancel all (but not less than all) of the outstanding CVRs at the average trading price of the CVRs if the volume-weighted average CVR trading price is less than fifty cents over forty-five trading days and Lemtrada® sales in the prior four quarter period were less than \$1 billion in the aggregate.

A copy of the form of CVR Agreement is on file with the SEC as Annex B to Amendment No. 2 to the Registration Statement on Form F-4 filed with the Securities and Exchange Commission on March 24, 2011. Reference is made to such exhibit for a more complete description of the terms and conditions of the CVR Agreement, and the foregoing summary of such terms and conditions is qualified in its entirety by such exhibit.

D. Exchange Controls

French exchange control regulations currently do not limit the amount of payments that we may remit to non-residents of France. Laws and regulations concerning foreign exchange controls do require, however, that all payments or transfers of funds made by a French resident to a non-resident be handled by an accredited intermediary.

E. Taxation

General

The following generally summarizes the material French and U.S. federal income tax consequences to U.S. holders (as defined below) of purchasing, owning and disposing of our ADSs and ordinary shares (collectively the "Securities"). This discussion is intended only as a descriptive summary and does not purport to be a complete analysis or listing of all potential tax effects of the purchase, ownership or disposition of our Securities. All of the following is subject to change. Such changes could apply retroactively and could affect the consequences described below.

This summary does not constitute a legal opinion or tax advice. Holders are urged to consult their own tax advisers regarding the tax consequences of the purchase, ownership and disposition of Securities in light of their particular circumstances, including the effect of any U.S. federal, state, local or other national tax laws.

A set of tax rules is applicable to French assets that are held by or in foreign trusts. These rules provide *inter alia* for the inclusion of trust assets in the settlor's net assets for purpose of applying the French wealth tax, for the application of French gift and death duties to French assets held in trust, for a specific tax on capital on the French assets of foreign trusts not already subject to the French wealth tax and for a number of French tax reporting and disclosure obligations. The following discussion does not address the French tax consequences applicable to Securities held in trusts. *If Securities are held in trust, the grantor, trustee and beneficiary are urged to consult their own tax adviser regarding the specific tax consequences of acquiring, owning and disposing of Securities.*

The description of the French and U.S. federal income tax consequences set forth below is based on the laws (including, for U.S. federal income tax purposes, the Internal Revenue Code of 1986, as amended (the "Code"), final, temporary and proposed U.S. Treasury Regulations promulgated thereunder and administrative and judicial interpretations thereof) in force as of the date of this annual report, the Convention Between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income and Capital of August 31, 1994 (the "Treaty"), which

Table of Contents

entered into force on December 30, 1995 (as amended by any subsequent protocols, including the protocol of January 13, 2009), and the tax regulations issued by the French tax authorities within the *Bulletin Officiel des Finances Publiques-Impôts* (the "Regulations") in force as of the date of this report. *U.S. holders are advised to consult their own tax advisers regarding their eligibility for Treaty benefits, especially with regard to the "Limitations on Benefits" provision, in light of their own particular circumstances.*

For the purposes of this discussion, a U.S. holder is a beneficial owner of Securities that is (i) an individual who is a U.S. citizen or resident for U.S. federal income tax purposes, (ii) a U.S. domestic corporation or certain other entities created or organized in or under the laws of the United States or any state thereof, including the District of Columbia, or (iii) otherwise subject to U.S. federal income taxation on a net income basis in respect of Securities. A non-U.S. holder is a person other than a U.S. holder.

If a partnership holds Securities, the tax treatment of a partner generally will depend upon the status of the partner and the activities of the partnership. *If a U.S. holder is a partner in a partnership that holds Securities, the holder is urged to consult its own tax adviser regarding the specific tax consequences of acquiring, owning and disposing of Securities.*

This discussion is intended only as a general summary and does not purport to be a complete analysis or listing of all potential tax effects of the acquisition, ownership or disposition of the Securities to any particular investor, and does not discuss tax considerations that arise from rules of general application or that are generally assumed to be known by investors. The discussion applies only to investors that hold our Securities as capital assets that have the U.S. dollar as their functional currency, that are entitled to Treaty benefits under the "Limitation on Benefits" provision contained in the Treaty, and whose ownership of the Securities is not effectively connected to a permanent establishment or a fixed base in France. Certain holders (including, but not limited to, U.S. expatriates, partnerships or other entities classified as partnerships for U.S. federal income tax purposes, banks, insurance companies, regulated investment companies, tax-exempt organizations, financial institutions, persons subject to the alternative minimum tax, persons who acquired the Securities pursuant to the exercise of employee stock options or otherwise as compensation, persons that own (directly, indirectly or by attribution) 5% or more of our voting stock or 5% or more of our outstanding share capital, dealers in securities or currencies, persons that elect to mark their securities to market for U.S. federal income tax purposes, persons that acquire ADSs in "pre-release" transactions (*i.e.*, prior to deposit of the relevant ordinary shares) and persons holding Securities as a position in a synthetic security, straddle or conversion transaction) may be subject to special rules not discussed below. *Holders of Securities are advised to consult their own tax advisers with regard to the application of French tax law and U.S. federal income tax law to their particular situations, as well as any tax consequences arising under the laws of any state, local or other foreign jurisdiction.*

French Taxes

Estate and Gift Taxes and Transfer Taxes

In general, a transfer of Securities by gift or by reason of death of a U.S. holder that would otherwise be subject to French gift or inheritance tax, respectively, will not be subject to such French tax by reason of the Convention between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Estates, Inheritances and Gifts, dated November 24, 1978, unless the donor or the transferor is domiciled in France at the time of making the gift or at the time of his or her death, or the Securities were used in, or held for use in, the conduct of a business through a permanent establishment or a fixed base in France.

Pursuant to Article 235 ter ZD of the French General Tax Code, purchases of Securities are subject to a 0.2% French tax on financial transactions (the "FTFF") provided that Sanofi's market capitalization exceeds 1 billion euros as of December 1 of the year preceding the taxation year. A list of companies whose market capitalization exceeds 1 billion euros as of December 1 of the year preceding the taxation year used to be published annually by the French Ministry of Economy. It is now published by the French tax authorities, and could be amended at any time. Pursuant to Regulations BOI-ANX-000467-20141216 issued on December 26, 2014, purchases of Sanofi's Securities in 2015 should be subject to the FTFF as the the market capitalization of Sanofi exceeded 1 billion euros as of December 1, 2014. In accordance with Article 726-II of the French General Tax Code, purchases which are subject to the FTFF should however not be subject to transfer taxes (*droits d'enregistrement*) in France.

Table of Contents

Wealth Tax

The French wealth tax *impôt de solidarité sur la fortune* applies only to individuals and does not generally apply to the Securities if the holder is a U.S. resident, as defined pursuant to the provisions of the Treaty, provided that the individual does not own directly or indirectly a shareholding exceeding 25% of the financial rights.

U.S. Taxes

Ownership of the Securities

Deposits and withdrawals by a U.S. holder of ordinary shares in exchange for ADSs, will not be taxable events for U.S. federal income tax purposes. For U.S. tax purposes, holders of ADSs will be treated as owners of the ordinary shares represented by such ADSs. Accordingly, the discussion that follows regarding the U.S. federal income tax consequences of acquiring, owning and disposing of ordinary shares is equally applicable to ADSs.

Information Reporting and Backup Withholding Tax

Distributions made to holders and proceeds paid from the sale, exchange, redemption or disposal of Securities may be subject to information reporting to the Internal Revenue Service. Such payments may be subject to backup withholding taxes unless the holder (i) is a corporation or other exempt recipient or (ii) provides a taxpayer identification number and certifies that no loss of exemption from backup withholding has occurred. Holders that are not U.S. persons generally are not subject to information reporting or backup withholding. However, such a holder may be required to provide a certification of its non-U.S. status in connection with payments received within the United States or through a U.S.-related financial intermediary to establish that it is an exempt recipient. Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a holder's U.S. federal income tax liability. A holder may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the Internal Revenue Service and furnishing any required information.

Foreign Asset Reporting

In addition, a U.S. holder that is an individual (and, to the extent provided in future regulations, an entity), may be subject to recently-enacted reporting obligations with respect to ordinary shares and ADSs if the aggregate value of these and certain other "specified foreign financial assets" exceeds \$50,000. If required, this disclosure is made by filing Form 8938 with the U.S. Internal Revenue Service. Significant penalties can apply if holders are required to make this disclosure and fail to do so. In addition, a U.S. holder should consider the possible obligation to file a Form TD F 90-22.1 Foreign Bank and Financial Accounts Report as a result of holding ordinary shares or ADSs. Holders are thus encouraged to consult their U.S. tax advisors with respect to these and other reporting requirements that may apply to their acquisition of ordinary shares and ADSs.

State and Local Taxes

In addition to U.S. federal income tax, U.S. holders of Securities may be subject to U.S. state and local taxes with respect to such Securities. *Holders of Securities are advised to consult their own tax advisers with regard to the application of U.S. state and local income tax law to their particular situation.*

ADSs-Ordinary Shares

French Taxes

Taxation of Dividends

Under French law, dividends paid by a French corporation, such as Sanofi, to non-residents of France are generally subject to French withholding tax at a rate of 30% (21% for distributions made to individuals that are resident in the European Economic Area, and 15% for distributions made to not-for-profit organizations with a head office in a Member State of the European Economic Area which would be subject to the tax regime set forth under article 206-5 of the French General Tax Code if its head office were located in France and which meet the criteria set forth in the administrative guidelines BOI-RPPM-RCM-30-30-10-70-20120912, n° 130). Dividends paid by a French corporation, such as Sanofi, towards non-cooperative States or territories, as defined in Article 238-0 A of the French General Tax Code, will generally be subject to French withholding tax at a rate of 75%, irrespective of the tax residence of the beneficiary of the dividends if the dividends are

received in such States or territories; however, eligible U.S. holders entitled to Treaty benefits under the "Limitation on Benefits" provision contained in the Treaty who are U.S. residents,

Table of Contents

as defined pursuant to the provisions of the Treaty and who receive dividends in non-cooperative States or territories, will not be subject to this 75% withholding tax rate.

Under the Treaty, the rate of French withholding tax on dividends paid to an eligible U.S. holder who is a U.S. resident as defined pursuant to the provisions of the Treaty and whose ownership of the ordinary shares or ADSs is not effectively connected with a permanent establishment or fixed base that such U.S. holder has in France, is reduced to 15%, or to 5% if such U.S. holder is a corporation and owns directly or indirectly at least 10% of the share capital of the issuing company; such U.S. holder may claim a refund from the French tax authorities of the amount withheld in excess of the Treaty rates of 15% or 5%, if any. For U.S. holders that are not individuals but are U.S. residents, as defined pursuant to the provisions of the Treaty, the requirements for eligibility for Treaty benefits, including the reduced 5% or 15% withholding tax rates contained in the "Limitation on Benefits" provision of the Treaty, are complicated, and certain technical changes were made to these requirements by the protocol of January 13, 2009. U.S. holders are advised to consult their own tax advisers regarding their eligibility for Treaty benefits in light of their own particular circumstances.

Dividends paid to an eligible U.S. holder may immediately be subject to the reduced rates of 5% or 15% provided that such holder establishes before the date of payment that it is a U.S. resident under the Treaty by completing and providing the depository with a treaty form (Form 5000). Dividends paid to a U.S. holder that has not filed the Form 5000 before the dividend payment date will be subject to French withholding tax at the rate of 30% and then reduced at a later date to 5% or 15%, provided that such holder duly completes and provides the French tax authorities with the treaty forms Form 5000 and Form 5001 before December 31 of the second calendar year following the year during which the dividend is paid. Pension funds and certain other tax-exempt entities are subject to the same general filing requirements as other U.S. holders except that they may have to supply additional documentation evidencing their entitlement to these benefits.

The depository agrees to use reasonable efforts to follow the procedures established, or that may be established, by the French tax authorities (i) to enable eligible U.S. holders to qualify for the reduced withholding tax rate provided by the Treaty, if available at the time the dividends are paid, or (ii) to recover any excess French withholding taxes initially withheld or deducted with respect to dividends and other distributions to which such U.S. holders may be eligible from the French tax authorities and (iii) to recover any other available tax credits. In particular, associated forms (including Form 5000 and Form 5001, together with their instructions), will be made available by the depository to all U.S. holders registered with the depository, and are also generally available from the U.S. Internal Revenue Service.

The withholding tax refund, if any, ordinarily is paid within 12 months of filing the applicable French Treasury Form, but not before January 15 of the year following the calendar year in which the related dividend is paid.

Tax on Sale or Other Disposition

In general, under the Treaty, a U.S. holder who is a U.S. resident for purposes of the Treaty will not be subject to French tax on any capital gain from the redemption (other than redemption proceeds characterized as dividends under French domestic law), sale or exchange of ordinary shares or ADSs unless the ordinary shares or the ADSs form part of the business property of a permanent establishment or fixed base that the U.S. holder has in France. Special rules apply to holders who are residents of more than one country.

U.S. Taxes

Taxation of Dividends

For U.S. federal income tax purposes, the gross amount of any distribution paid to U.S. holders (that is, the net distribution received plus any tax withheld therefrom) will be treated as ordinary dividend income to the extent paid or deemed paid out of the current or accumulated earnings and profits of Sanofi (as determined under U.S. federal income tax principles). Dividends paid by Sanofi will not be eligible for the dividends-received deduction generally allowed to corporate U.S. holders.

Subject to certain exceptions for short-term and hedged positions, the U.S. dollar amount of dividends received by an individual U.S. holder with respect to the ADSs or our ordinary shares is currently subject to taxation at a maximum rate of 20% if the dividends are "qualified dividends". Dividends paid on the ordinary shares or ADSs will be treated as qualified dividends if (i) the issuer is eligible for the benefits of a comprehensive income tax treaty with the United States that the Internal Revenue Service has approved for the purposes of the qualified dividend rules and (ii) the issuer was not, in the year prior to the year in which the dividend was paid, and is not, in the year in which the

Table of Contents

dividend is paid, a passive foreign investment company ("PFIC"). The Treaty has been approved for the purposes of the qualified dividend rules. Based on our audited financial statements and relevant market and shareholder data, we believe Sanofi was not a PFIC for U.S. federal income tax purposes with respect to its 2014 taxable year. In addition, based on its current expectations regarding the value and nature of its assets, the sources and nature of its income, and relevant market and shareholder data, we do not anticipate that Sanofi will become a PFIC for its 2015 taxable year. *Holders of ordinary shares and ADSs should consult their own tax advisers regarding the availability of the reduced dividend tax rate in light of their own particular circumstances.*

If you are a U.S. holder, dividend income received by you with respect to ADSs or ordinary shares generally will be treated as foreign source income for foreign tax credit purposes. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. Distributions out of earnings and profits with respect to the ADSs or ordinary shares generally will be treated as "passive category" income (or, in the case of certain U.S. holders, "general category" income). Subject to certain limitations, French income tax withheld in connection with any distribution with respect to the ADSs or ordinary shares may be claimed as a credit against the U.S. federal income tax liability of a U.S. holder if such U.S. holder elects for that year to credit all foreign income taxes. Alternatively, such French withholding tax may be taken as a deduction against taxable income. Foreign tax credits will not be allowed for withholding taxes imposed in respect of certain short-term or hedged positions in Securities and may not be allowed in respect of certain arrangements in which a U.S. holder's expected economic profit is insubstantial. *The U.S. federal income tax rules governing the availability and computation of foreign tax credits are complex. U.S. holders should consult their own tax advisers concerning the implications of these rules in light of their particular circumstances.*

To the extent that an amount received by a U.S. holder exceeds the allocable share of our current and accumulated earnings and profits, such excess will be applied first to reduce such U.S. holder's tax basis in its ordinary shares or ADSs and then, to the extent it exceeds the U.S. holder's tax basis, it will constitute capital gain from a deemed sale or exchange of such ordinary shares or ADSs (see "Tax on Sale or Other Disposition", below).

The amount of any distribution paid in euros will be equal to the U.S. dollar value of the euro amount distributed, calculated by reference to the exchange rate in effect on the date the dividend is received by a U.S. holder of ordinary shares (or by the depositary, in the case of ADSs) regardless of whether the payment is in fact converted into U.S. dollars on such date. *U.S. holders should consult their own tax advisers regarding the treatment of foreign currency gain or loss, if any, on any euros received by a U.S. holder that are converted into U.S. dollars on a date subsequent to receipt.*

Distributions to holders of additional ordinary shares (or ADSs) with respect to their ordinary shares (or ADSs) that are made as part of a pro rata distribution to all ordinary shareholders generally will not be subject to U.S. federal income tax. However, if a U.S. holder has the option to receive a distribution in shares (or ADSs) or to receive cash in lieu of such shares (or ADSs), the distribution of shares (or ADSs) will be taxable as if the holder had received an amount equal to the fair market value of the distributed shares (or ADSs), and such holder's tax basis in the distributed shares (or ADSs) will be equal to such amount.

Tax on Sale or Other Disposition

In general, for U.S. federal income tax purposes, a U.S. holder that sells, exchanges or otherwise disposes of its ordinary shares or ADSs will recognize capital gain or loss in an amount equal to the U.S. dollar value of the difference between the amount realized for the ordinary shares or ADSs and the U.S. holder's adjusted tax basis (determined in U.S. dollars and under U.S. federal income tax rules) in the ordinary shares or ADSs. Such gain or loss generally will be U.S.-source gain or loss, and will be treated as long term capital gain or loss if the U.S. holder's holding period in the ordinary shares or ADSs exceeds one year at the time of disposition. If the U.S. holder is an individual, any capital gain generally will be subject to U.S. federal income tax at preferential rates (currently a maximum of 20%) if specified minimum holding periods are met. The deductibility of capital losses is subject to significant limitations.

Medicare Tax

Certain U.S. holders who are individuals, estates or trusts are now required to pay a Medicare tax of 3.8% (in addition to taxes they would otherwise be subject to) on their "net investment income" which would include, among other things, dividends and capital gains from the ordinary shares and ADSs.

Table of Contents

F. Dividends and Paying Agents

N/A

G. Statement by Experts

N/A

H. Documents on Display

We are subject to the information requirements of the U.S. Securities Exchange Act of 1934, as amended, or Exchange Act, and, in accordance therewith, we are required to file reports, including this annual report on Form 20-F, and other information with the U.S. Securities and Exchange Commission, or Commission, by electronic means.

You may review a copy of our filings with the Commission, as well as other information furnished to the Commission, including exhibits and schedules filed with it, at the Commission's public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Please call the SEC at 1-800-SEC- 0330 for further information. In addition, the Commission maintains an Internet site at <http://www.sec.gov> that contains reports and other information regarding issuers that file electronically with the Commission (these documents are not incorporated by reference in this annual report).

I. Subsidiary Information

N/A

Table of Contents

Item 11. Quantitative and Qualitative Disclosures about Market Risk⁽¹⁾

General Policy

Liquidity risk, foreign exchange risk and interest rate risk, as well as related counterparty risks, are managed centrally by our dedicated treasury team within the Group Finance Department. Where it is not possible to manage those risks centrally in particular due to regulatory restrictions (such as foreign exchange controls) or local tax restrictions credit facilities and/or currency lines, guaranteed whenever necessary by the parent company, are contracted by our subsidiaries locally with banks, under the supervision of the central treasury team.

Our financing and investment strategies, and our interest rate and currency hedging strategies, are reviewed monthly by the Group Finance Department.

Our policy prohibits the use of derivatives for speculative purposes.

Liquidity Risk

We operate a centralized treasury platform whereby all surplus cash and financing needs of our subsidiaries are invested with or funded by the parent company (where permitted by local legislation). The central treasury department manages the Group's current and projected financing, and ensures that the Group is able to meet its financial commitments by maintaining sufficient cash and confirmed credit facilities for the size of our operations and the maturity of our debt (see Notes D.17.c and D.17.g to the consolidated financial statements).

The Group diversifies its short-term investments with leading banks using money-market products with instant access or with a maturity of less than three months. As of December 31, 2014, our cash and cash equivalents amounted to €7,341 million and our short-term investments predominantly comprised:

collective investments in 'short-term money market' and 'money market' euro-denominated funds based on the European classification used by the *Autorité des Marchés Financiers*. All such funds can be traded on a daily basis and the amount invested in each fund may not exceed 10% of the aggregate amount invested in such funds;

bank current-account deposits, bank term deposits and certificates of deposit with a maturity of no more than three months;

amounts invested directly with non-financial institutions in the form of commercial paper and euro commercial paper with a maturity of no more than three months.

As of December 31, 2014, the Group also had €8 billion of undrawn general corporate purpose confirmed credit facilities, expiring December 2019. Those credit facilities are not subject to financial covenant ratios.

Our policy is to diversify our sources of funding through public or private issuances of debt securities, in the United States (shelf registration statement) and Europe (Euro Medium Term Note program). In addition, our A-1+/P-1 short-term rating gives us access to commercial paper programs in the United States and, to a lesser extent, in France. The average maturity of our total debt was 4.6 years as of December 31, 2014, compared with 4.1 years as of December 31, 2013. During 2014, the French commercial paper program was not drawn down. Average drawdowns under the U.S. commercial paper program during 2014 were €2.1 billion (maximum €3.1 billion); the average maturity of those drawdowns was two months. As of December 31, 2014, neither of those programs was drawn down.

In the event of a liquidity crisis, we could be exposed to difficulties in calling up our available cash, a scarcity of sources of funding including the above-mentioned programs, and/or a deterioration in their terms. This situation could damage our capacity to refinance our debt or to issue new debt on reasonable terms.

Interest Rate Risk

Since the financing of the Genzyme acquisition, the Group has managed its net debt in two currencies: the euro and the U.S. dollar (see note D.17 to the consolidated financial statements). The floating-rate portion of this debt exposes the Group to rises in interest rates,

primarily in the Eonia and Euribor benchmark rates (for the euro) and in the U.S. Libor and Federal Fund Effective rates (for the U.S. dollar). To optimize (or reduce the volatility of) our cost of debt, we use interest rate swaps, cross-currency swaps and where appropriate interest rate options that alter the fixed/floating rate split of our debt. Those derivative instruments are predominantly denominated in euros and in U.S. dollars.

(1) *The disclosures in this section supplement those provided in Note B.8.8. to the consolidated financial statements as regards the disclosure requirements of IFRS 7, and are covered by the statutory auditors' opinion on the consolidated financial statements.*

Table of Contents

The projected full-year sensitivity to interest rate fluctuations of our debt, net of cash and cash equivalents for 2015 is as follows:

Change in EUR, USD and CHF short-term interest rates	Impact on pre-tax net income (€ million)	Impact on pre-tax income/(expense) recognized directly in equity (€ million)
+100 bp	19	11
+25 bp	5	3
-25 bp	(5)	(3)
-100 bp	(19)	(11)

Foreign Exchange Risk**a. Operating Foreign Exchange Risk**

A substantial portion of our net sales is generated in countries where the euro, which is our reporting currency, is not the functional currency. In 2014, for example, 34% of our consolidated net sales were generated 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. Although we also incur expenses in those countries, the impact of those expenses is not enough wholly to offset the impact of exchange rates on our net sales. Consequently, our operating income may be materially affected by fluctuations in exchange rates between the euro and other currencies.

We operate a foreign exchange risk hedging policy to reduce the exposure of our operating income to exchange rate movements. This policy involves regular assessments of our worldwide foreign currency exposure, based on foreign-currency transactions carried out by the parent company and its subsidiaries. Those transactions mainly comprise sales, purchases, research costs, co-marketing and co-promotion expenses, and royalties. To reduce the exposure of those transactions to exchange rate movements, we contract hedges using liquid derivative instruments, mainly forward currency purchases and sales, and also currency swaps.

The table below shows our operating currency hedging instruments in place as of December 31, 2014, with the notional amount translated into euros at the relevant closing exchange rate. See also Note D.20 to the consolidated financial statements for the accounting classification of these instruments as of December 31, 2014.

Operating foreign exchange derivatives as of December 31, 2014⁽¹⁾:

<i>(€ million)</i>	Notional amount	Fair value
Forward currency sales	2,981	4
of which		
U.S. dollar	1,409	(34)
Japanese yen	273	5
Chinese yuan renminbi	237	(6)
Russian rouble	211	51
Singapore dollar	126	(1)

	Forward currency purchases	1,137	
of which	U.S. dollar	377	6
	Singapore dollar	139	2
	Japanese yen	109	
	Hungarian forint	99	(2)
	Mexican peso	69	2
	Total	4,118	4

(1)

As of December 31, 2013, the notional amount of forward currency sales was €2,943 million with a fair value of €32 million (including forward sales of U.S. dollars of a notional amount of €1,379 million with a fair value of €14 million). As of December 31, 2013, the notional amount of forward currency purchases was €537 million with a fair value of -€1 million (including forward purchases of U.S. dollars of a notional amount of €51 million with an immaterial fair value).

Table of Contents

The above positions mainly hedge future material foreign-currency cash flows arising after the balance sheet date in relation to transactions carried out during the year ended December 31, 2014 and recognized in the balance sheet at that date. Gains and losses on hedging instruments (forward contracts) have been and will continue to be calculated and recognized in parallel with the recognition of gains and losses on the hedged items. Due to this hedging relationship, the commercial foreign exchange difference on these items (hedging instruments and hedged transactions) will be immaterial in 2015.

b. Financial Foreign Exchange Risk

The cash pooling arrangements for our foreign subsidiaries outside the euro zone, and some of our financing activities, expose certain of our entities to financial foreign exchange risk (i.e., the risk of changes in the value of borrowings and loans denominated in a currency other than the functional currency of the borrower or lender). That foreign exchange exposure is hedged by the Sanofi holding company using firm financial instruments (usually currency swaps or forward contracts) contracted with banking counterparties.

Although we incur the majority of our costs within the euro zone, our revenues are mainly denominated in U.S. dollars. Consequently, we maintain a significant portion of our indebtedness in U.S. dollars.

The table below shows financial currency hedging instruments in place as of December 31, 2014, with the notional amount translated into euros at the relevant closing exchange rate. See also Note D.20 to the consolidated financial statements for the accounting classification of these instruments as of December 31, 2014.

Financial foreign exchange derivatives as of December 31, 2014⁽¹⁾:

<i>(€ million)</i>		Notional amount	Fair value	Expiry
Forward currency sales		5,869	(111)	
of which	U.S. dollar ⁽²⁾	4,840	(111)	2015
	Japanese yen	571	11	2015
	Pound sterling	104	(2)	2015
Forward currency purchases		2,686	16	
of which	Singapore dollar	563	5	2015
	U.S. dollar	498	2	2015
	Pound sterling	487	12	2015
Total		8,555	(95)	

(1)

As of December 31, 2013, the notional amount of forward currency sales was €1,860 million with a fair value of €63 million (including forward sales of U.S. dollars of a notional amount of €833 million with a fair value of €8 million). As of December 31, 2013, the notional amount of forward currency purchases was €2,197 million with a fair value of -€9 million (including forward purchases of U.S. dollars of a notional amount of €389 million with a fair value of -€1 million).

(2)

Includes U.S.\$43 million designated as a hedge of a net investment in a foreign operation as of December 31, 2014.

These forward currency contracts generate a net financial foreign exchange gain or loss arising from the interest rate differential between the hedged currency and the euro, given that the foreign exchange gain or loss on the foreign-currency borrowing and loans is offset by the change in the intrinsic value of the hedging instruments.

We may also hedge some future foreign-currency investment or divestment cash flows.

c. Other Foreign Exchange Risks

A significant proportion of our net assets is denominated in U.S. dollars (see Note D.35 to the consolidated financial statements). As a result, any fluctuation in the exchange rate of the U.S. dollar against the euro automatically impacts the amount of our equity as expressed in euros. As of December 31, 2014, we had no derivative instruments in place to limit the effect of such fluctuations, but a significant proportion of our debt is still denominated in U.S. dollars.

In addition, we use the euro as our reporting currency. Consequently, if one or more European Union member states were to abandon the euro as a currency, the resulting economic upheavals in particular, fluctuations in

Table of Contents

exchange rates could have a significant impact on the terms under which we can obtain financing and on our financial results, the extent and consequences of which are not currently foreseeable.

Counterparty Risk

Our financing and investing transactions, and our currency and interest rate hedges, are contracted with leading banks. We set limits for investment and derivative transactions with individual banks, depending on the rating of each bank. Compliance with these limits, which are based on notional amounts weighted by the residual maturity and the nature of the commitment, is monitored on a daily basis.

The table below shows our total exposure as of December 31, 2014 by rating and in terms of our percentage exposure to the dominant counterparty.

<i>(€ million)</i>	Cash and cash equivalents (excluding mutual funds)(1)	Notional amounts of currency hedges(2)	Notional amounts of interest rate hedges(2)	General corporate purpose credit facilities
AA-	803	1,333	1,124	500
A+	1,248	2,342	1,091	1,500
A	1,499	5,065	1,754	4,000
A-	427	3,374	707	1,500
BBB+	369	373	400	500
BBB	200			
Not split	258	186		
Total	4,804	12,673	5,076	8,000
<i>% / rating of dominant counterparty</i>	17% / AA-	18% / A-	22% / AA-	6% / BBB+

- (1) *Cash equivalents include mutual fund investments of €2,537 million.*
- (2) *Notional amounts are translated into euros at the closing exchange rate as of December 31, 2014.*

As of December 31, 2014, Sanofi held investments in 'short-term money market' and 'money market' euro-denominated funds based on the European classification used by the *Autorité des Marchés Financiers*. Those instruments have low volatility, low sensitivity to interest rate risk, and a very low probability of loss of principal. The depositary banks of the mutual funds, and of Sanofi itself, have a long-term rating of at least A.

Realization of counterparty risk could impact our liquidity in certain circumstances.

Stock Market Risk

It is our policy not to trade on the stock market for speculative purposes.

Table of Contents

Item 12. Description of Securities other than Equity Securities

12.A Debt Securities

Not applicable.

12.B Warrants and Rights

Not applicable.

12.C Other Securities

Not applicable.

12.D American Depositary Shares

General

JPMorgan Chase Bank, N.A. ("JPMorgan"), as depositary, issues Sanofi ADSs in certificated form (evidenced by an ADR) or book-entry form. Each ADR is a certificate evidencing a specific number of Sanofi ADSs. Each Sanofi ADS represents one-half of one Sanofi ordinary share (or the right to receive one-half of one Sanofi ordinary share) deposited with the Paris, France office of BNP Paribas, as custodian. Each Sanofi ADS also represents an interest in any other securities, cash or other property that may be held by the depositary under the deposit agreement. The depositary's office is located at 4 New York Plaza, 12th Floor, New York, New York 10004.

A holder may hold Sanofi ADSs either directly or indirectly through his or her broker or other financial institution. The following description assumes holders hold their Sanofi ADSs directly, in certificated form evidenced by ADRs. Holders who hold the Sanofi ADSs indirectly must rely on the procedures of their broker or other financial institution to assert the rights of ADR holders described in this section. Holders should consult with their broker or financial institution to find out what those procedures are.

Holders of Sanofi ADSs do not have the same rights as holders of Sanofi shares. French law governs shareholder rights. The rights of holders of Sanofi ADSs are set forth in the deposit agreement between Sanofi and JPMorgan and in the ADR. New York law governs the deposit agreement and the ADRs.

The following is a summary of certain terms of the deposit agreement, as amended. Our form of second amended and restated deposit agreement was filed as an exhibit to our Post-Effective Amendment No. 1 to Form F-6 filed on February 13, 2015. To the extent any portion of the amendment and restatement would prejudice any substantial existing right of holders of ADSs under the first amended and restated deposit agreement, such portion shall not become effective as to such holders until 30 days after holders have received notice thereof. For more complete information, holders should read the entire second amended and restated deposit agreement and the ADR itself. Holders may also inspect a copy of the current deposit agreement at the depositary's office.

Share Dividends and Other Distributions

Receipt of dividends and other distributions

The depositary has agreed to pay to holders of Sanofi ADSs the cash dividends or other distributions that it or the custodian receives on the deposited Sanofi ordinary shares and other deposited securities after deducting its fees and expenses. Holders of Sanofi ADSs will receive these distributions in proportion to the number of Sanofi ADSs that they hold.

Cash. The depositary will convert any cash dividend or other cash distribution paid on the shares into U.S. dollars if, in its judgment, it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If the depositary determines that such a conversion and transfer is not possible, or if any approval from the French government is needed and cannot be obtained within a reasonable period, then the depositary may (1) distribute the foreign currency received by it to the holders of Sanofi ADSs or (2) hold the foreign currency distribution (uninvested and without liability for any interest) for the account of holders of Sanofi ADSs.

Edgar Filing: Sanofi - Form 20-F

In addition, if any conversion of foreign currency, in whole or in part, cannot be effected to some holders of Sanofi ADSs, the deposit agreement allows the depositary to distribute the dividends only to those ADR holders to whom it is

Table of Contents

possible to do so. It will hold the foreign currency it cannot convert into U.S. dollars for the account of the ADR holders who have not been paid. It will not invest the funds it holds and it will not be liable for any interest.

Before making a distribution, any withholding taxes that must be paid under French law will be deducted. The depositary will distribute only whole U.S. dollars and cents and will round fractional cents down to the nearest whole cent. ***Exchange rate fluctuations during a period when the depositary cannot convert euros into U.S. dollars may result in holders losing some or all of the value of a distribution.***

Shares. The depositary may, and at our request will, distribute new ADRs representing any shares we distribute as a dividend or free distribution, if we furnish it promptly with satisfactory evidence that it is legal to do so. At its option, the depositary may distribute fractional Sanofi ADSs. If the depositary does not distribute additional Sanofi ADSs, the outstanding ADRs will also represent the new shares. The depositary may withhold any tax or other governmental charges, or require the payment of any required fees and expenses, prior to making any distribution of additional Sanofi ADSs.

Rights to Receive Additional Shares. If we offer holders of Sanofi ordinary shares any rights to subscribe for additional shares or any other rights, the depositary, after consultation with us, will, in its discretion, either (1) make these rights available to holders or (2) dispose of such rights on behalf of holders and make the net proceeds available to holders. The depositary may make rights available to certain holders but not others if it determines it is lawful and feasible to do so. However, if, under the terms of the offering or for any other reason, the depositary may not make such rights available or dispose of such rights and make the net proceeds available, it will allow the rights to lapse. In that case, holders of Sanofi ADSs will receive no value for them.

In circumstances where rights would not otherwise be distributed by the depositary to holders of Sanofi ADSs, a holder of Sanofi ADSs may nonetheless request, and will receive from the depositary, any instruments or other documents necessary to exercise the rights allocable to that holder if the depositary first receives written notice from Sanofi that (1) Sanofi has elected, in its sole discretion, to permit the rights to be exercised and (2) such holder has executed the documents Sanofi has determined, in its sole discretion, are reasonably required under applicable law.

If the depositary makes rights available to holders of Sanofi ADSs, upon instruction from such holders, it will exercise the rights and purchase the shares on such holder's behalf. The depositary will then deposit the shares and deliver ADRs to such holders. It will only exercise rights if holders of Sanofi ADSs pay it the exercise price and any other charges the rights require such holders to pay.

U.S. securities laws may restrict the sale, deposit, cancellation or transfer of ADRs issued upon exercise of rights. For example, holders of Sanofi ADSs may not be able to trade Sanofi ADSs freely in the United States. In this case, the depositary may deliver Sanofi ADSs under a separate restricted deposit agreement that will contain the same provisions as the deposit agreement, except for changes needed to implement the required restrictions.

Other Distributions. The depositary will distribute to holders of Sanofi ADSs anything else we may distribute on deposited securities (after deduction or upon payment of fees and expenses or any taxes or other governmental charges) by any means it thinks is legal, equitable and practical. If, for any reason, it cannot make the distribution in that way, the depositary may sell what we distributed and distribute the net proceeds of the sale in the same way it distributes cash dividends, or it may choose any other method to distribute the property it deems equitable and practicable.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of Sanofi ADSs. We have no obligation to register Sanofi ADSs, shares, rights or other securities under the U.S. Securities Act of 1933, as amended. We also have no obligation to take any other action to permit the distribution of ADRs, shares, rights or anything else to holders of Sanofi ADSs. This means that holders may not receive the distribution we make on our shares or any value for them if it is illegal or impractical for the depositary to make them available to such holders.

Elective Distributions. Whenever we intend to distribute a dividend payable at the election of shareholders either in cash or in additional shares, we will give prior notice thereof to the depositary and will indicate whether we wish the elective distribution to be made available to holders of Sanofi ADSs. In that case, we will assist the depositary in determining whether that distribution is lawful and reasonably practicable. The depositary will make the election available to holders of Sanofi ADSs only if it is reasonably practicable and if we have provided all the documentation contemplated in the deposit agreement. In that case, the depositary will establish procedures to enable holders of Sanofi ADSs to elect to receive either cash or additional ADSs, in each case as described in the deposit agreement. If the election is not made available to holders of Sanofi ADSs, such holders will receive either cash or additional Sanofi

Table of Contents

ADSs, depending on what a shareholder in France would receive for failing to make an election, as more fully described in the deposit agreement.

Deposit, Withdrawal and Cancellation

Delivery of ADRs

The depositary will deliver ADRs if the holder or his or her broker deposit shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of Sanofi ADSs in the names the holder requests and will deliver the ADRs to the persons the holder requests at its office.

Obtaining Sanofi ordinary shares

A holder may turn in his or her ADRs at the depositary's office. Upon payment of its fees and expenses and any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver (1) the underlying shares to an account designated by the holder and (2) any other deposited securities underlying the ADR at the office of a custodian or, at the holder's request, risk and expense, the depositary will deliver the deposited securities at its office.

Voting Rights

A holder may instruct the depositary to vote the Sanofi ordinary shares underlying his or her Sanofi ADSs at any meeting of Sanofi shareholders, but only if we request that the depositary ask for holder instructions. Otherwise, holders will not be able to exercise their right to vote unless they withdraw the underlying ordinary shares from the ADR program and vote as an ordinary shareholder. However, holders may not know about the meeting sufficiently in advance to timely withdraw the underlying ordinary shares.

If we ask for holder instructions in connection with a meeting of Sanofi shareholders, the depositary will provide materials to holders of Sanofi ADSs in the manner described under the heading "Notices and Reports; Rights of Holders to Inspect Books" below. For any instructions to be valid, the depositary must receive them on or before the date specified in the materials distributed by the depositary. The depositary will endeavor, in so far as practical, subject to French law and the provisions of our *statuts*, to vote or to have its agents vote the shares or other deposited securities as holders may validly instruct. The depositary will only vote or attempt to vote shares as holders validly instruct.

We cannot guarantee holders that they will receive the voting materials with sufficient time to enable them to return any voting instructions to the depositary in a timely manner to vote their shares. As long as they act in good faith, neither the depositary nor its agents will be responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. ***This means that holders may not be able to exercise their right to vote and there may be nothing holders can do if their shares are not voted as they requested.***

Similar to our shares, Sanofi ADSs evidenced by ADRs that are registered in the name of the same owner for at least two (2) years are eligible for double voting rights so long as certain procedures are followed, as set out in the deposit agreement. For additional information regarding double voting rights, see "Item 10. Additional Information B. Memorandum and Articles of Association Voting Rights".

The deposit agreement allows the depositary and Sanofi to change the voting procedures or require additional voting procedures in addition to the ones described above if necessary or appropriate. ***For example, holders might be required to arrange to have their Sanofi ADSs deposited in a blocked account for a specified period of time prior to a shareholders' meeting in order to be allowed to give voting instructions.***

Notices and Reports; Rights of Holders to Inspect Books

On or before the first date on which we give notice, by publication or otherwise, of any meeting of holders of shares or other deposited securities, or of any adjourned meeting of such holders, or of the taking of any action in respect of any cash or other distributions or the offering of any rights, we will transmit to the depositary a copy of the notice.

Upon notice of any meeting of holders of shares or other deposited securities, if requested in writing by Sanofi, the depositary will, as soon as practicable, mail to the holders of Sanofi ADSs a notice, the form of which is in the

Table of Contents

discretion of the depositary, containing (1) a summary in English of the information contained in the notice of meeting provided by Sanofi to the depositary, (2) a statement that the holders as of the close of business on a specified record date will be entitled, subject to any applicable provision of French law and of our *statuts*, to instruct the depositary as to the exercise of the voting rights, if any, pertaining to the amount of shares or other deposited securities represented by their respective ADSs and (3) a statement as to the manner in which such instructions may be given. Notwithstanding the above, the depositary may, to the extent not prohibited by law or regulations, or by the requirements of the NYSE, in lieu of distribution of the materials provided to the depositary as described above, distribute to the holders a notice that provides holders with, or otherwise publicizes to holders, instructions on how to retrieve such materials or receive such materials upon request (i.e., by reference to a website containing the materials for retrieval or a contact for requesting copies of the materials).

The depositary will make available for inspection by ADS holders at the depositary's office any reports and communications, including any proxy soliciting material, received from us that are both (1) received by the depositary as the holder of the deposited securities and (2) made generally available to the holders of such deposited securities by us. The depositary will also, upon written request, send to ADS holders copies of such reports when furnished by us pursuant to the deposit agreement. Any such reports and communications, including any such proxy soliciting material, furnished to the depositary by us will be furnished in English to the extent such materials are required to be translated into English pursuant to any regulations of the SEC.

The depositary will keep books for the registration of ADRs and transfers of ADRs that at all reasonable times will be open for inspection by the holders provided that such inspection is not for the purpose of communicating with holders in the interest of a business or object other than our business or a matter related to the deposit agreement or the ADRs.

Table of Contents

Fees and Expenses

Fees Payable By ADS Holders

Pursuant to the deposit agreement, holders of our ADSs may have to pay to JPMorgan, either directly or indirectly, fees or charges up to the amounts set forth in the table below.

Associated Fee

\$5.00 or less per 100 ADSs (or portion thereof)

\$0.05 or less per ADS (or portion thereof)

Registration fees in effect for the registration of transfers of shares generally on the share register of the company or foreign registrar and applicable to transfers of shares to or from the name of JPMorgan or its nominee to the custodian or its nominee on the making of deposits and withdrawals
 A fee equal to the fee for the execution and delivery of ADSs which would have been charged as a result of the deposit of such securities
 A fee for the reimbursement of such fees, charges and expenses as are incurred by JPMorgan, its agents (and their agents), including BNP Paribas, as custodian (by deductions from cash dividends or other cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them)
 Expenses incurred by JPMorgan

Depository Action

Execution and delivery of ADRs for distributions and dividends in shares and rights to subscribe for additional shares or rights of any other nature and surrender of ADRs for the purposes of withdrawal, including the termination of the deposit agreement
 Any cash distribution made pursuant to the deposit agreement, including, among other things:

cash distributions or dividends,

distributions other than cash, shares or rights,

distributions in shares, and

rights of any other nature, including rights to subscribe for additional shares.

As applicable

Distributions of securities other than cash, shares or rights

Compliance with foreign exchange control regulations or any law or regulation relating to foreign investment, servicing of shares or other deposited securities, sale of securities, delivery of deposited securities or otherwise

Cable, telex and facsimile transmission (where expressly provided for in the deposit agreement)

Foreign currency conversion into U.S. dollars

In addition to the fees outlined above, each holder will be responsible for any taxes or other governmental charges payable on his or her Sanofi ADSs or on the deposited securities underlying his or her Sanofi ADSs. The depositary may refuse to transfer a holder's Sanofi ADSs or allow a holder to withdraw the deposited securities underlying his or her Sanofi ADSs until such taxes or other charges are paid. It may apply payments owed to a holder or sell deposited securities underlying a holder's Sanofi ADSs to pay any taxes owed, and the holder will remain liable for any deficiency. If it sells deposited securities, it will, if appropriate, reduce the number of Sanofi ADSs to reflect the sale and pay to the holder any proceeds, or send to the holder any property, remaining after it has paid the taxes. For additional information regarding taxation, see "Item 10. Additional Information E. Taxation".

Fees Paid to Sanofi by the Depositary

JPMorgan, as depositary, has agreed to reimburse Sanofi for certain expenses (subject to certain limits) Sanofi incurs relating to legal fees, investor relations servicing, investor-related presentations, ADR-related advertising and public relations in those jurisdictions in which the ADRs may be listed or otherwise quoted, investor relations channel, perception studies, accountants' fees in relation to our annual report on Form 20-F or any other expenses directly or indirectly relating to managing the program or servicing the ADR holders. The depositary has also agreed to provide additional amounts to us based on certain performance indicators relating to the ADR facility and fees collected by it. From January 1, 2014 to December 31, 2014, we received a total amount of \$9,489,655 from JPMorgan. In addition

Table of Contents

to these payments, JPMorgan has agreed to waive servicing fees we may incur in connection with routine corporate actions such as annual general meetings and dividend distributions, as well as for other assistance JPMorgan may provide to us, such as preparation of tax and regulatory compliance documents for holders and investor relations advisory services.

Changes Affecting Deposited Securities

If we:

change the nominal or par value of our Sanofi ordinary shares;

recapitalize, reorganize, merge or consolidate, liquidate, sell assets, or take any similar action;

reclassify, split up or consolidate any of the deposited securities; or

distribute securities on the deposited securities that are not distributed to holders;

then either:

the cash, shares or other securities received by the depositary will become deposited securities and each Sanofi ADS will automatically represent its equal share of the new deposited securities; or

the depositary may, and will if we ask it to, distribute some or all of the cash, shares or other securities it receives. It may also deliver new ADRs or ask holders to surrender their outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

Disclosure of Interests

The obligation of a holder or other person with an interest in our shares to disclose information under French law and under our *statuts* also applies to holders and any other persons, other than the depositary, who have an interest in the Sanofi ADSs. The consequences for failing to comply with these provisions are the same for holders and any other persons with an interest as a holder of our ordinary shares. For additional information regarding these obligations, see "Item 10. Additional Information B. Memorandum and Articles of Association Requirements for Holdings Exceeding Certain Percentages".

Amendment and Termination

We may agree with the depositary to amend the deposit agreement and the ADRs without the consent of the ADS holders for any reason. If the amendment adds or increases fees or charges, except for taxes and other governmental charges or registration fees, cable, telex or facsimile transmission costs, delivery costs or other such expenses, or prejudices a substantial right of holders of Sanofi ADSs, it will only become effective 30 days after the depositary notifies such holders of the amendment. However, we may not be able to provide holders of Sanofi ADSs with prior notice of the effectiveness of any modifications or supplements that are required to accommodate compliance with applicable provisions of law, whether or not those modifications or supplements could be considered to be materially prejudicial to the substantial rights of holders of Sanofi ADSs. *At the time an amendment becomes effective, such holders will be considered, by continuing to hold their ADR, to have agreed to the amendment and to be bound by the ADR and the deposit agreement as amended.*

The depositary will terminate the agreement if we ask it to do so. The depositary may also terminate the agreement if the depositary has told us that it would like to resign and we have not appointed a new depositary bank within 90 days. In both cases, the depositary must notify holders of Sanofi ADSs at least 30 days before termination.

After termination, the depositary and its agents will be required to do only the following under the deposit agreement: (1) collect distributions on the deposited securities, (2) sell rights and other property as provided in the deposit agreement and (3) deliver shares and other

Edgar Filing: Sanofi - Form 20-F

deposited securities upon cancellation of ADRs. Six months or more after termination, the depositary may sell any remaining deposited securities by public or private sale. After that, the depositary will hold the money it receives on the sale, as well as any other cash it is holding under the deposit agreement, for the pro rata benefit of the holders of Sanofi ADSs that have not surrendered their Sanofi ADSs. It will have no liability for interest. Upon termination of the deposit agreement, the depositary's only obligations will be to account for the proceeds of the sale and other cash and with respect to indemnification. After termination, our only obligation will be with respect to indemnification and to pay certain amounts to the depositary.

Table of Contents

Limitations on Obligations and Liability to Holders of Sanofi ADSs

The deposit agreement expressly limits our obligations and the obligations of the depository, and it limits our liability and the liability of the depository. In particular, please note the following:

we and the depository are obligated only to take the actions specifically set forth in the deposit agreement without gross negligence or bad faith;

we and the depository are not liable if either is prevented or delayed by law or circumstances beyond its control from performing its obligations under the deposit agreement;

we and the depository are not liable if either exercises, or fails to exercise, any discretion permitted under the deposit agreement;

we and the depository have no obligation to become involved in a lawsuit or other proceeding related to the Sanofi ADSs or the deposit agreement on holders' behalf or on behalf of any other party, unless indemnity satisfactory to it against all expense and liability is furnished as often as may be required;

we and the depository are not liable for the acts or omissions made by, or the insolvency of, any securities depository, clearing agency or settlement system or the custodian, subject to certain exceptions and to the extent the custodian is not a branch or affiliate of JPMorgan;

the depository is not liable for the price received in connection with any sale of securities, the timing thereof or any delays, acts, omissions to act, errors, defaults or negligence on the part of the party so retained in connection with any such sale or proposed sale;

we and the depository may rely without any liability upon any written notice, request, direction, instruction or other document believed by either of us to be genuine and to have been signed or presented by the proper parties; and

we and the depository are not liable for any action or nonaction taken in reliance upon the advice of or information from legal counsel, accountants, any person presenting ordinary shares for deposit, any ADS holder, or any other person believed in good faith to be competent to give such advice or information.

In addition, the depository will not be liable for any acts or omissions made by a successor depository. Moreover, neither we nor the depository nor any of our respective agents will be liable to any holder of Sanofi ADSs for any indirect, special, punitive or consequential damages.

Pursuant to the terms of the deposit agreement, we and the depository have agreed to indemnify each other under certain circumstances.

Requirements for Depository Actions

Before the depository will deliver or register the transfer of Sanofi ADSs, make a distribution on Sanofi ADSs or process a withdrawal of shares, the depository may require:

payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;

Edgar Filing: Sanofi - Form 20-F

production of satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and

compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver Sanofi ADSs, register transfers of Sanofi ADSs or permit withdrawals of shares when the transfer books of the depositary or our transfer books are closed, or at any time if the depositary or we think it advisable to do so.

Right to Receive the Shares Underlying the Sanofi ADSs

Holders have the right to cancel their Sanofi ADSs and withdraw the underlying Sanofi ordinary shares at any time except:

when temporary delays arise when we or the depositary have closed our transfer books or the deposit of shares in connection with voting at a shareholders' meeting, or the payment of dividends;

Table of Contents

when the holder or other holders of Sanofi ADSs seeking to withdraw shares owe money to pay fees, taxes and similar charges; or

when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to Sanofi ADSs or to the withdrawal of shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Pre-Release of Sanofi ADSs

Unless we instruct the depository not to, the deposit agreement permits the depository to deliver Sanofi ADSs before deposit of the underlying shares. This is called a pre-release of the Sanofi ADSs. The depository may also deliver shares upon cancellation of pre-released Sanofi ADSs (even if the Sanofi ADSs are cancelled before the pre-release transaction has been closed out). A pre-release is closed out as soon as the underlying shares are delivered to the depository. The depository may receive Sanofi ADSs instead of shares to close out a pre-release. Unless otherwise agreed in writing, the depository may pre-release Sanofi ADSs only under the following conditions: (1) before or at the time of the pre-release, the person to whom the pre-release is being made must represent to the depository in writing that it or its customer (i) owns the shares or Sanofi ADSs to be deposited, (ii) assigns all beneficial rights, title and interest in such shares or ADRs to the depository in its capacity as depository and (iii) will not take any action with respect to such shares or ADRs that is inconsistent with the transfer of beneficial ownership, other than in satisfaction of such pre-release; (2) the pre-release must be fully collateralized with cash, U.S. government securities or other collateral that the depository considers appropriate; (3) the depository must be able to close out the pre-release on not more than five business days' notice; and (4) the depository may require such further indemnities and credit regulations as it deems appropriate. In addition, the depository will limit the number of Sanofi ADSs that may be outstanding at any time as a result of pre-release, although the depository may disregard the limit from time to time, if it thinks it is appropriate to do so. The depository may retain for its own account any compensation received by it in connection with the foregoing. Any holder of pre-release ADRs should consult its tax and other advisors about the implications of pre-release for its particular situation.

Table of Contents

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies

N/A

Item 14. Material Modifications to the Rights of Security Holders

N/A

Item 15. Controls and Procedures

- (a) Our Chief Executive Officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) as of the end of the period covered by this Form 20-F, have concluded that, as of such date, our disclosure controls and procedures were effective to ensure that material information relating to Sanofi was timely made known to them by others within the Group.
- (b) Report of Management on Internal Control Over Financial Reporting
- Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Management assessed the effectiveness of internal control over financial reporting as of December 31, 2014 based on the framework in "Internal Control – Integrated Framework" (2013 framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).
- Based on that assessment, management has concluded that the Company's internal control over financial reporting was effective as of December 31, 2014 to provide reasonable assurance regarding the reliability of its financial reporting and the preparation of its financial statements for external purposes, in accordance with generally accepted accounting principles.
- Due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements, and can only provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.
- The effectiveness of the Company's internal control over financial reporting has been audited by PricewaterhouseCoopers Audit and Ernst & Young et Autres, independent registered public accounting firms, as stated in their report on the Company's internal control over financial reporting as of December 31, 2014, which is included herein. See paragraph (c) of the present Item 15, below.
- (c) See report of PricewaterhouseCoopers Audit and Ernst & Young et Autres, independent registered public accounting firms, included under "Item 18. Financial Statements" on page F-3.
- (d) There were no changes to our internal control over financial reporting that occurred during the period covered by this Form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 16.

[Reserved]

Item 16A. Audit Committee Financial Expert

Our Board of Directors has determined that Klaus Pohle, Robert Castaigne, Fabienne Lecorvaisier, Christian Mulliez and Gérard Van Kemmel, directors serving on the Audit Committee, are independent financial experts within the meaning of paragraph 407 of the Sarbanes-Oxley Act of 2002.

The Board of Directors deemed Klaus Pohle to be a financial expert taking into account his education and professional experience in financial matters, accountancy and internal control. The Board of Directors determined that Robert Castaigne qualifies as a financial expert based on his education and his experience as Chief Financial Officer of Total, a major corporation. The Board of Directors deemed Fabienne Lecorvaisier to be a financial expert taking into account her experience in corporate finance in various international banks and as Chief Financial Officer

Table of Contents

of Essilor and now Air Liquide. The Board of Directors deemed Christian Mulliez to be a financial expert taking into account his experience as Vice President, General Manager Administration and Finance of L'Oréal and graduate of the *Ecole Supérieure des Sciences Economiques et Commerciales* (ESSEC). The Board of Directors determined that Gérard Van Kemmel qualifies as a financial expert based on his experience as a partner at an international accounting firm.

The Board of Directors has determined that all six directors meet the independence criteria of U.S. Securities and Exchange Commission Rule 10A-3, although only Carole Piwnica, Robert Castaigne, Fabienne Lecorvaisier, Klaus Pohle and Gérard Van Kemmel meet the French AFEP-MEDEF Code criteria of independence applied by the Board of Directors for general corporate governance purposes (see Item 16G, below).

Item 16B. Code of Ethics

We have adopted a financial code of ethics, as defined in Item 16B. of Form 20-F under the Exchange Act. Our financial code of ethics applies to our Chief Executive Officer, Chief Financial Officer, Chief Accounting Officer and other officers performing similar functions, as designated from time to time. Our financial code of ethics is available on our Website at www.sanofi.com (information on our website is not incorporated by reference in this annual report). A copy of our financial code of ethics may also be obtained without charge by addressing a written request to the attention of Individual Shareholder Relations at our headquarters in Paris. We will disclose any amendment to the provisions of such financial code of ethics on our website.

Item 16C. Principal Accountants' Fees and Services

See Note E. to our consolidated financial statements included at Item 18 of this annual report.

Item 16D. Exemptions from the Listing Standards for Audit Committees

N/A

Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

In 2014, Sanofi made the following purchases of its ordinary shares.

Period	(a) Total Number of Shares Purchased	(b) Average Price Paid per Share	(c) Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs(1)	(d) Approximate Value of Shares that May Yet Be Purchased Under the Plans or Programs(2)
February 2014	982,646	€71.75	982,646	12,812
March 2014	3,776,264	€75.26	3,776,264	12,528
April 2014	3,249,016	€75.42	3,249,016	12,283
May 2014	1,620,000	€77.53	1,620,000	12,158

Edgar Filing: Sanofi - Form 20-F

June 2014	3,602,421	€78.73	3,602,421	11,874
July 2014	1,176,789	€77.14	1,176,789	11,783
November 2014	2,501,000	€75.41	2,501,000	11,595
December 2014	6,761,903	€75.26	6,761,903	11,086

(1)

The Company was authorized to repurchase up to €12,883,098,900 of shares for a period of eighteen months (i.e., through November 5, 2015) by the Annual Shareholders' Meeting held on May 5, 2014.

(2)

Millions of euros.

This schedule does not include purchases and sales conducted by Exane under a liquidity contract entered into in 2010 and that is still in effect. For more information see Item 10.B *Memorandum and Articles of Association Use of Share Repurchase Programs.*

Item 16F. Change in Registrant's Certifying Accountant

N/A

Table of Contents

Item 16G. Corporate Governance

Sanofi is incorporated under the laws of France, with securities listed on regulated public markets in the United States (New York Stock Exchange) and France (Euronext Paris). Consequently, as described further in our annual report, our corporate governance framework reflects the mandatory provisions of French corporate law, the securities laws and regulations of France and the United States and the rules of the aforementioned public markets. In addition, we generally follow the "AFEP-MEDEF" corporate governance recommendations for French listed issuers (hereafter referred to as the "AFEP-MEDEF Code"). As a result, our corporate governance framework is similar in many respects to, and provides investor protections that are comparable to or in some cases, more stringent than the corresponding rules of the New York Stock Exchange. Nevertheless, there are important differences to keep in mind.

In line with New York Stock Exchange rules applicable to domestic issuers, Sanofi maintains a board of directors of which at least half of the members are independent. Sanofi evaluates the independence of members of our Board of Directors using the standards of the French AFEP-MEDEF Code as the principal reference. We believe that AFEP-MEDEF's overarching criteria for independence no relationship of any kind whatsoever with the Company, its group or the management of either that is such as to color a Board member's judgment are on the whole consistent with the goals of the New York Stock Exchange's rules although the specific tests proposed under the two standards may vary on some points. We have complied with the audit committee independence and other requirements of the Rule 10A-3 under the U.S. Securities Exchange Act of 1934, as amended, adopted pursuant to the Sarbanes-Oxley Act of 2002. Our Compensation Committee includes one non-independent member, Christian Mulliez, which is permitted under the AFEP-MEDEF Code but would not be compliant with the rules of the New York Stock Exchange for domestic issuers.

Under French law, the committees of our Board of Directors are advisory only, and where the New York Stock Exchange Listed Company Manual would vest certain decision-making powers with specific committees by delegation (*e.g.*, appointment or audit committees), under French law our Board of Directors remains the only competent body to take such decisions, albeit taking into account the recommendation of the relevant committees. Additionally, under French corporate law, it is the Shareholders' General Meeting of Sanofi that is competent to appoint our auditors upon the proposal of our Board of Directors, although our Board Charter provides that the Board of Directors will make its proposal on the basis of the recommendation of our Audit Committee. We believe that this requirement of French law, together with the additional legal requirement that two sets of statutory auditors be appointed, share the New York Stock Exchange's underlying goal of ensuring that the audit of our accounts be conducted by auditors independent from company management.

In addition to the oversight role of our Compensation Committee for questions of management compensation including by way of equity, under French law any option or restricted share plans or other share capital increases, whether for the benefit of senior management or employees, may only be adopted by the Board of Directors pursuant to and within the limits of a shareholder resolution approving the related capital increase and delegating to the Board the authority to implement such operations.

As described above, a number of issues, which could be resolved directly by a board or its committees in the United States, require the additional protection of direct shareholder consultation in France. On the other hand, there is not a tradition of non-executive Board of Directors sessions. Our Audit Committee is entirely composed of independent directors as that term is defined in Rule 10A-3 under the U.S. Securities Exchange Act of 1934, as amended, adopted pursuant to the Sarbanes-Oxley Act of 2002. The composition of our Audit Committee, Compensation Committee, and Appointments and Governance Committee includes directors who are also officers of our largest shareholder.

As a 'foreign private issuer' under the U.S. securities laws, our Chief Executive Officer and our Chief Financial Officer issue the certifications required by §302 and §906 of the Sarbanes Oxley Act of 2002 on an annual basis (with the filing of our annual report on U.S. Form 20-F) rather than on a quarterly basis as would be the case of a U.S. corporation filing quarterly reports on U.S. Form 10-Q.

French corporate law provides that the Board of Directors must vote to approve a broadly defined range of transactions that could potentially create conflicts of interest between Sanofi on the one hand and its Directors and Chief Executive Officer on the other hand, which are then presented to shareholders for approval at the next annual meeting. This legal safeguard provides shareholders with an opportunity to approve significant aspects of the Chief Executive Officer's compensation package, and it operates in place of certain provisions of the NYSE Listed Company Manual.

Item 16H. Mine Safety Disclosure

N/A

Table of Contents

PART III

Item 17. Financial Statements

See Item 18.

Item 18. Financial Statements

See pages F-1 through F-114 incorporated herein by reference.

Item 19. Exhibits

- 1.1 Articles of association (*statuts*) of Sanofi (English translation)
- 1.2 Board Charter (*Règlement Intérieur*) of Sanofi (English translation)
- 2. The total amount of long-term debt securities authorized under any instrument does not exceed 10% of the total assets of the Company and its subsidiaries on a consolidated basis. We hereby agree to furnish to the SEC, upon its request, a copy of any instrument defining the rights of holders of long-term debt of the Company or of its subsidiaries for which consolidated or unconsolidated financial statements are required to be filed.
- 4.1 Form of Contingent Value Rights Agreement by and among Sanofi and Trustee (*on file with the SEC as Annex B to Amendment No. 2 to the Registration Statement on Form F-4 filed on March 24, 2011*)
- 8.1 List of significant subsidiaries, see "Item 4. Information on the Company C. Organizational Structure" of this 20-F.
- 12.1 Certification by Serge Weinberg, Chairman and Chief Executive Officer, required by Section 302 of the Sarbanes-Oxley Act of 2002
- 12.2 Certification by Jérôme Contamine, Principal Financial Officer, required by Section 302 of the Sarbanes-Oxley Act of 2002
- 13.1 Certification by Serge Weinberg, Chairman and Chief Executive Officer, required by Section 906 of the Sarbanes-Oxley Act of 2002
- 13.2 Certification by Jérôme Contamine, Principal Financial Officer, required by Section 906 of the Sarbanes-Oxley Act of 2002
- 23.1 Consent of Ernst & Young et Autres dated March 10, 2015
- 23.2 Consent of PricewaterhouseCoopers Audit dated March 10, 2015
- 99.1 Report of the Chairman of the Board of Directors for 2014 as required by Art. L. 225- 37 paragraph 6 of the French Commercial Code

Table of Contents

Signatures

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Sanofi

By: /s/ SERGE WEINBERG

Name: **Serge Weinberg**

Title: **Chairman and Chief Executive Officer**

Date: March 10, 2015

Table of Contents

2014 ANNUAL CONSOLIDATED FINANCIAL STATEMENTS

**The financial statements are presented in accordance with
International Financial Reporting Standards (IFRS).**

<u>CONSOLIDATED BALANCE SHEETS – ASSETS</u>	F-4
<u>CONSOLIDATED BALANCE SHEETS – LIABILITIES AND EQUITY</u>	F-5
<u>CONSOLIDATED INCOME STATEMENTS</u>	F-6
<u>CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME</u>	F-7
<u>CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY</u>	F-8
<u>CONSOLIDATED STATEMENTS OF CASH FLOWS</u>	F-10
<u>NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS</u>	F-11
A/ BASIS OF PREPARATION	F-11
B/ SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES	F-14
C/ PRINCIPAL ALLIANCES	F-37
D/ PRESENTATION OF THE FINANCIAL STATEMENTS	F-40
E/ PRINCIPAL ACCOUNTANTS' FEES AND SERVICES	F-109
F/ LIST OF PRINCIPAL COMPANIES INCLUDED IN THE CONSOLIDATION FOR THE YEAR ENDED DECEMBER 31, 2014	F-110

Table of Contents

**REPORT OF INDEPENDENT REGISTERED
PUBLIC ACCOUNTING FIRMS**

To the Board of Directors and Shareholders of Sanofi,

We have audited the accompanying consolidated balance sheets of Sanofi and its subsidiaries (together the "Group") as of December 31, 2014, 2013 and 2012, and the related consolidated statements of income, comprehensive income, changes in equity and cash flows for each of the three years in the period ended December 31, 2014. These financial statements are the responsibility of the Group's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board of the United States of America (the "PCAOB"). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Group as of December 31, 2014, 2013 and 2012, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

We also have audited, in accordance with the standards of the PCAOB, the effectiveness of the Group's internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) and our report dated March 10, 2015 expressed an unqualified opinion thereon.

Neuilly-sur-Seine and Paris-La Défense, March 10, 2015

PricewaterhouseCoopers Audit

/s/ Xavier Cauchois

Ernst & Young et Autres

/s/ Nicolas Pfeuty

Table of Contents

**REPORT OF INDEPENDENT REGISTERED
PUBLIC ACCOUNTING FIRMS**

SANOFI

To the Board of Directors and Shareholders of Sanofi,

We have audited internal control over financial reporting of Sanofi and its subsidiaries (together "the Group") as of December 31, 2014, based on criteria established in **Internal Control-Integrated Framework** issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) (the COSO criteria). The Group's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Report of Management on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board of the United States of America (the "PCAOB"). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Group maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on the COSO criteria.

We also have audited, in accordance with the standards of the PCAOB, the consolidated balance sheets of the Group as of December 31, 2014, 2013 and 2012, and the related consolidated statements of income, comprehensive income, changes in equity and cash flows for each of the three years in the period ended December 31, 2014 and our report dated March 10, 2015 expressed an unqualified opinion thereon.

Neuilly-sur-Seine and Paris-La Défense, March 10, 2015

PricewaterhouseCoopers Audit

/s/ Xavier Cauchois

Ernst & Young et Autres

/s/ Nicolas Pfeuty

Table of Contents

CONSOLIDATED BALANCE SHEETS ASSETS

<i>(€ million)</i>	Note	December 31, 2014	December 31, 2013(1)	December 31, 2012(1)
Property, plant and equipment	D.3.	10,396	10,182	10,578
Goodwill	D.4.	39,197	37,134	38,073
Other intangible assets	D.4.	14,543	15,395	20,192
Investments in associates and joint ventures	D.6.	2,384	448	487
Other non-current assets	D.7.	2,575	4,826	3,799
Deferred tax assets	D.14.	4,860	4,144	4,369
Non-current assets		73,955	72,129	77,498
Inventories	D.9.	6,562	6,352	6,379
Accounts receivable	D.10.	7,149	6,831	7,507
Other current assets	D.11.	2,157	2,287	2,355
Current financial assets	D.12.	218	185	178
Cash and cash equivalents	D.13. D.17.	7,341	8,257	6,381
Current assets		23,427	23,912	22,800
Assets held for sale or exchange	D.8.	10	14	101
TOTAL ASSETS		97,392	96,055	100,399

(1)

Includes the impact of applying IFRIC 21 (see Note A.2.2.).

The accompanying notes on pages F-11 to F-114 are an integral part of the consolidated financial statements.

Table of Contents**CONSOLIDATED BALANCE SHEETS LIABILITIES AND EQUITY**

<i>(€ million)</i>	Note	December 31, 2014	December 31, 2013(1)	December 31, 2012(1)
Equity attributable to equity holders of Sanofi	D.15.	56,120	56,904	57,352
Equity attributable to non-controlling interests	D.15.10.	148	129	134
Total equity		56,268	57,033	57,486
Long-term debt	D.17.	13,276	10,414	10,719
Non-current liabilities related to business combinations and to non-controlling interests	D.18.	1,133	884	1,350
Provisions and other non-current liabilities	D.19.	9,578	8,735	11,043
Deferred tax liabilities	D.14.	4,105	5,060	5,932
Non-current liabilities		28,092	25,093	29,044
Accounts payable		3,651	3,003	3,190
Other current liabilities	D.19.4.	7,712	6,725	6,728
Current liabilities related to business combinations and to non-controlling interests	D.18.	131	24	100
Short-term debt and current portion of long-term debt	D.17.	1,538	4,176	3,812
Current liabilities		13,032	13,928	13,830
Liabilities related to assets held for sale or exchange	D.8.		1	39
TOTAL LIABILITIES & EQUITY		97,392	96,055	100,399

(1)

Includes the impact of applying IFRIC 21 (see Note A.2.2.).

The accompanying notes on pages F-11 to F-114 are an integral part of the consolidated financial statements.

Table of Contents**CONSOLIDATED INCOME STATEMENTS**

<i>(€ million)</i>	Note	2014	2013(1)	2012(1)
Net sales	D.34.	33,770	32,951	34,947
Other revenues		339	355	1,010
Cost of sales		(11,029)	(10,991)	(11,098)
Gross profit		23,080	22,315	24,859
Research and development expenses		(4,824)	(4,770)	(4,905)
Selling and general expenses		(9,107)	(8,603)	(8,931)
Other operating income	D.25.	327	691	562
Other operating expenses	D.26.	(163)	(241)	(414)
Amortization of intangible assets		(2,482)	(2,914)	(3,291)
Impairment of intangible assets	D.5.	26	(1,387)	(117)
Fair value remeasurement of contingent consideration liabilities	D.18.	(303)	314	(192)
Restructuring costs	D.27.	(411)	(300)	(1,141)
Other gains and losses, and litigation	D.28.			
Operating income		6,143	5,105	6,430
Financial expenses	D.29.	(605)	(612)	(751)
Financial income	D.29.	193	109	93
Income before tax and associates and joint ventures	D.35.1.	5,731	4,602	5,772
Income tax expense	D.30.	(1,171)	(763)	(1,108)
Share of profit/(loss) of associates and joint ventures	D.31.	(51)	35	393
Net income		4,509	3,874	5,057
Net income attributable to non-controlling interests	D.32.	119	158	169
Net income attributable to equity holders of Sanofi		4,390	3,716	4,888
Average number of shares outstanding (million)	D.15.9.	1,315.8	1,323.1	1,319.5
Average number of shares outstanding after dilution (million)	D.15.9.	1,331.1	1,339.1	1,329.6

Edgar Filing: Sanofi - Form 20-F

Basic earnings per share (in euros)	3.34	2.81	3.70
Diluted earnings per share (in euros)	3.30	2.77	3.68

(1)

Includes the impact of applying IFRIC 21 (see Note A.2.2.).

The accompanying notes on pages F-11 to F-114 are an integral part of the consolidated financial statements.

F-6

Table of Contents

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

<i>(€ million)</i>	Note	2014	2013(1)	2012(1)
Net income		4,509	3,874	5,057
<i>Attributable to equity holders of Sanofi</i>		<i>4,390</i>	<i>3,716</i>	<i>4,888</i>
<i>Attributable to non-controlling interests</i>		<i>119</i>	<i>158</i>	<i>169</i>
Other comprehensive income:				
Actuarial gains/(losses)	D.15.7.	(869)	810	(1,445)
Tax effects	D.15.7.	303	(152)	464
Sub-total: items not subsequently reclassifiable to profit or loss (a)		(566)	658	(981)
Available-for-sale financial assets		(2,760)	1,208	1,451
Cash flow hedges			(3)	(5)
Change in currency translation differences	D.15.7.	2,506	(1,804)	(532)
Tax effects	D.15.7.	250	(208)	(116)
Sub-total: items subsequently reclassifiable to profit or loss (b)		(4)	(807)	798
Other comprehensive income for the period, net of taxes (a+b)		(570)	(149)	(183)
Comprehensive income		3,939	3,725	4,874
<i>Attributable to equity holders of Sanofi</i>		<i>3,810</i>	<i>3,581</i>	<i>4,712</i>
<i>Attributable to non-controlling interests</i>		<i>129</i>	<i>144</i>	<i>162</i>

(1)

Includes the impact of applying IFRIC 21 (see Note A.2.2.).

The accompanying notes on pages F-11 to F-114 are an integral part of the consolidated financial statements.

F-7

Table of Contents

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

<i>(€million)</i>	Share capital	Additional paid-in capital and retained earnings(1)	Treasury shares	Stock options and other share-based payment	Other comprehensive income	Attributable to equity- holders of Sanofi(1)	Non-controlling interests	Total equity(1)
Balance at January 1, 2012 per the published financial statements	2,682	53,439	(933)	1,980	(975)	56,193	170	56,363
Impact of applying IFRIC 21		21				21		21
Balance at January 1, 2012 after applying IFRIC 21	2,682	53,460	(933)	1,980	(975)	56,214	170	56,384
Other comprehensive income for the period		(981)			805	(176)	(7)	(183)
Net income for the period		4,888				4,888	169	5,057
Comprehensive income for the period		3,907			805	4,712	162	4,874
Dividend paid out of 2011 earnings (€2.65 per share)		(3,487)				(3,487)		(3,487)
Payment of dividends to non-controlling interests							(178)	(178)

Share repurchase program(2)			(823)	(823)	(823)
Reduction in share capital(2)	(55)	(1,493)	1,548		
Share-based payment plans:					
Exercise of stock options(2)	24	621		645	645
Issuance of restricted shares(2)	2	(2)			