

Sanofi
Form 20-F
March 07, 2014

Use these links to rapidly review the document

[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, 2013

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, 2013 was:**

Ordinary shares: 1,324,320,881

**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, 2013.

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® trademark of Warner Chilcott; Avilomics® a trademark of Avila Therapeutics Inc.; 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.; Pancreate belonging to CureDM; Prevelle® a trademark of Mentor Worldwide LLC USA; RetinoStat® a trademark of Oxford Biomedica;

trademarks sold by Sanofi and/or its affiliates to a third party, such as Altace® a trademark of King Pharmaceuticals in the United States; Benzaclin® a trademark of Valeant in the United States and Canada; Carac® a trademark of Valeant in the United States; 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 Warner Chilcott 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; Gel One® a trademark of Seikagaku Kogyo Kabushiki Kaisha, DBA Seikagaku Corporation; Humaneered® a trademark of KaloBios Pharmaceuticals; iPhone® and iPod Touch® trademarks of Apple Inc.; Lactacyd® a trademark of Omega Pharma NV in the EU and several other European countries; Stargen and UshStat® trademarks of Oxford BioMedica; Unisom® a trademark of Johnson & Johnson on certain geographical areas (except the United States where it is a trademark of Signal Investment); and Xyzal® a trademark of GSK in certain countries and of UCB Farchim SA in some others.

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 Markets Marketing and distribution," are based on sales data from IMS Health MIDAS (IMS), retail and hospital, for calendar year 2013, 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

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
-

Table of Contents

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

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

Data relative to market shares and ranking information presented herein for our animal health business are based on sales data from Vetnosis unless stated otherwise.

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

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

projections of operating revenues, net income, business net income, earnings per share, business earnings per share, capital expenditures, cost savings, restructuring costs, positive or negative synergies, dividends, capital structure or other financial items or ratios;

statements of our profit forecasts, trends, plans, objectives or goals, including those relating to products, clinical trials, regulatory approvals and competition; and

statements about our future events and economic performance or that of France, the United States or any other countries in which we operate.

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

Words such as "believe," "anticipate," "plan," "expect," "intend," "target," "estimate," "project," "predict," "forecast," "guideline," "should" and similar expressions are intended to identify forward-looking statements but are not the exclusive means of identifying such statements.

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

Risk factors which could affect the future results and cause actual results to differ materially from those contained in any forward-looking statements are discussed under "Item 3. Key Information D. Risk Factors". Additional risks, not currently known or considered immaterial by the Group, may have the same unfavorable effect and investors may lose all or part of their investment.

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

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>18</u>
	<u>A. History and Development of the Company</u>	<u>19</u>
	<u>B. Business Overview</u>	<u>20</u>
	<u>C. Organizational Structure</u>	<u>75</u>
	<u>D. Property, Plant and Equipment</u>	<u>76</u>
<u>Item 4A.</u>	<u>Unresolved Staff Comments</u>	<u>81</u>
<u>Item 5.</u>	<u>Operating and Financial Review and Prospects</u>	<u>82</u>
<u>Item 6.</u>	<u>Directors, Senior Management and Employees</u>	<u>134</u>
	<u>A. Directors and Senior Management</u>	<u>134</u>
	<u>B. Compensation</u>	<u>158</u>
	<u>C. Board Practices</u>	<u>172</u>
	<u>D. Employees</u>	<u>177</u>
	<u>E. Share Ownership</u>	<u>180</u>
<u>Item 7.</u>	<u>Major Shareholders and Related Party Transactions</u>	<u>185</u>
	<u>A. Major Shareholders</u>	<u>185</u>
	<u>B. Related Party Transactions</u>	<u>186</u>
	<u>C. Interests of Experts and Counsel</u>	<u>186</u>
<u>Item 8.</u>	<u>Financial Information</u>	<u>186</u>
	<u>A. Consolidated Financial Statements and Other Financial Information</u>	<u>186</u>
	<u>B. Significant Changes</u>	<u>190</u>
<u>Item 9.</u>	<u>The Offer and Listing</u>	<u>191</u>
	<u>A. Offer and Listing Details</u>	<u>191</u>
	<u>B. Plan of Distribution</u>	<u>192</u>
	<u>C. Markets</u>	<u>192</u>
	<u>D. Selling Shareholders</u>	<u>192</u>
	<u>E. Dilution</u>	<u>192</u>
	<u>F. Expenses of the Issue</u>	<u>192</u>
<u>Item 10.</u>	<u>Additional Information</u>	<u>192</u>
	<u>A. Share Capital</u>	<u>192</u>
	<u>B. Memorandum and Articles of Association</u>	<u>192</u>
	<u>C. Material Contracts</u>	<u>209</u>
	<u>D. Exchange Controls</u>	<u>210</u>
	<u>E. Taxation</u>	<u>210</u>
	<u>F. Dividends and Paying Agents</u>	<u>214</u>
	<u>G. Statement by Experts</u>	<u>214</u>
	<u>H. Documents on Display</u>	<u>214</u>
	<u>I. Subsidiary Information</u>	<u>214</u>
<u>Item 11.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	<u>214</u>
<u>Item 12.</u>	<u>Description of Securities other than Equity Securities</u>	<u>218</u>
<u>Part II</u>		
<u>Item 13.</u>	<u>Defaults, Dividend Arrearages and Delinquencies</u>	<u>226</u>
<u>Item 14.</u>	<u>Material Modifications to the Rights of Security Holders</u>	<u>226</u>
<u>Item 15.</u>	<u>Controls and Procedures</u>	<u>226</u>
<u>Item 16.</u>	<u>[Reserved]</u>	<u>226</u>
<u>Item 16A.</u>	<u>Audit Committee Financial Expert</u>	<u>226</u>
<u>Item 16B.</u>	<u>Code of Ethics</u>	<u>227</u>

Edgar Filing: Sanofi - Form 20-F

<u>Item 16C.</u>	<u>Principal Accountants' Fees and Services</u>	<u>227</u>
<u>Item 16D.</u>	<u>Exemptions from the Listing Standards for Audit Committees</u>	<u>227</u>
<u>Item 16E.</u>	<u>Purchases of Equity Securities by the Issuer and Affiliated Purchasers</u>	<u>227</u>
<u>Item 16F.</u>	<u>Change in Registrant's Certifying Accountant</u>	<u>227</u>
<u>Item 16G.</u>	<u>Corporate Governance</u>	<u>227</u>
<u>Item 16H.</u>	<u>Mine Safety Disclosure</u>	<u>228</u>
<u>Part III</u>		
<u>Item 17.</u>	<u>Financial Statements</u>	<u>229</u>
<u>Item 18.</u>	<u>Financial Statements</u>	<u>229</u>
<u>Item 19.</u>	<u>Exhibits</u>	<u>229</u>

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, 2013, 2012 and 2011 are included in Item 18 of this annual report.

The consolidated financial statements of Sanofi for the years ended December 31, 2013, 2012 and 2011 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, 2013. 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, 2013.

Sanofi reports its financial results in euros.

Table of Contents

SELECTED CONDENSED FINANCIAL INFORMATION

As of and for the year ended December 31,

<i>(€ million, except per share data)</i>	2013	2012(a)	2011(a)	2010	2009
IFRS Income statement data^(b)					
Net sales	32,951	34,947	33,389	32,367	29,785
Gross profit	22,316	24,859	24,193	24,638	23,125
Operating income	5,106	6,432	5,861	6,535	6,435
Net income attributable to equity holders of Sanofi	3,717	4,889	5,646	5,467	5,265
Basic earnings per share (€^(b)) / (c):					
Net income attributable to equity holders of Sanofi	2.81	3.71	4.27	4.19	4.03
Diluted earnings per share (€^(b)) / (d):					
Net income attributable to equity holders of Sanofi	2.78	3.68	4.26	4.18	4.03
IFRS Balance sheet data					
Goodwill and other intangible assets	52,529	58,265	62,221	44,411	43,480
Total assets	96,065	100,409	100,672	85,264	80,251
Outstanding share capital	2,641	2,646	2,647	2,610	2,618
Equity attributable to equity holders of Sanofi	56,885	57,332	56,193	53,097	48,322
Long term debt	10,414	10,719	12,499	6,695	5,961
Cash dividend paid per share (€ ^(e))	2.80&zwsp; ^(f)	2.77	2.65	2.50	2.40
Cash dividend paid per share (\$) ^{(e) / (g)}	3.86&zwsp; ^(f)	3.65	3.43	3.34	3.46

(a)

Includes the impacts of applying the revised IAS 19 (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 and 2009, 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 1,323.1 million shares in 2013, 1,319.5 million shares in 2012, 1,321.7 million shares in 2011, 1,305.3 million shares in 2010, and 1,305.9 million shares in 2009.

(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., 1,339.1 million shares in 2013, 1,329.6 million shares in 2012, 1,326.7 million shares in 2011, 1,308.2 million shares in 2010, and 1,307.4 million shares in 2009.

(e)

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

(f)

Dividends for 2013 will be proposed for approval at the annual general meeting scheduled for May 5, 2014.

(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 2009 through March 2014 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)			
2009	1.43	1.40	1.51	1.25
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
Last 6 months				
2013				
September	1.35	1.34	1.35	1.31
October	1.36	1.36	1.38	1.35
November	1.36	1.35	1.36	1.34
December	1.38	1.37	1.38	1.36
2014				
January	1.35	1.36	1.37	1.35
February	1.38	1.37	1.38	1.35
March ⁽²⁾	1.37	1.38	1.38	1.37

(1)

The average of the Noon Buying Rates on the last business day of each month during the relevant period for the full year average, and on each business day of the month for the monthly average. The latest available Noon Buying Rate being February 28, 2014, we have used European Central Bank Rates for the period from March 3, 2014 through March 6, 2014.

(2)

In each case, measured through March 6, 2014.

On March 6, 2014 the European Central Bank Rate was 1.3745 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 from product to product and country to country and may not be sufficient to maintain effective product exclusivity because of local differences in the patents, in national laws or legal systems, development in law or jurisprudence, or inconsistent judgments.

Moreover, patent rights are limited in time and do not always provide effective protection for our products. Indeed, competitors may successfully avoid patents, for example, through design innovation, and we may not hold sufficient evidence of infringement to bring suit. Manufacturers of generic products are also increasingly seeking to challenge patents before they expire, and our infringement claims may not result in a decision that our rights are valid, enforceable or infringed.

Also, some countries are becoming more likely to consider granting a compulsory license to patents protecting an innovator's product which limits the protection granted to these products.

We are involved in litigation worldwide to enforce certain of our patent rights against generics and proposed generics (see "Item 8. Financial Information – A. Consolidated Financial Statements and Other Financial Information – Information on Legal or Arbitration Proceedings" for additional information) of our small molecule and biologics 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 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 biologic therapeutics in our pipeline relative to traditional small molecule pharmaceutical products. With the statutory pathways provided in the U.S. and Europe for biosimilars, biosimilars can be a threat to our exclusivity of any biological therapeutics we sell, similar to the small molecule generic threat described hereinabove (see "Changes in the laws or regulations that apply to us could affect the Group's business, results of operations and financial condition").

However, with our increasing presence in 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 would be successful.

In certain cases, we or our partners may be required to obtain licenses from the holders of valid 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 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, which may limit our profitability.

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 ongoing 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.

Table of Contents

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.

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. This trend has been reinforced by the new European pharmacovigilance legislation which has entered in force since July 2012. The Company and the European Regulatory Agencies (under the supervision of the PRAC (Pharmacovigilance Risk Assessment Committee)) have implemented systematic and intensive safety signal detection systems which may detect safety issues even with mature products that have been used for a long time. This can result in market authorization suspension or withdrawals, such as the suspension we experienced with our tetrazepam product (Myolastan®) in 2013.

As a result of a recall or a withdrawal, several pharmaceutical companies now face significant product liability claims.

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 each of these claims or will not face additional claims in the future.

Furthermore, we commercialize several devices 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." below).

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 Insurance and Risk Coverage"). 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 comply with the regulations or maintain the approvals.

Each regulatory authority may impose its own requirements either at the time of the filing of the dossier or later during its review in order to grant a license to market the product, including requiring local clinical studies, and may delay or refuse to grant approval, even though a product has already been approved in another country. For example, in December 2013, while the same dossier had been approved in September 2013 by the EMA, Genzyme received a Complete Response Letter from the FDA for its supplemental Biologics License Application seeking approval of Lemtrada (alemtuzumab) informing Genzyme that its application was not ready for approval. The FDA took the position that Genzyme had not submitted evidence from adequate and well-controlled studies that demonstrated the benefits of Lemtrada outweighed its serious adverse effects.

Table of Contents

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 regular inspections conducted at manufacturing facilities in Canada and France, Sanofi Pasteur submitted a remediation plan to the FDA and has begun its implementation. However, if we fail to adequately respond to this or any other warning letter identifying a deficiency, or otherwise fail to comply with applicable regulatory requirements, 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 60% of our current development portfolio consists of biological products that may in the future bring new therapeutic responses to current unmet medical needs, but that may also lead to more technical constraints and costly investments from an industrial standpoint as biological products are regulated by more stringent international rules than small molecule products. These constraints and costs could adversely affect our business, results of operations and financial condition.

Claims and investigations relating to competition law, marketing practices, pricing, compliance, 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 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 law could lead to substantial liabilities and repercussions on 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 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 whistle blower litigation. In China, the pharmaceutical sector is under scrutiny, the outcome of which is difficult to predict. The Group also faces significant litigation and government investigations or audits, including allegations of securities law violations, corruption, claims related to employment matters, patent and intellectual property disputes, consumer law claims and tax audits. See "Item 8. Financial Information A. Consolidated Financial Statements and Other Financial Information Information on Legal or Arbitration Proceedings" and Note D.22. to our consolidated financial statements included at Item 18 of this annual report. Responding to such investigations is costly and distracts management's attention from our business.

Unfavorable outcomes in any of these matters, or in similar matters to be faced in the future, could preclude the commercialization of products, harm our reputation, negatively affect the profitability of existing products and subject us to substantial fines (including treble damages), punitive damages, penalties and injunctive or administrative remedies, potentially leading to the imposition of additional regulatory controls or exclusion from government reimbursement programs or market and could have a material adverse effect on our business, results of operations or financial conditions.

Table of Contents

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 may require companies to enter into a Corporate Integrity Agreement, which is intended to regulate company behavior for a specified period of years for example, in December 2013, Genzyme Corporation 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.

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 Competition" and "Item 4. Information on the Company B. Business Overview Regulatory framework".

In addition, changes in tax laws or 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. Also due to the complexity of tax contingencies, 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 compliance costs 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 take the place of products facing expiration of patent and regulatory data exclusivity or competition from new products that are perceived as being superior. In 2013, we spent €4,770 million on research and development, amounting to 14.5% 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.

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 Pharmaceutical Research & Development".

Table of Contents

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.

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.

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, 2013 compared with year ended December 31, 2012 Net Sales by Product Pharmaceuticals segment"), which represented 47.3% of the Group's consolidated revenues in 2013. Lantus® is particularly important; it was the Group's leading product with revenues of €5,715 million in 2013, representing 17.3% of the Group's consolidated revenues for the year. Lantus® is a flagship product of the Diabetes division, one of the Group's growth platforms.

In general, if the products referred to above were to encounter problems such as loss of patent protection, 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 there were a reduction in sales of one or more of our flagship products or in their growth, the adverse impact on our business, results of operations and financial condition could be significant.

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

Many of our products are manufactured using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. Third parties supply us with a substantial portion of our raw materials, active ingredients and medical devices, which exposes us to the risk of a supply shortage or interruption in the event that these suppliers experience financial difficulties or are unable to manufacture a sufficient supply of our products meeting Group quality standards. It also increases the risk of quality issues, even with the most scrupulously selected suppliers. 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®. We have also faced price fluctuations with heparin purchase prices. See "Item 4. Information on the Company B. Business Overview Production and Raw Materials" for a description of these outsourcing arrangements. Any of these factors could adversely affect our business, operating results or financial condition.

Our products are also increasingly reliant on the use of product-specific devices for administration which may result in technical issues.

We must also be able to produce sufficient quantities of the products to satisfy demand. Our biologic products (including vaccines) 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 example, starting from April 2012 and through 2013, Sanofi Pasteur imposed supply limitations for Pentacel® and Daptacel® vaccines in the U.S. due to a manufacturing delay that temporarily reduced the effective capacity to below the level needed to fully satisfy market demand in the

Table of Contents

U.S. 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 products, for example, cold storage for certain vaccines and insulin-based products.

The complexity of these processes, as well as strict internal and government 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 for certain products, particularly for biologic products. For instance, all of our bulk Cerezyme® products are produced solely at our Allston, Massachusetts facility. 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. For instance our protamin product which is the only approved antidote to heparin in France is made from salmon sourced from Japan. Following the Fukushima nuclear disaster, we moved our fishing zone to avoid contamination risks. This change to our supply channel was time consuming and forced us to import a similar ingredient commercialized in the United Kingdom.

Supply shortages are also subject to public scrutiny and are subject to even greater public criticism when they occur with respect to life saving medicines with limited or no viable therapeutic alternatives. Such shortages can have a negative impact on the image of the Group independent of the level of revenues lost as a result of the shortage of a particular product. Government authorities and regulators in the United States and in the European Union are also considering measures to reduce these risks. It cannot be ruled out that these ongoing initiatives may generate additional costs for the Group if they result in a requirement to establish back up supply channels or to increase inventory levels to avoid shortages.

We may lose market share to competing remedies or generic brands if they are perceived to be equivalent or superior products.

We are faced with intense competition from generic products and brand-name drugs including from retail chains and distributors. 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 to the market to realize the full value of our investment in its development.

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 sharply lower prices, resulting in both an adverse price and volume effect for our genericized products. For example, Plavix® lost its market exclusivity in the United States in May 2012 and as a result, its sales dropped by 90% in this country within the two months following the loss of market exclusivity.

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 or 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.

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. 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 further details concerning this law and a description of certain regulatory pricing systems that affect our Group see "Item 4. Information on the Company B. Business Overview Pricing & Reimbursement"). 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.

Furthermore there is a growing number of mergers of retail chains and distributors, this consolidation of distribution channels increases their capacity to negotiation 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.

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

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

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

If disruptions or quality concerns were to arise in the third-party supply of raw materials, active ingredients or medical devices, this could adversely affect our ability to sell our products in the quantities demanded by the market and could damage our reputation and relationships with our customers. See also " The manufacture of our products is technically complex, and supply interruptions, product recalls or inventory losses caused by unforeseen events may reduce sales, adversely affect our operating results and financial condition, delay the launch of new products

and negatively impact our image" above.

We also 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 collaborative arrangements with Regeneron for the discovery, development and commercialization of therapies based on monoclonal antibodies, and with Merck & Co., Inc. for the distribution of vaccines in Europe (See "Item 4. Information on the Company B. Business Overview Pharmaceutical Products Main pharmaceutical

Table of Contents

products" and "Item 4. Information on the Company B. Business Overview Vaccine Products" for more information on our alliances). We may also rely on partners to design and manufacture medical devices, notably for the administration of our products. 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 deadlocks, 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 58% 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 18.0% 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 (for more information see "Item 5. Operating and Financial Review and Prospects Liquidity.").

The ongoing slowdown of global economic growth and the 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. Such a slowdown has 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.

Our animal health business could also be adversely impacted as difficult economic conditions may limit the financial resources of livestock producers, causing some to switch to lower-priced products.

Although macroeconomic and financial measures have been taken since 2012 by governments and monetary authorities, notably in Europe, to reduce the risk of failure of a State, the slowing economic environment, the default or failure of major players including wholesalers or public sector buyers financed by insolvent States may affect the financial situation of the Group but can also cause the Group to experience disruptions in the distribution of its products as well as the adverse effects described above at "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

(1) *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 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 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

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."

Counterfeit versions of our products harm our business.

Counterfeiting activities and the presence of counterfeit products in a growing 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 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, stopped research and development program, 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.

Finally, the financial environment and in particular the economic difficulties affecting certain European countries could also negatively affect the value of our assets (see " The ongoing slowdown of global economic growth and the financial environment could have negative consequences for our business" above and " Fluctuations in currency exchange rates could adversely affect our results of operations and financial condition" below)

Any new or revised accounting standards, rules and interpretations issued 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.

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 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 technology capabilities. We are commercializing 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 have invested heavily in the protection of data and information technology systems, there can be no assurance that our efforts or those of our third-party service providers to implement adequate security and quality measures for data processing 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.

Table of Contents

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" above).

Once identified, 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.

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 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 diversification of the Group's business exposes us to increased risks.

As a global healthcare leader within the health industry, we are exposed to a number of risks inherent in sectors in which, in the past, we have been either less active or not present at all. Examples are set forth below:

The business model and the trade channels of the generic and consumer health care (CHC) sectors are different from the traditional pharmaceutical activity with which we are more traditionally familiar. For example, the traditional pharmaceutical business focuses its promotional effort on physicians to drive demand. Depending on geographic location, the generic business concentrates on trade channels such as pharmacies, wholesalers and/or physicians. CHC focuses its

Edgar Filing: Sanofi - Form 20-F

promotional effort on pharmacies and consumers. In addition, the CHC and generic businesses have other factors that can impact purchasing patterns and pharmacy inventories more than in the traditional pharmaceutical businesses, such as trade terms to pharmacies which are variable and linked to competition or seasonality.

Table of Contents

The contribution of our Animal Health business to the Group's income may be adversely affected by a number of risks including some which are specific to this business i.e., the outbreak of an epidemic or pandemic that could kill large numbers of animals, the weather, and the effect of reduced veterinary expenditures during an economic crisis (see " The ongoing slowdown of global economic growth and the financial environment could have negative consequences for our business" above).

Specialty products (such as those developed by Genzyme) that treat rare, life-threatening diseases that are used by a small number of patients are often expensive to develop compared to the market opportunity. Third-party payers trying to limit health-care expenses may become less willing to support their per-unit cost. Also for the research and development of drugs relating to rare diseases, we produce relatively small amounts of material at early stages. Even if a product candidate receives all necessary approvals for commercialization, we may not be able to successfully scale-up production of the product material at a reasonable cost or at all. In addition, we may not receive additional manufacturing approvals in sufficient time to meet product demand.

All these risks could affect our business, results of operations or financial condition.

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

Emerging Markets have been identified as one of our growth platforms and 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.

For example, in 2013, our sales in Emerging Markets continued to grow but at a slower pace. The significant expansion of our activities in Emerging Markets may further expose us to more volatile economic conditions, political instability, competition from companies that are already well established in these markets, the inability to adequately respond to the unique characteristics of these 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," above)), and compliance issues including corruption and fraud (see " Claims and investigations relating to competition law, marketing practices, pricing, compliance, as well as other legal matters, could adversely affect our business, results of operations and financial condition " above).

Our strategic objectives may not be fully realized.

Our strategy is focused on four pillars in order to deliver sustainable long-term growth and maximize shareholder returns: grow a global healthcare leader with synergistic platforms, 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.

For example, our strategy involves concentrating efforts around identified growth platforms and meeting significant growth objectives. There is no guarantee that we will meet these objectives or that these platforms will grow in line with anticipated growth rates. A failure to continue to expand our business in targeted growth platforms could affect our business, results of operations or financial condition.

As a further example, we are pursuing a Group-wide cost savings program by 2015. There is no assurance that the Group will successfully realize this program which could materially and adversely affect our financial results.

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.

Table of Contents

These operating risks can cause personal injury, property damage and environmental contamination, and may result in:

the shutdown of affected facilities; and

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, we cannot assure you that this insurance will be adequate to cover fully all potential hazards incidental to our business.

Environmental liabilities and compliance costs 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 Health, Safety and Environment (HSE)" for additional information regarding our environmental policies. In particular, our provisions for these obligations may be insufficient if the assumptions underlying these provisions prove incorrect or if we are held responsible for additional, currently undiscovered contamination. These judgments and estimates may later prove inaccurate, and any shortfalls could have a material adverse effect on our results of operations and financial condition.

Furthermore, we are or may become involved in claims, lawsuits and administrative proceedings relating to environmental matters. Some current and former Sanofi's subsidiaries have been named as "potentially responsible parties" or the equivalent under the U.S. Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended (also known as "Superfund"), and similar statutes in France, Germany, Italy, Brazil and elsewhere. As a matter of statutory or contractual obligation, we and/or our subsidiaries may retain responsibility for environmental liabilities at some of the sites of our predecessor companies, or our subsidiaries that we demerged, 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 costs 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 Health, Safety and Environment (HSE)."

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

Edgar Filing: Sanofi - Form 20-F

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

Table of Contents

and production capacity. As a result, our operations 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 countries. In 2013, 32% of our net sales were realized in the United States, 33% in emerging countries and 8% 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 do 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 them, the depository 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 depository how to vote their shares. Because of this extra procedural step involving the depository, the process for exercising voting rights will take longer for holders of ADSs than for holders of shares. ADSs for which the depository does not receive timely voting instructions will not be voted at any meeting.

French tax legislation applicable to the ADSs may affect their attractiveness.

The implementation of tax legislation such as the French financial transaction tax of 0.2% (*Taxe sur les Transactions Financières* - TTF) enacted in 2012 (see "Item 10. E. Taxation"), which applies by its terms to trading in our shares and ADSs without regard to territoriality could increase the costs linked to the issuance, transfer and cancellation of ADSs. Moreover, uncertainties regarding how such a tax is assessed and collected from beneficial owners or financial intermediaries outside of France could negatively impact such instruments.

We cannot foresee the extent to which this tax and uncertainty over its technical and practical aspects may reduce the liquidity and economic value of our ADSs.

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

As of December 31, 2013, L'Oréal held approximately 8.93% of our issued share capital, accounting for approximately 16.17% of the voting rights (excluding treasury shares) of Sanofi. See "Item 7. Major Shareholders and

(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

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 heightened 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.

To our knowledge, L'Oréal 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 to it. 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.

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 U.S. regulatory approval of Lemtrada (alemtuzumab for treatment of multiple sclerosis), and on achievement of certain aggregate net sales thresholds. 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 the milestones specified in the CVR agreement are not achieved for any reason within the time periods specified therein, and if net sales do not exceed the thresholds set forth in the CVR agreement for any reason within the time periods specified therein, no payment will be made under the CVRs and the CVRs will expire without value;

since the U.S. federal income tax treatment of the CVRs is unclear, any part of any CVR payment could be treated as ordinary income and required to be included in income prior to the receipt of the CVR payment;

any payments in respect of the CVRs rank at parity with our other unsecured unsubordinated indebtedness;

we are not prohibited from acquiring the CVRs, whether in open market transactions, private transactions or otherwise and we have already purchased CVRs on several occasions (for more information see "Item 5. Operating and Financial Review and Prospectus Liquidity.");

we may, under certain circumstances, purchase and cancel all outstanding CVRs; and

Edgar Filing: Sanofi - Form 20-F

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 first milestone was not met and, following the Complete Response Letter received from the FDA in December 2013, the milestone of U.S. approval will not be met. 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

We are a global healthcare company focused on patient needs and engaged in the research, development, manufacture and marketing of healthcare products. In 2013, our net sales amounted to €32,951 million. We are the third largest pharmaceutical group in the world and the second largest pharmaceutical group in Europe. Sanofi is the parent of a consolidated group of companies. A list of the principal subsidiaries included in this consolidation is shown at Note F. to our consolidated financial statements included at Item 18 of this annual report.

The Sanofi 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).

In parallel, the Group operates through seven growth platforms (see "B. Business Overview – Strategy" below): Emerging Markets⁽¹⁾, Diabetes Solutions, Vaccines, Consumer Health Care (CHC), Animal Health, Genzyme, and Other Innovative Products⁽²⁾. Unlike the other growth platforms, the Vaccines and Animal Health growth platforms are also operating segments within the meaning of IFRS 8. The Diabetes Solutions, CHC, Genzyme, and Other Innovative Products growth platforms are units whose performance is monitored primarily on the basis of their net sales; the products they sell and their related activities are part of our Pharmaceuticals segment. The Emerging Markets growth platform is a unit whose performance is monitored primarily on the basis of its net sales; the products it sells are derived from all three of our principal activities: Pharmaceuticals, Human Vaccines and Animal Health. For an analysis of the net sales of our growth platforms in 2013 and 2012, refer to "Item 5. Results of Operations – Year Ended December 31, 2013 Compared with Year Ended December 31, 2012".

In our Pharmaceuticals activity, which generated net sales of €27,250 million in 2013, our major product categories are:

Diabetes Solutions: our main products are Lantus®, a long-acting analog of human insulin which is the leading brand in the insulin market; Amaryl®, an oral once-daily sulfonylurea; Apidra®, a rapid-acting analog of human insulin; Insuman®, a range of human insulin solutions and suspensions; Lyxumia®, a once-daily prandial GLP-1 receptor agonist; and BGStar®, iBGStar® and MyStar Extra , blood glucose meters.

Rare Diseases: our principal products are enzyme replacement therapies: Cerezyme® to treat Gaucher disease, Myozyme®/Lumizyme®, to treat Pompe disease, Fabrazyme®, to treat Fabry disease, and Aldurazyme®, to treat mucopolysaccharidosis Type I (MPS I).

Multiple sclerosis (MS): our MS franchise consists of Aubagio®- a once daily, oral immunomodulator and Lemtrada , a humanized monoclonal antibody that selectively targets CD52. Both products have been developed to treat patients with relapsing forms of MS.

Rare Diseases and MS are the therapeutic areas of the "Genzyme" growth platform.

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

Other prescription products: our 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 agent, and Aprovei®/CoAprovei®, two hypertension treatments. Our renal business includes Renewel®/Renvela®, oral phosphate binders used in patients with chronic kidney disease (CKD) on dialysis to treat high

Edgar Filing: Sanofi - Form 20-F

phosphorus levels. Our biosurgery business includes Synvisc® and Synvisc-One®, viscosupplements used to treat pain associated with osteoarthritis of certain joints.

Our global pharmaceutical portfolio also includes a wide range of products in CHC, a category in which we have become the third largest player in terms of global sales, and other prescription drugs including generics.

-
- (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) *"Other Innovative Products" covers new product launches which do not belong to the other growth platforms listed: Multaq®, Jevtana®, Auvi-Q , Mozobil® and Zaltrap®.*

Table of Contents

Sanofi Pasteur is a worldwide leader in the vaccine industry. Its net sales amounted to €3,716 million in 2013, 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's leading animal healthcare companies, dedicated to the research, development, manufacture and delivery of innovative pharmaceuticals and vaccines used by veterinarians, farmers and pet owners and providing a comprehensive line of products to enhance the health, well-being and performance of a wide range of production and companion animals. The net sales of Merial amounted to €1,985 million in 2013.

Partnerships are essential to our business, and many of our products on the market or in development have been in-licensed from third parties or rely on third party technologies and rights.

In the description of our business activities below, the following should be kept in mind:

A drug can be referred to either by its international non-proprietary name (INN) or by its brand name, which is normally exclusive to the company that markets it. In most cases, our brand names, which may vary from country to country, are protected by trademark registrations. In general, we have chosen in this annual report to refer to our products by the brand names we use in France, except for Allegra® (sold in France as Telfast®), Tritace® (sold in France as Triatec®), Amaryl® (sold in France as Amarel®), Eloxatin® (sold in France as Eloxatine®), Ambien® CR (an extended-release formulation of zolpidem tartrate, not sold in France), and Thymoglobulin® (sold in France as Thymoglobuline®).

For our pharmaceutical activity, except where otherwise stated, all market share percentages and rankings are based on full-year 2013 sales figures from IMS Health MIDAS (retail and hospital).

For the vaccines activity, market shares 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, market shares and rankings are based on sales data from Vetnosis.

A. History and Development of the Company

We are present in approximately 100 countries on five continents with 112,128 employees at year end 2013.

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.

History of the Company

The Group has more than a century of experience 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.

Important Corporate Developments since 2009

Starting in 2009, Sanofi began a strategy of targeted acquisitions to become a diversified healthcare company, and created or strengthened various platforms including CHC and Generics.

Edgar Filing: Sanofi - Form 20-F

In 2009, we acquired Zentiva, a Prague-based branded generics group and Medley, a leading generics company in Brazil;

On February 9, 2010, Sanofi successfully completed its tender offer for all outstanding shares of common stock of Chattem, Inc., a leading U.S. consumer healthcare company;

In 2011, Merial became Sanofi's dedicated Animal Health division. Merial was founded in 1997 for animal health activities, and was initially a joint venture in which we and Merck & Co. Inc. (Merck) each held 50%. On September 17, 2009, we acquired Merck's entire interest in Merial. See Note D.2. to our consolidated financial statements included at Item 18 of this annual report; and

Table of Contents

On April 4, 2011, following a tender offer, Sanofi acquired Genzyme Corporation, a leading biotechnology group headquartered in Cambridge, Massachusetts and specializing in the treatment of rare diseases, renal diseases, endocrinology, oncology and biosurgery. The agreement is described at "Item 10. Additional Information C. Material Contracts".

B. Business Overview

B.1. Strategy

Sanofi is a global healthcare leader offering solutions across areas of core historical strength and multiple growth platforms. Like other groups active in the pharmaceutical industry, we have been facing competition from generics for several of our major products, in an environment subject to cost containment pressures from both third party payers and healthcare authorities. We responded to these major challenges by implementing a strategy with the objective of repositioning Sanofi for more stable and sustainable revenue and earnings growth. Over the past several years, we have transformed the Group by decreasing our reliance on existing "blockbuster" medicines (medicines with over \$1 billion in global sales), optimizing our approach to research and development (R&D), increasing our diversification, and investing in seven growth platforms (Emerging Markets, Diabetes Solutions, Vaccines, CHC, Animal Health, Genzyme, and Other Innovative Products). We regularly review our strategy and its implementation, and are continuing to execute our strategy along four prongs:

Growing a global healthcare leader with synergistic platforms

Our ambition is to offer an integrated set of businesses within the healthcare space with opportunities to create synergies across activities both upstream at the R&D level and downstream in the market place.

Bringing innovative products to market

We regularly review our R&D portfolio in order to improve the allocation of our resources. Our decision making processes integrate commercial potential and scope for value creation into our development choices. The result is an ongoing rationalization and optimization of our portfolio allowing us to focus on high-value projects and, when appropriate, reallocate part of our resources from internal infrastructure to partnerships and collaborations. We have redesigned our R&D footprint, including increasing our presence in the Boston, Massachusetts area (United States) with its concentration of universities and innovative biotechnology companies. Our R&D is based on an organizational structure focused on patient needs and encouraging entrepreneurship. This network based organization, open to external opportunities, enables our R&D portfolio to more effectively capitalize on innovation from a wide range of sources.

In line with this policy, we signed new alliance and licensing agreements in 2013 to give us access to new technologies, and/or to broaden or strengthen our existing fields of research. We have also made progress on our objective of offering more products that add value for patients, with, in 2013, seven approvals of new products and two projects in registration. We expect nine potential filings of late-stage projects between now and the end of 2018.

Seizing value enhancing growth opportunities

Business development remains an integral and disciplined pillar of our overall strategy, targeting acquisitions and alliances that create and/or strengthen platforms for long-term growth and create value for our shareholders. Since January 2009, we have invested a total of approximately €24 billion in external growth. During 2013, we pursued this targeted policy, announcing 13 new transactions, including 1 acquisition and 12 R&D alliances. Pursuit of this strategy in 2013 led to the signature in January 2014 of a collaboration with Alnylam for the development of products for rare genetic diseases, and of an amendment of our investor agreement with Regeneron.

In the years to come, we expect our sound financial position to provide us the potential to create value through external growth opportunities and to strengthen our diversification and growth platforms through new acquisitions and partnerships. We will remain financially disciplined, within the aims of our business development activities, so that we can execute strategically important transactions and partnerships that deliver a return on investment in excess of our cost of capital.

Adapting our structure for future opportunities and challenges

Edgar Filing: Sanofi - Form 20-F

We have adapted our operating model, previously focused on the best-selling prescription drugs in our traditional markets, to a broader set of products and services that better reflect the diversity of our activities and our

Table of Contents

geographical reach. In particular, we have tailored our strategy, structure and product offering to each region's needs, so as to deliver the most appropriate solution to each patient. The result is a dramatic shift in business mix from our top 15 products to key growth platforms. In 2008, 61% of our sales originated from our top 15 products while in 2013, 72.5% of our sales were generated by our growth platforms. In addition, 33.3% of our 2013 sales were in Emerging Markets, where we have enhanced our offerings in high growth segments such as Generics and CHC.

We have also realigned our industrial capacity to reflect our expectation of changes in volumes and our analyses of growth opportunities. Combined with the streamlining of our R&D structures and tight control over selling, general and administrative expenses, this has helped us successfully navigate a period in which many of our leading products faced the loss of patent exclusivity protection, in a tougher economic environment with new healthcare cost containment measures in many markets.

B.2. Main Pharmaceutical Products

Within our Pharmaceuticals business, we focus on the following therapeutic areas: diabetes solutions, rare diseases, MS, and oncology. We also have flagship products in such fields as anti-thrombotics, cardiovascular, renal and biosurgery and have developed leading businesses in CHC and Generics.

The sections that follow provide additional information on the indications and market position of our key 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 following table sets forth the net sales of our main pharmaceutical products for the year ended December 31, 2013.

Therapeutic Area / Product Name	2013 Net Sales (€ million)	Drug Category / Main Areas of Use
Diabetes Solutions		
Lantus® (insulin glargine)	5,715	Long-acting analog of human insulin Type 1 and 2 diabetes mellitus
Amaryl® (glimepiride)	375	Sulfonylurea Type 2 diabetes mellitus
Apidra® (insulin glulisine)	288	Rapid-acting analog of human insulin Type 1 and 2 diabetes mellitus
Insuman® (insulin)	132	Human insulin (rapid and intermediate acting) Type 1 and 2 diabetes mellitus
Lyxumia® (lixisenatide)	9	GLP-1 receptor agonist Type 2 diabetes mellitus
Rare Diseases		
Cerezyme® (imiglucerase for injection)	688	Enzyme replacement therapy Gaucher disease
Myozyme®/Lumizyme® (alglucosidase alpha)	500	Enzyme replacement therapy Pompe disease
Fabrazyme® (agalsidase beta)	383	Enzyme replacement therapy Fabry disease
Aldurazyme® (laronidase)	159	Enzyme replacement therapy Mucopolysaccharidosis Type I
Multiple Sclerosis		
Aubagio® (teriflunomide)	166	Oral immunomodulating agent MS
Lemtrada (alemtuzumab)	2	Humanized monoclonal antibody targeting CD52 antigen MS
Oncology		
Taxotere® (docetaxel)	409	Cytotoxic agent Breast cancer Non small cell lung cancer Prostate cancer Gastric cancer Head and neck cancer
Jevtana® (cabazitaxel)	231	Cytotoxic agent Prostate cancer
Eloxatin® (oxaliplatin)	221	Cytotoxic agent Colorectal cancer
Thymoglobulin® (anti-thymocyte globulin (rabbit))	198	Polyclonal anti-human thymocyte antibody preparation Acute rejection in organ transplantation Aplastic anemia Graft-versus-Host Disease
Mozobil® (plerixafor)	101	Hematopoietic stem cell mobilizer Hematologic malignancies
Zaltrap® (aflibercept)	53	Recombinant fusion protein Oxaliplatin resistant metastatic colorectal cancer

Table of Contents

Therapeutic Area / Product Name	2013 Net Sales (€ million)	Drug Category / Main Areas of Use
Other Prescription Drugs		
Plavix® (clopidogrel bisulfate)	1,857	Platelet adenosine disphosphate receptor antagonist Atherothrombosis Acute coronary syndrome with and without ST segment elevation
Lovenox® (enoxaparin sodium)	1,703	Low molecular weight heparin Treatment and prevention of deep vein thrombosis Treatment of acute coronary syndromes
Aprovel® (irbesartan) / CoAprovel® (irbesartan & hydrochlorothiazide)	882	Angiotensin II receptor antagonist Hypertension
Renagel® (sevelamer hydrochloride) / Renvala® (sevelamer carbonate)	750	Oral phosphate binders High phosphorus levels in patients with chronic kidney disease (CKD) on dialysis
Allegra® (fexofenadine hydrochloride)	406 ⁽¹⁾	Anti-histamine Allergic rhinitis Urticaria
Depakine® (sodium valproate)	405	Anti-epileptic Epilepsy
Stilnox® / Ambien® / Myslee® (zolpidem tartrate)	391	Hypnotic Sleep disorders
Synvisc® / Synvisc-One® (hylan G-F 20)	371	Viscosupplements Pain associated with osteoarthritis of the knee
Multaq® (dronedarone)	269	Anti-arrhythmic drug Atrial Fibrillation (AF)
Actonel® (risedronate sodium)	100	Biphosphonate Osteoporosis Paget's disease
Auvi-Q	51	Adrenalin auto-injector Emergency treatment of allergic reactions
Consumer Health Care		
Total	3,004	
Generics		
Total	1,625	

(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 authorisation in Europe for Lyxumia®, a once-daily prandial GLP-1 receptor agonist.

Lantus®

Edgar Filing: Sanofi - Form 20-F

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 and with type 1 diabetes mellitus.

Table of Contents

Lantus® is the most studied basal insulin with over 10 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® is a pre-filled disposable pen available in over 120 countries worldwide. It is the only disposable pen that combines a low injection force, up to 80 units per injection, and ease-of-use;

ClikSTAR® is a reusable insulin pen first approved in 2009 in the European Union and Canada. It is now available in more than 30 countries worldwide; and

AllSTAR® is the first state-of-the-art, re-usable insulin pen developed especially 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.

Lantus® is the world number-one selling insulin brand in terms of both sales and units (source: IMS, 2013 sales) and is available in over 120 countries worldwide. The leading countries for sales of Lantus® in 2013 were the United States, France, China, and Japan.

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.

A number of generics have received marketing authorization and have been launched in Europe, 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 diabetes, or in type 2 diabetes for supplementary glycemic control. Apidra® has a more rapid onset and shorter duration of action than fast-acting human insulin and can be used in combination with long-acting insulins such as Lantus® for supplementary glycemic control at mealtimes. Apidra® can be administered subcutaneously using syringes or specific pens including the Apidra® SoloSTAR® disposable pen and the ClikSTAR® reusable pen.

Apidra® is available in over 100 countries worldwide.

Insuman®

Insuman® (human insulin) is a range of insulin solutions and suspensions for injection and is indicated for diabetes patients where treatment with insulin is required. Human insulin is produced by recombinant DNA technology in Escherichia coli strains. Insuman® is supplied in vials, cartridges, pre-filled disposable pens (OptiSet® and SoloSTAR®), or reusable pens (ClickSTAR®). The Insuman® range is comprised of rapid-acting insulin solutions (Insuman® Rapid and Insuman® Infusat) that contain soluble insulin, an intermediate-acting insulin suspension (Insuman® Basal) that contains isophane insulin, and combinations of fast-acting and intermediate-acting insulins in various proportions (Insuman® Comb).

Insuman® is principally sold in Germany and in Emerging Markets.

Table of Contents

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® throughout the European Union. Applications for regulatory approval have also been submitted in several other countries around the world and are being reviewed. Lyxumia® has also been approved for use in Australia, Brazil, Colombia, Chile, Ecuador, Japan, and Mexico.

The FDA application was withdrawn in September 2013, to avoid the potential risk that public disclosure of interim data 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.

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 with respect to the diabetes management experience for people with diabetes as well as healthcare providers. These blood glucose monitoring solutions are exclusive to Sanofi and are designed to be synergistic with the rest of its 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:

iBGStar® is the first blood glucose meter that seamlessly connects to the iPhone and iPod touch. It comes with the iBGStar® Diabetes Manager Application (DMA), allowing patients to capture and analyze diabetes-related information on the go, simplifying their daily diabetes management.

BGStar® integrates convenient, accurate, and easy-to-use blood glucose management with decision-making support services.

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.

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

MyStar Extra launched in October 2013 is available in Italy and Spain. BGStar® and iBGStar® are available in France, Germany, Spain, Italy, the Netherlands, Switzerland, Belgium, Luxembourg, Canada, Estonia, Australia, the UK and the Philippines.

b) Rare Diseases

The acquisition of Genzyme in 2011 brought to the Group specific expertise in rare diseases, a sector where there are still many unmet needs, and expanded Sanofi's 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.

Table of Contents

Cerezyme® is the only therapy with an 18-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.

Myozyme® / Lumizyme®

Myozyme® / Lumizyme® (α-glucosidase 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 E.U. and is currently available in 48 markets worldwide. Lumizyme® has been marketed since June 2010. It is the first treatment approved in the United States specifically to treat patients with late-onset Pompe disease and patients over eight years of age without evidence of cardiac hypertrophy.

Myozyme® and Lumizyme® are administered by intravenous infusion. Both products are a recombinant form of the same human enzyme but are manufactured using different sized bioreactors.

Fabrazyme®

Fabrazyme® (β-galactosidase beta) is an enzyme replacement therapy used to treat Fabry disease, an inherited, progressive and potentially life-threatening LSD. Fabry disease is estimated to affect between 5,000 and 10,000 people worldwide. Fabrazyme® is administered by intravenous infusion.

Fabrazyme® is available in over 30 countries, including the United States and Europe.

In 2013, Fabrazyme® continued to increase market share and accrue new patients.

Aldurazyme®

Aldurazyme® (laronidase) 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)

The Multiple Sclerosis activity is focused on the development and commercialization of therapies to treat this chronic autoimmune disease of the central nervous system (CNS). More than 2 million people suffer from MS worldwide. The MS franchise consists of Aubagio® (teriflunomide), a once daily, oral immunomodulator, and Lemtrada® (alemtuzumab), a monoclonal antibody. Both products have been developed to treat patients with relapsing forms of MS.

Aubagio®

Aubagio® (teriflunomide), a small molecule immunomodulatory agent with anti-inflammatory properties, reversibly inhibits dihydroorotate dehydrogenase, a mitochondrial enzyme involved in 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. In April 2013, top-line results were reported from the TOPIC trial, which was designed to assess whether early initiation of Aubagio® in patients who experienced their first neurological symptoms consistent with Clinically Isolated Syndrome (CIS) could prevent or delay conversion to clinically definite multiple sclerosis (CDMS). In the TOPIC trial, patients receiving Aubagio® 14 mg and 7 mg were

Table of Contents

significantly less likely to develop CDMS, defined as occurrence of a second clinical attack, the primary endpoint, as compared to placebo.

Aubagio® was approved in the United States and Australia in 2012 for patients with relapsing forms of MS. In August 2013, Aubagio® was approved in the EU for the treatment of adult patients with relapsing remitting multiple sclerosis. The product was also approved during 2013 in Argentina, Chile, Mexico, New Zealand, South Korea and Switzerland, and is under review by additional regulatory agencies around the world.

Lemtrada

Lemtrada (alemtuzumab) is a humanized monoclonal antibody targeting CD52 antigen abundant on the surface of B and T lymphocytes leading to changes in the circulating lymphocyte pool. Alemtuzumab has been developed to treat patients with relapsing forms of MS. In March 2013, interim results from the first year of the extension study of the CARE MS studies were presented at the annual meeting of the American Academy of Neurology. 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 third year of follow-up (first year of the extension study), relapse rates and sustained accumulation of disability remained low. Approximately 80 percent of patients did not receive further treatment with Lemtrada during the first year of the extension study and less than 2% received another MS treatment.

In September 2013, Lemtrada was granted marketing authorization in the E.U. for treatment of adult patients with relapsing forms of MS with active disease defined by clinical or imaging features. Lemtrada was also approved by regulatory authorities in Canada and Australia during the fourth quarter of 2013. In December 2013, Genzyme received a Complete Response Letter from the FDA for its supplemental Biologics License Application seeking approval of Lemtrada for the treatment of relapsing forms of MS. A Complete Response Letter informs companies that an application is not ready for approval. Genzyme is preparing the appeal of the FDA's decision. Additional marketing applications for Lemtrada are under review by regulatory agencies around the world.

d) Oncology

Sanofi has started to diversify its presence in the oncology field beyond chemotherapy (Taxotere®, Jevtana®, Eloxatin®), Thymoglobulin® and Mozobil®, and launched an angiogenesis inhibitor, Zaltrap®, in 2012 in the U.S. and in 2013 in the E.U.

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 and resulting, ultimately, in death in 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 (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 2013 were the United States, Japan, China and Russia. Generics of docetaxel were launched at the end of 2010 in Europe, in April 2011 in the U.S., and in December 2012 in Japan (see " Patents, Intellectual Property and Other Rights" below).

Jevtana®

Jevtana® (cabazitaxel) is a taxane derivative 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.

Table of Contents

Jevtana® was launched in the United States in 2010. Jevtana® therapy is now covered by CMS (Committee for Medicare and Medicaid Services), and by most of the private insurance companies that pay for oncology care. In addition, the safety profile observed in clinical practice has been consistent with that seen in the pivotal TROPIC study.

In March 2011, Jevtana® received marketing authorization from the European Commission. The product was launched during the second quarter of 2011 in Germany and the UK. Jevtana® is now approved in over 80 countries. Regulatory approval in Japan is ongoing and anticipated in June 2014.

Sanofi has initiated a broad development program with Jevtana®. The clinical program is projected to evaluate Jevtana® in first- and second-line treatment of prostate cancer patients, and pediatric patients with brain cancer.

The main countries contributing to sales of Jevtana® in 2013 were the U.S., Germany, France, the UK, and Italy.

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. The top three countries contributing to sales of Eloxatin® in 2013 were Canada, China, and South Korea. In the second quarter of 2013, Eloxatin® received regulatory approval for advanced Hepatocellular Carcinoma (HCC) in China.

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 on August 9, 2012. Several generics of oxaliplatin are available globally, except in Canada where Eloxatin® still has exclusivity.

Thymoglobulin®

Thymoglobulin® (Anti-thymocyte Globulin (Rabbit)) 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 2013 were the U.S., France, China, and Japan. Thymoglobulin® was launched in Russia in May 2013.

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 2013 were the U.S., Germany, France, the U.K. and Italy.

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.

Table of Contents

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

In the 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.

Zaltrap® was also approved in Australia, Ecuador, Israel, South Korea, Switzerland and Taiwan. Marketing authorization application dossiers are under review in several other countries worldwide.

The main countries contributing to sales of Zaltrap® in 2013 were the U.S., Germany, and the UK.

The marketing of Zaltrap® is organized through our collaboration with Regeneron (see "Item 5 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 long-term 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 secondary prevention of atherothrombosis regardless of the location of the arteries initially affected (heart, brain, lower limbs). Plavix® is now also 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.

In 2011, on the basis of the ACTIVE A study results (7,554 patients), the EMA granted marketing authorization for Plavix® in combination with ASA for the prevention of atherothrombotic and thromboembolic events, including stroke, in patients with Atrial Fibrillation (AF) who have at least one risk factor for vascular events, are not suitable for treatment with Vitamin K antagonists (VKA), and have a low bleeding risk.

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.

The marketing of Plavix® / CoPlavix® / DuoPlavin® is organized through our alliance with Bristol-Myers Squibb (BMS) which was restructured in 2012 and effective on January 1, 2013 (see "Item 5 Alliance Arrangements with Bristol-Myers Squibb"). Sanofi's sales of Plavix® in Japan are outside the scope of our alliance with BMS. A number of generics have been launched in Europe, in the U.S. and other markets.

Plavix® is the leading anti-platelet in the Chinese and Japanese markets.

Lovenox® / Clethane®

Lovenox® (enoxaparin sodium) is available in over 100 countries. It has been used to treat over 350 million patients since its launch.

Lovenox® has the broadest range of indications amongst low molecular weight heparins (LMWH). A comprehensive clinical development plan has demonstrated the efficacy and safety of Lovenox® in the prevention and treatment of venous thrombo-embolism (VTE) and in the management of the full spectrum of acute coronary syndromes (ACS).

In VTE management, Lovenox® is continuing to grow as a treatment for the prevention of VTE, mainly in acutely ill patients not undergoing surgery.

Table of Contents

Two generics of enoxaparin and our authorized generic of Lovenox® are available in the U.S. No biosimilar has been approved in the European Union. See "Item 5. Operating and Financial Review and Prospects Impacts from generic competition".

In 2013, Lovenox® was the leading anti-thrombotic in Germany, France, Italy, Spain, and the United Kingdom.

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.

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 who are likely to need multiple drugs to achieve their blood pressure goals (in the United States only).

Aprovel® and CoAprovel® are marketed in more than 80 countries. The marketing of Aprovel® and CoAprovel® is organized through an alliance with BMS which was restructured in 2012 (see "Item 5 Alliance Arrangements with Bristol-Myers Squibb" below). In Japan, the product is licensed to Shionogi Co. Ltd and sub-licensed Dainippon Sumitomo Pharma Co. Ltd.

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 E.U. and 65,000 in Brazil. In the E.U., Renvela® is also approved to treat CKD patients not on dialysis.

We market Renagel® and Renvela® directly to nephrologists through Sanofi's employee sales force and distribute these products through wholesalers and distributors. In Japan and several Pacific Rim countries, Renagel® is marketed by Chugai Pharmaceutical Co., Ltd and its sublicensee, Kyowa Hakko Kirin Co., Ltd.

In the United States, as part of an amendment to the ANDA settlement, Sanofi has agreed to grant Impax a license to sell a specific allotment of bottles of an authorized generic version of Renvela® tablets on April 16, 2014. The specific allotment corresponds to 7-10% of the total 2013 sevelamer sales in the United States. This amendment does not change Sanofi's prior settlement agreement with Impax to sell generic versions of two other sevelamer products, Renvela® for oral suspension and Renagel®, starting on September 16, 2014, which is conditioned on their receiving FDA ANDA approval.

The top five countries contributing to the sales of Renagel® and Renvela® in 2013 were the U.S., France, Italy, Brazil, and UK.

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 for the treatment of uncomplicated hives. It offers patients significant relief from allergy symptoms without causing drowsiness.

Table of Contents

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 "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").

Depakine®

Depakine® (sodium valproate) is a broad-spectrum anti-epileptic that has been prescribed for more than 40 years. Numerous clinical trials and long years of experience have shown that it is effective for most forms of epilepsy, and that it is generally well tolerated. Consequently, Depakine® remains a reference treatment for epilepsy worldwide.

Depakine® is also a mood stabilizer, registered in numerous countries in the treatment of manic episodes associated with bipolar disorder and in the prevention of mood episodes.

We provide a wide range of formulations of Depakine® enabling it to be adapted to most types of patients: syrup, oral solution, injection, enteric-coated tablets, Depakine® Chrono (a sustained release formulation in tablets), and Depakine® Chronosphere (sustained release formulation of Depakine® packaged in sachets, facilitating its use by children, the elderly and adults with difficulties swallowing).

Depakine® is marketed in over 100 countries, and is generally subject to generic competition.

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 June 2012.

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 2013, the top countries contributing to Synvisc® and Synvisc-One® sales were the U.S., France, Mexico, Canada, Japan, and Brazil.

Multaq®

Multaq® (dronedaron) is the most extensively studied anti-arrhythmic drug (AAD) in 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.

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/Atrial Flutter.

The main countries contributing to Multaq® sales in 2013 were the U.S., Germany and Spain.

Actonel®

Actonel® (risedronate sodium) is a bisphosphonate used for the treatment of osteoporosis and Paget's disease. The product is marketed through an alliance with Warner Chilcott (see note C-3 to our consolidated financial statements).

Auvi-Q

At the end of January 2013, Sanofi launched Auvi-Q (epinephrine injection, USP), in the U.S. Auvi-Q is the first-and-only epinephrine auto-injector with audio and visual cues 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 for anaphylaxis, although the precise incidence is unknown and likely underreported.

Sanofi US licensed the North American commercialization rights to Auvi-Q from Intelliject, Inc.

f) Consumer Health Care (CHC)

Consumer Health Care is a growth platform in our global strategy. In 2013, we set up a Global Consumer Health Care Division, to identify development priorities more proactively and co-ordinate international delivery on these priorities. The division is focused on 6 key categories: Anti-Allergics, Analgesics, Cough and Cold Remedies, Digestive System Products, Feminine Hygiene Products, and Vitamins, Minerals & Supplements (VMS). This new global division, which is being rolled out from the start of 2014, will direct the growth of our CHC activities over the coming years.

In 2013, our CHC sales reached €3,004 million, up 5.2% year-on-year; nearly half of these sales were generated in Emerging Markets, 22% in Western Europe, and 21% in the United States.

In the U.S., mid-September 2013 saw the relaunch of the Rolaid® brand, that we had acquired at the start of the year from McNeil Consumer Healthcare®. An antacid sold over-the-counter through all American distribution channels, Rolaid® is now once again available to the people who suffer from heartburn and acid reflux. Still in the U.S., we have obtained approval from the FDA in October 2013 for the over-the-counter sale of Nasacort® Allergy 24H, a nasal spray indicated for seasonal and perennial allergies of the upper respiratory tract (allergic rhinitis) in adults and in children aged two and over. Launched in February 2014 in the U.S., Nasacort® (triamcinolone) is the first and to date only treatment in its category to be available over-the-counter.

Growth during 2013 was also supported by our full range of CHC products, which give us a well-established presence in analgesics and the digestive system.

Doliprane® offers a range of paracetamol-based products for pain and fever. Thanks to a broad range of dosage options (from suspensions containing 2.4% paracetamol to 1-gram formulations) and pharmaceutical forms (suspensions, pills, powders, suppositories), Doliprane® meets 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 spasm, period pains and bladder spasm; it is sold mainly in Russia and Eastern Europe.

Enterogermina® is a probiotic, which is available as a drinkable suspension in 5-ml mini-bottles or in 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® has historically been sold in Europe, and is now enjoying strong growth in Latin America, India, Ukraine and Belarus.

Essentiale® is a plant-based product used in the treatment of liver problems. Composed of essential phospholipids extracted from highly purified soya, it is rich in phosphatidylcholine, a major component of cell membrane. Essentiale® is used to alleviate symptoms such as loss of appetite, oppression of the right

Table of Contents

epigastrium, food-related liver lesions and hepatitis. Essentiale® is sold mainly in Russia, Eastern Europe, various countries in South-East Asia and China.

Maalox® is a well-established brand that contains two antacids: aluminium hydroxide and magnesium hydroxide. Maalox® is available in various forms (pills, drinkable suspension, sachets), giving consumers a choice of suitable solutions. Initially launched in France in 1972, 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 (pre-menstrual stress and menopausal problems). Magne B6® is available in Europe and Russia.

The Lactacyd® range covers a number of intimate feminine hygiene products. Lactacyd® is sold primarily in Brazil and in Asia, where the range is enjoying growth driven by a number of new presentations.

In addition to these historical brands:

The principal products marketed by Chattem in the U.S. (apart from Allegra® OTC) are ACT®, Gold Bond®, Icy Hot®, Cortizone-10®, Selsun Blue® and Unisom®.

Oenobiol® products are food supplements with applications in beauty (sunscreen, slimming, haircare and skincare), wellbeing (digestive aids, anti-stress) and menopause, and are sold mainly in France.

In China, BMP Sunstone markets Haowawa® (which means "Good Baby" in Chinese), a leading brand of children's cough and cold remedies, alongside a portfolio of over-the-counter Western medicines and traditional Chinese remedies.

Also in China, Minsheng Pharmaceuticals Co. Ltd markets 21 Super Vita, one of the leading vitamin and mineral supplements in the local market.

Universal Medicare, a leading player in India, sells nutraceuticals and other products including vitamins, antioxidants, mineral supplements, and anti-arthritis products such as Seacod®, CoQ®10, Collaflex® and Multivit®. At the end of 2013, the marketing of Universal Medicare products was extended to Pakistan.

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

g) Generics

To reinforce its generics business, Sanofi created a global "Generics" division in October 2013. The main missions of this division are to:

pursue the alignment of the Generics Portfolio strategy and the coordination of the different Generics platforms;

drive Generics business performance through specific performance management indicators;

establish centers of reference in Generics-specific expertise and skills.

Edgar Filing: Sanofi - Form 20-F

In 2013, sales of the Generics business reached €1,625 million, a decrease of 11.9% from 2012 (8.2% at constant exchange rates). Performance was impacted by temporary difficulties with inventory levels in Brazil as well as by lower sales of Lovenox®, Aprovel® and Taxotere® authorized generics in the U.S.

During the second quarter of 2013, Sanofi became aware that distribution channels in Brazil were holding inventory in excess of the volumes needed to meet demand (see "Item 5. Operating and Financial Review and Prospects Results of Operations Year Ended December 31, 2013 Compared with Year Ended December 31, 2012." for further explanations). The re-order point was reached in August and sales have been improving progressively since that date.

In Latin America, Sanofi completed the acquisition of Genfar S.A., a leading Columbian pharmaceuticals manufacturer, headquartered in Bogota, Colombia, and expanded its leading presence in affordable quality pharmaceuticals.

In Europe, despite significant price pressure, sales of generics grew 4.7%, driven by strong volume performance overall, led by Western European countries such as France and Italy. However, increased volume did not totally compensate price pressure in Central and East European countries (such as the Czech Republic).

Table of Contents

Emerging Markets significantly contributed to the 2013 performance with remarkable growth in Russia and Africa, the expansion of Medreich products in Nigeria and increased antiretroviral business in South Africa.

B.3. Vaccine Products

Sanofi Pasteur, the vaccine division of Sanofi, offers a broad range of vaccines. In 2013, 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 €3,716 million. Sales were favorably impacted by record sales of influenza vaccines, especially in the United States, and strong growth in Emerging Markets. Nevertheless, 2013 sales were negatively impacted by Pentacel® and Adacel® supply delays due to manufacturing 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 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, Sanofi Pasteur MSD also distributes Merck vaccines, such as Gardasil® and Zostavax®. In 2013, Sanofi Pasteur MSD net sales amounted to €876 million.

Sanofi Pasteur is 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 " Vaccines Research and Development" below for a presentation of the Sanofi Pasteur R&D portfolio.

The table below lists net vaccine sales by product range:

<i>(€million)</i>	2013 Net Sales
Polio/Pertussis/Hib Vaccines	1,148
Influenza Vaccines	929
Meningitis/Pneumonia Vaccines	496
Adult Booster Vaccines	391
Travel and Other Endemic Vaccines	382
Other Vaccines	370
Total Human Vaccines	3,716

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 combination vaccine protecting against diphtheria, tetanus, pertussis, polio and *Haemophilus influenzae* type b (Hib), was first marketed in 1997. To date, more than 180 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 23 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 February 2013, the EMA recommended market approval for this hexavalent pediatric vaccine in the

Edgar Filing: Sanofi - Form 20-F

E.U., commercialized 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 10 countries have already included Hexaxim® in their public or private immunization programs.

Table of Contents

Pentacel®, a vaccine protecting against five diseases (diphtheria, tetanus, pertussis, polio and Hib) was launched in the U.S. in 2008. In 2013, supply issues were responsible for a delay in U.S. market delivery. These issues have now been resolved and supplies of Pentacel® have improved progressively from mid-October 2013.

Pediacel®, a fully liquid pentavalent vaccine, has been the standard of care in the United Kingdom since 2004 for 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. In 2008, Act-HIB® became the first Hib vaccine to be approved in Japan.

Quadracel® is a combination vaccine against diphtheria, tetanus, pertussis and polio. It is proposed 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 Phase III clinical study is currently underway in order to submit an application for the licensure of Quadracel® in the U.S..

Sanofi Pasteur is co-developing, with Merck, a combination vaccine (6-in-1 vaccine PR5i) designed to help protect against six diseases. This new vaccine will protect against diphtheria, tetanus, pertussis, polio, Hib and hepatitis B. Phase III clinical studies conducted in the U.S. and in Europe were concluded in 2013.

Sanofi Pasteur is one of the world's leading developers and manufacturers of polio vaccines, with both oral polio vaccines (OPV) and injectable polio vaccines (IPV) in its portfolio. Sanofi Pasteur is a preferred partner for the supply of OPV and IPV for the Global Polio Eradication Initiative led by the WHO and UNICEF. 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 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 polio immunization programs before the end of 2015. Consequently, Sanofi Pasteur expects the use of IPV to increase considerably in the coming five years. As a result, Sanofi Pasteur is expanding its production capacity to meet the growing demand.

Shantha Biotechnics (Shantha), in India, is currently pursuing requalification of Shan5 , a combination vaccine protecting against diphtheria, tetanus, pertussis, Hib and hepatitis B, with the WHO. Shantha has worked closely with Sanofi Pasteur to improve key manufacturing steps in the production of the antigen components of the vaccine. The path to obtaining prequalification status has been discussed extensively with the WHO and local Indian regulators. If ongoing clinical studies results are positive, Shan5® should regain WHO prequalification in 2014.

b) Influenza Vaccines

Sanofi Pasteur is a world leader in the production and marketing of influenza vaccines with over 200 million doses delivered in 2013. In recent years, influenza vaccine demand has experienced strong growth in many countries, particularly 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 wider government immunization recommendations.

Sanofi Pasteur remains focused on meeting the increasing demand for both pandemic and 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 new product launches:

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 65 or older. In August, 2013, top line results of a large scale study in people 65 or older showed a superior clinical benefit for Fluzone® High-Dose vaccine, compared to Fluzone® vaccine, in preventing influenza (Fluzone® High-Dose vaccine was 24% more effective than Fluzone vaccine). The strong sales growth registered by this new vaccine since its launch was confirmed in 2013.

Fluzone® ID (intradermal) continues its growth following its launch in the U.S. in 2012. The advantages of this vaccine are, in particular, its convenience and ease of administration. Fluzone ID® and Intanza®/IDflu® vaccines are now approved in Australia, Canada, the E.U., the U.S. and several other countries.

Edgar Filing: Sanofi - Form 20-F

Fluzone® QIV 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

Table of Contents

will provide increased protection against the most prevalent strains. In June 2013, Sanofi Pasteur obtained FDA authorization for Fluzone® QIV to be commercialized in the U.S. for children over 6 months, adolescents and adults.

Sanofi Pasteur recently made the decision to withdraw the QIV marketing authorization application submitted in Europe through a decentralized procedure, in order to update the pharmaceutical section at the request of the regulatory authorities. Sanofi Pasteur will take the opportunity of this update to extend the target group to children aged 36 months. A Phase III study will start in 2014 with the objective of providing the necessary data.

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 higher sales for this product group in recent years.

Adacel®, the first trivalent adolescent and adult booster 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 millions 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 too young to be immunized or only partially vaccinated. Adacel® is now registered in more than 60 countries.

Repevax® (also marketed under the trademark Adacel-Polio®) is a combination vaccine that provides all the benefits of Adacel® along with polio vaccine. This product is useful in those markets that recommend adolescent/adult immunizations to protect against both pertussis and polio. This vaccine is licensed in more than 30 countries.

d) Meningitis and Pneumonia Vaccines

Sanofi Pasteur is at the forefront in the development of vaccines to prevent bacterial meningitis. In 2005, Sanofi Pasteur introduced Menactra®, the first quadrivalent conjugate vaccine against meningococcal meningitis, considered by many as the deadliest form of meningitis in the world. In April, 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 other countries in Latin America, the Middle East and Asia Pacific regions.

Sanofi Pasteur is developing a second-generation 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.

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 serums are used in endemic settings in the developing world and are the basis of important partnerships with governments and organizations such as UNICEF. They are also used by travelers and military in endemic areas. Sanofi Pasteur is the leader in most of the world's travel and endemic vaccine markets.

In December, 2009, Shantha launched Shanchol , the first oral cholera vaccine for children and adults made in India. Shanchol received WHO prequalification in 2011, and in 2013 the WHO approved the creation of a stockpile of over 2 million doses.

IMOJEV®, a Japanese encephalitis vaccine, the most recent travel and endemic vaccines portfolio addition, was successfully launched in Australia and Thailand in December 2012, for use in individuals aged 12 months and over, and was then launched in 2013 in Malaysia and the Philippines. An extension of the indication to include children aged nine months and older has been submitted and is currently under approval in the Asia Pacific region.

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, is a strategic asset that enables us to be closer to our customers and better understand their needs, and to offer a broad product portfolio of both Sanofi Pasteur and non-group products.

Table of Contents

B.4. Animal Health: Merial

Our Animal Health activity is carried out through Merial, one of the world's leading animal healthcare companies (source: Vetnosis), dedicated to the research, development, manufacture and delivery of innovative pharmaceuticals and vaccines used by veterinarians, farmers, and pet owners. Merial provides a comprehensive range of products to enhance the health, well-being and performance of a wide range of production and companion animals. Its net sales for 2013 amounted to €1,985 million.

Merial became Sanofi's dedicated Animal Health division following the end of Sanofi and Merck's agreement to create a new animal health joint venture by combining their respective animal health segments in March 2011. See Note D.2. to our consolidated financial statements included at Item 18 of this annual report.

The Animal Health product range comprises four major segments: parasiticides, anti-infectious drugs, other pharmaceutical products (such as anti-inflammatory agents, anti-ulcerous agents, etc.), and vaccines. Merial's top-selling products include Frontline®, a topical anti-parasitic flea and tick brand for dogs and cats, the highest selling veterinary product in the world (source: Vetnosis); Heartgard®, a parasiticide for control of heartworm in companion animals; 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 cattle; and Circovac®, a PCV2 (porcine circovirus type 2) vaccine for swine. Merial plays a key role in the veterinary public health activities of governments around the world. It is the world leader in vaccines for Foot-and-Mouth disease (FMD), rabies, and bluetongue (BTV) (source: Vetnosis).

In 2013, Merial's antiparasiticide product range for companion animals was extended to include:

NexGard (afoxolaner), monthly beef flavored soft chewables for treatment and prevention of flea and tick infestations in dogs and puppies. The product was approved by the FDA in September 2013, by the EMA in February 2014, and launched in the U.S. in January 2014.

Broadline , a broad spectrum parasite treatment and prevention for cats sold throughout the European Union. Broadline is a combination of four active ingredients and helps protect cats for one month. The product was approved by the EMA in December 2013.

The compound patent protecting fipronil, the active ingredient of Frontline®, expired in 2009 in Japan and in some European countries, including France, Germany, Italy, and the United Kingdom, and in August 2010 in the United States. In those markets where the fipronil compound patent has expired, Frontline® products are generally still protected through formulation patents (directed to combinations) which expire in 2017 in Europe (August 2016 in the United States). Frontline® is also protected by a method of use patent in the United States and the European Patent area (Germany, France, Italy, and the United Kingdom), which expires in March 2018.

As with human pharmaceutical products, patent protection for animal pharmaceutical products extends in most cases for 20 years from the filing date of the priority application.

From a regulatory standpoint, in Europe veterinary products (pharmaceutical products and vaccines) enjoy eight-year regulatory exclusivity for data and a ten-year exclusivity period for commercialization.

In the United States, there is no exclusivity for animal vaccines. For animal pharmaceutical products, those approved by the Environmental Agency (EPA) enjoy ten-year regulatory exclusivity, with the possibility of obtaining an additional five-year period of exclusivity during which any generics products that cite the innovator's data must indemnify the innovator. For pharmaceutical products approved by the FDA, a five-year regulatory exclusivity period is granted for a new chemical entity, and a three-year period for a previously-approved active ingredient.

In June 2013, Merial finalized the acquisition of the animal health division of the Indian company Dosch Pharmaceuticals Private Limited, creating a market entry for Merial in that country's strategically important and growing animal health sector. Dosch Pharmaceuticals commercializes 86 products under 50 brands for ruminants, poultry and companion animals.

The 2013 performance of Merial was mainly affected by the decrease in Frontline® sales in the U.S. and in Europe, impacted by the cold weather conditions and increased competition. Sales from the rest of Merial's portfolio are increasing, mainly driven by the performance of avian products (notably Vaxxitek®) and the pet vaccine range.

Table of Contents

Merial's major markets are the United States, France, Brazil, Italy, the United Kingdom, Australia, Germany, Japan, Spain, China, and Canada. Emerging Markets now account for 30% of total Merial sales, with particularly strong growth in China (18% in 2013).

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 an integrated organization, encompassing a wide range of therapeutic areas that represent a large and growing burden on populations and healthcare systems, in line with global trends and the most pressing health needs.

These include:

Pharma activities (see Section 5.2. below)

Diabetes. Diabetes is a rapidly growing health problem in all parts of the world. The current global prevalence of diabetes is approximately 366 million and this number is expected to exceed half a billion people by 2030 (source: www.idf.org). Despite numerous therapeutic offerings, people with diabetes are at considerably higher risk of premature death and debilitating complications, impairing their quality of life and imposing massive costs on health care systems around the world.

Cardiovascular diseases. Despite medical advances, cardiovascular diseases account for the largest number of deaths worldwide. Today over 17 million annual deaths are attributable to cardiovascular diseases and because of an aging population and a global epidemic of metabolic disease these numbers are expected to double over the next 25 years (source: WHO 2008).

Oncology. Cancer remains a leading cause of death worldwide accounting for over 7 million deaths per year. Deaths from cancer are projected to continue to rise with over 13 million deaths projected in 2030 (source: WHO 2008). While progress has been made in some cancers, development of new therapies is desperately needed.

Immune mediated diseases (including MS). Immune disorders correspond to a dysfunction of the immune system leading to an over or an under activation of the system and can be characterized by whether the condition is congenital or acquired. More than 150 primary immunodeficiency congenital diseases have been identified and figures for the acquired diseases are even greater (source: International Union of Immunological Societies 2007).

Age-related degenerative diseases. The increasing proportion of older people in the global population is contributing to a rise in age-related degenerative diseases and has serious implications for health care systems. Care-givers, health systems and societies need to be ready to manage the growing needs of the elderly in every part of the world.

Infectious diseases. These create significant and critical unmet medical needs both in the developed and developing worlds. Hospital-acquired infections are a major concern for public health in industrialized countries. Every year in the United States, 1.7 million people fall victim to hospital-acquired bacterial infections. In low-income countries, mortality is predominantly due to infectious diseases such as lung infections, tuberculosis and malaria.

Rare diseases. Approximately 7,000 rare disorders are known to exist and new ones are discovered each year. Rare diseases affect between 25-30 million people in the United States, and about 30 million people in the European Union (source: European Organization for Rares Diseases).

Vaccines (see Section B.5.3. below).

Animal Health.

To carry out our mission, meet these challenges and maximize our impact we are striving to bring innovation to patients and to build a pipeline of high value projects.

Table of Contents

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.

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. The open innovation and large collaboration processes applied worldwide helped us to deliver the best and most innovative solutions for patients. By implementing new operating models to ensure optimal progress on our projects, especially during clinical development phases, we will improve our operational effectiveness and deliver the right therapeutic solutions to patients more quickly.

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.

Sanofi Pharma R&D, which is dedicated to the discovery and development of human medicines. This is a project-driven organization, consisting of two divisions (Diabetes and Oncology, a launch unit (PCSK9) and Therapeutic Strategic Units (TSUs), supported by Scientific Platforms, responsible for the operational aspects of R&D.

Genzyme R&D, which has strong expertise in rare diseases, is now fully integrated into Sanofi Pharma R&D.

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

Merial R&D, which aims to deliver and support effective, innovative, safe and cost-effective animal health products. Although the specifics of animal health are different from human health, there are many potential synergies opening up a wide range of new research avenues.

We have developed geographically-focused integrated research innovation hubs in four areas: North America, Germany, France and Asia.

Our R&D is now organized to promote the best use of our resources within the local ecosystem. Our network-based organization is open to external opportunities, and enables us to more effectively capitalize on innovation from a wide range of sources.

B.5.2. Pharmaceuticals

In 2013, R&D again conducted a rigorous and comprehensive portfolio review. Projects were assessed using two key criteria which allow management to rapidly understand how the portfolio performs in terms of innovation, unmet medical needs, risk and value. The two key criteria are:

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

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

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

As described at "Item 3. Key Information D. Risk Factors Risks Relating to Our Business We may fail to adequately renew our product portfolio whether through our own R&D or through acquisitions and strategic alliances." our product development efforts are subject to the risks and uncertainties inherent in any new product development program.

Table of Contents

The clinical portfolio for new products can be summarized as follows:

	Phase I	Phase II	Phase III / registration
Diabetes Solutions	Insulin biosimilar program		Lyxumia® (lixisenatide) Lixilan® (lixisenatide / insulin glargine) U300
Oncology	SAR125844 SAR153192 SAR245408 SAR260301 SAR307746 SAR405838 SAR566658 SAR650984	SAR245409 SAR256212 SAR3419	
Cardiovascular diseases		fresolumimab	alirocumab
Immune Mediated diseases (including Multiple Sclerosis)	SAR113244 SAR252067	SAR100842 SAR156597 SAR339658 dupilumab	Lemtrada (alemtuzumab) sarilumab Aubagio® (teriflunomide)
Age Related Degenerative Diseases	SAR228810	SAR391786	
Infectious diseases		ferroquine (combo OZ439) SAR279356	
Rare diseases	GZ402665 GZ402666 GZ402671		Cerdelga (eliglustat) patisiran (SAR438027)
Ophthalmology	GZ402663 StarGen UhsStat RetinoStat®	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.

Edgar Filing: Sanofi - Form 20-F

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 " Pharmaceutical Products Main Pharmaceutical Products" above.)

The main compounds currently in Phase III clinical development in the Diabetes field are

Investigational New Insulin U300:

A new formulation of insulin glargine has been shown in Phase I studies to have an improved pharmacodynamic profile with even longer, more stable and flatter activity than Lantus®, with the potential to translate into good glycemic outcomes with less hypoglycemia.

The completed Phase III program includes four studies (EDITION I, II, III and IV) and two studies in Japanese patients (EDITION JPI and JPPII). The Phase III program is assessing the efficacy and safety of U300 compared with Lantus® in various populations. The results of Edition I and II have demonstrated similar level of glycemic control

Table of Contents

between U300 and Lantus®, while U300 was consistently associated with a reduction in risk of hypoglycemia. Topline results of EDITION III, IV and JPI showed a similar level of glycemic control in both groups. In EDITION III, fewer patients were affected by the nocturnal severe or confirmed hypoglycemic events in the U300 group but the difference was not statistically significant. The analysis of this criterion was not planned as main secondary endpoint in EDITION IV and JPI.

Lixilan® Fixed-Ratio: Lixilan® Fixed-Ratio, a combination of insulin glargine and lixisenatide, is also under clinical development. A proof-of-concept study to examine the glycemic control of Lixilan® versus insulin glargine alone over 24 weeks has been completed. The Lixilan® Phase III program started recently in the first quarter of 2014 with two clinical studies:

LixiLan-O study in patients insufficiently controlled on oral antidiabetics drugs;

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

Lixilan® has the potential to be the first combination of Basal Insulin/GLP-1 in a single daily injection marketed in the U.S.

Sanofi Diabetes maintains a significant network of R&D collaborations with world leading academic institutions, including partnerships with the Joslin Diabetes Center (an affiliate of Harvard Medical School), the Charite in Berlin and the Helmholtz Zentrum in Munich. Collaborations with Gentofte Hospital (Copenhagen), and Gubra (a Danish biotech company specialized in gut hormone R&D) were recently established, and collaboration on innovative implantable glucose sensors was extended. Sanofi and JDRF continue to jointly fund selected innovation projects in the field of type I diabetes research.

b) Oncology

The main compounds currently in Phase II clinical development are:

SAR256212 (MM-121). Under an exclusive global collaboration and licensing agreement, Merrimack Pharmaceuticals, Inc. and Sanofi are co-developing SAR256212, a fully human monoclonal antibody targeting ErbB3. ErbB3 has been identified as a key node in tumor growth and survival. SAR256212 is in Phase II stage of development in Breast, Lung and Ovarian cancers.

SAR245409 (XL765) was in-licensed from Exelixis, Inc. and is being developed by Sanofi. This oral agent is an inhibitor of phosphoinositide-3-kinase (PI3K) and also acts against 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 is 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: refractory/relapse Diffuse Large B Cell Lymphoma (DLBCL, aggressive lymphoma type) with the aim of confirming clinical activity both as a single agent and in combination with rituximab (Rituxan®, anti CD20 mAb).

Early stage products:

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).

SAR650984 is a naked humanized immunoglobulin (IgG1) monoclonal antibody (mAb) that has been in-licensed from Immunogen Inc. SAR650984 selectively binds to CD38, a cell surface antigen widely expressed in multiple myeloma cancer cells, and other hematological malignancies. The program is in Phase I with 2 ongoing studies: as a single agent and in

Edgar Filing: Sanofi - Form 20-F

combination with lenalidomide/dexamethasone in heavily pretreated relapsed multiple myeloma patients.

Two compounds, **SAR260301** (PI3K β selective inhibitor) and **SAR405838** (P53/HDM2 antagonist) were added to the Sanofi Phase I pipeline.

A Phase I trial of a novel combination with **SAR405838**/pimasertib in solid tumors has been initiated.

Projects discontinued in 2013:

Iniparib (SAR240550; BSI-201) The project, whose initial Phase III trial in triple-negative breast cancer was negative in 2011, was discontinued following an additional negative Phase III trial in advanced squamous non-small cell lung cancer, as well as inconclusive results of the two Phase II trials in ovarian cancer.

Table of Contents

Fedratinib (SAR302503; TG101348) was acquired when we purchased TargeGen, Inc. in 2010 and has been developed exclusively by Sanofi. Fedratinib is a selective oral, small molecule inhibitor of the JAK2 kinase. Sanofi recently announced its decision to halt all clinical trials and cancel plans for regulatory filings with fedratinib following reports of cases consistent with Wernicke's encephalopathy in patients participating in fedratinib clinical trials and a thorough risk-benefit analysis which determined that the risk to patient safety outweighed the benefit that fedratinib would bring to patients.

c) Cardiovascular diseases

Alirocumab (SAR236553), developed in collaboration with Regeneron: positive results from a Phase III study (ODYSSEY mono) with alirocumab, an investigational monoclonal antibody targeting PCSK9 (proprotein convertase subtilisin/kexin type 9), were obtained in 2013.

The mean low-density lipoprotein-cholesterol (LDL-C) reduction from baseline to week 24, the primary efficacy endpoint of the study, was significantly greater in patients randomized to alirocumab, as compared to patients randomized to ezetimibe. In the trial, which employed a dose increase (up-titration) for patients who did not achieve an LDL-C level of 70 milligrams/deciliter (mg/dL), the majority of patients remained on the initial low dose of alirocumab of 75 milligrams (mg).

A large Phase III clinical program (ODYSSEY 14 studies) is ongoing to assess the product efficacy in different populations, and new results are expected during the second and third quarters of 2014.

Sanofi and Regeneron have been advised by the FDA that it has become aware of neurocognitive adverse events in the PCSK9 inhibitor class. Neurocognitive adverse events have also been associated with the use of statins for lowering LDL cholesterol. Neither company knows the circumstances under which the FDA became aware of these adverse events or whether these adverse events were observed with a drug candidate tested as monotherapy or in combination with a statin or other cholesterol-lowering agent. The FDA has requested that Sanofi and Regeneron make an assessment of potential neurocognitive adverse events across the global development program for alirocumab, especially in the longer-term studies. Additionally, the FDA requested to be informed about the feasibility of incorporating neurocognitive testing into at least a subset of patients in the ODYSSEY OUTCOMES trial or other long-term Phase III trial(s). While neither company is aware of any neurocognitive adverse event signal relating to alirocumab, if this or another adverse event signal is detected, the further development of alirocumab may be delayed or fail, or its commercial value diminished, which could severely harm future prospects.

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

d) Immune Mediated diseases and Multiple Sclerosis

Lemtrada (Alemtuzumab), a humanized monoclonal antibody targeting CD52 antigen, has been developed and is registered in Europe (dossier under discussion in the U.S.) to treat patients with relapsing forms of MS. The current development activities are described in the section " Pharmaceutical Products Main Pharmaceutical Products" above.

Aubagio® (Teriflunomide), a once daily, oral immunomodulator approved in the United States and Europe in the treatment of MS. The current development activities are described in the section " Pharmaceutical Products Main Pharmaceutical Products" above.

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 and four 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

Edgar Filing: Sanofi - Form 20-F

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;

Table of Contents

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-COMPARE study is evaluating the strategy of using IL-6 inhibition with sarilumab in combination with MTX in patients who have had an inadequate response to open-label adalimumab + MTX after 16 weeks of therapy. Those patients identified as inadequate responders are then randomized to a second TNF-alpha inhibitor (etanercept) + MTX or sarilumab + MTX.

Additional studies in the SARIL-RA clinical program are to be implemented in 2014.

Dupilumab (SAR231893), a monoclonal antibody against the Interleukin-4 alpha Receptor (anti IL-4R alpha) derived from our alliance with Regeneron, is currently being developed in two indications. Dupilumab modulates signaling of both IL 4 and IL 13 pathways. Atopic dermatitis will enter Phase III in the fourth quarter of 2014. Asthma will enter Phase III in the second quarter of 2015.

SAR339658 (GBR500), a 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 inflammatory bowel disease such as Ulcerative Colitis or Crohn's disease. The compound successfully completed Phase I in 2010 and entered Phase IIA in 2012. Enrollment continued in 2013.

SAR100842 (Genzyme, LPA1 receptor antagonist): a Phase IIA study in the treatment of systemic sclerosis has started in 2013 and is currently ongoing.

SAR156597 (Genzyme, 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.

e) Age Related Degenerative Diseases

One compound has progressed into phase II clinical development:

SAR391786 REGN1033 (Anti GDF8 mAb in sarcopenia) in collaboration with Regeneron

One compound has completed Phase I single rising dose in with Alzheimer's disease (AD) patients and started multiple ascending dosing:

SAR228810 (anti-protofibrillar AB mAb for the treatment of patients with mild cognitive impairment due to AD)

Three compounds have been terminated:

SAR110894 (H3 receptor antagonist for the treatment of Alzheimer's disease)

SAR113945 (IKK- β kinase inhibitor for the treatment of osteoarthritis by intra-articular administration)

SAR292833 (TRPV3 antagonist for the oral treatment of chronic pain)

f) Infectious Diseases

Ferroquine/OZ439, a combination for malaria (Partnership with Medicines for Malaria Venture (MMV)). Ferroquine is a new 4-amino-quinoline being developed for the treatment of acute uncomplicated malaria, and is active against chloroquine-sensitive and chloroquine-resistant *Plasmodium* strains. Due to its long half-life it has the potential to be part of single dose cure regimens for the treatment of both *P. vivax* and *P. falciparum* malaria. OZ439 is a synthetic peroxide antimalarial drug candidate from MMV designed to provide a single dose oral cure in humans.

A Phase I study of combination of the two compounds was conducted in 2013. A Phase IIB clinical study of the combination will commence in the second half of 2014.

SAR279356 (a first-in-class human monoclonal antibody for the prevention and possible treatment of *S. aureus*, *S. epidermidis*, *E. coli*, *Y. pestis* and other serious infections) Following the successful completion of a Phase I study in early 2011, further extensive preclinical credentialing experiments have been successfully completed to further validate the potential for application of the product in the prevention of nosocomial infections and support a future Phase II clinical proof of concept study.

Table of Contents

g) Rare Diseases (Genzyme)

Cerdelga (Eliglustat) a substrate reduction therapy targeted for the treatment of Gaucher disease type 1. This product candidate is administered orally in capsule form and has the potential to transform the treatment experience of patients by providing an alternative to bi-weekly infusions. Eliglustat was submitted for licensure in both Europe and the U.S. in September 2013. In November 2013 the FDA gave the eliglustat submission Fast Track status. The approval is expected for the second half of 2014.

Patisiran (SAR438027) (mRNA inhibition Alnylam ALN-TTR02). 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). The Phase III program has just started. It is proposed that a Japanese Phase I trial begin in early 2014. Genzyme's exclusive territory rights for the ALN-TTR programs were extended to the rest of world excluding North America and Western Europe on January 14, 2014.

GZ402665 (rhASM) an enzyme replacement therapy targeting the treatment of Niemann-Pick B disease. A Phase Ib study was fully enrolled in July 2013.

GZ402666 (Neo GAA) in Phase I in the treatment of Pompe disease.

GZ402671 (CGS inhibitor) in Phase I in the treatment of Fabry's disease.

GZ404477 (AAV-AADC) Gene therapy based on AAV vector targeting the treatment of moderate to severe Parkinson's disease. Phase I was completed in 2013. Genzyme discontinued development on this program due to strategic considerations.

h) Ophthalmology portfolio (Sanofi-fovea)

A proof-of-concept study is being conducted for **SAR153191 sarilumab** (Phase II) in an ophthalmology indication: this anti-IL-6-receptor mAb could be a safe and efficient option to treat non-infectious uveitis affecting the posterior segment of the eye at risk of vision loss.

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;

Retino Stat® (SAR421868) Phase I): a gene therapy to treat wet Age-related Macular Degeneration (AMD); Retino Stat® is being developed with Oxford BioMedica and is still under opt-in conditions.

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;

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.

Table of Contents

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

Phase I	Phase II	Phase III	Submitted
Streptococcus pneumonia* Pneumonia and meningitis vaccine	Meningitis A,C,Y,W conj. 2nd generation Meningococcal conjugate vaccine	Dengue* Mild-to-severe dengue fever vaccine	
Tuberculosis* Recombinant subunit vaccine	Rabies VRVg Purified vero rabies vaccine	C. difficile toxoid vaccine* Toxoid vaccine against <i>clostridium difficile</i>	
Pseudomonas aeruginosa* Antibody fragment product for prevention of ventilator-associated pneumonia	Rotavirus Live attenuated tetravalent oral rotavirus vaccine	DTP-HepB-Polio-Hib⁽¹⁾ Pediatric hexavalent vaccine	
Herpes Simplex* Live attenuated viral vaccine		Fluzone® QIV ID Quadrivalent inactivated intradermal influenza 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*

Table of Contents

Project highlights

This section focuses on Phase I and Phase II compounds and novel targets in Phase III. Other vaccines in Phase III (excluding novel targets) are described in the "B.3. Vaccine Products" section above.

Influenza

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 "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.

Pediatric Combination & Adolescent/Adult Boosters

Several pediatric vaccines are under development. Tailored for specific markets, they are aimed at protecting against five or all six of the following diseases: diphtheria, tetanus, pertussis, polio, Hib and hepatitis B (see "Vaccine Products").

Meningitis

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. Ongoing projects around a new generation of meningococcal conjugate vaccine are aimed at lowering the age at which this vaccine can first be administered. (see "Vaccine Products").

Pneumococcal Vaccine

Streptococcus pneumoniae bacteria are the leading etiological agent causing severe infections (over three million deaths per year worldwide, including one million children). 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 is 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 are expected in 2014.

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 January, 2011. In China, the completion of the clinical development confirmed its non-inferiority against Verorab® in the Chinese population, enabling a registration file to be submitted in 2013. The clinical development plan for licensure in the U.S. is currently ongoing.

New Vaccine Targets

Dengue Dengue fever constitutes a major medical and economic burden in the endemic areas of Asia-Pacific, Latin America and Africa; 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. In 2013, dengue once again proved how unpredictable it can be with record breaking epidemics in Brazil, French overseas territories and Singapore. In response to this global threat, 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 one is to reduce morbidity by 25% and mortality by 50% by 2020.

In 2012, the results of the world's first efficacy study conducted in Thailand confirmed the excellent safety profile of the Sanofi Pasteur dengue vaccine candidate which targets four viral serotypes. Nevertheless, this study showed vaccine efficacy against 3 types of dengue virus out of four (61.2% against dengue virus type 1, 81.9% against type 3 and 90% against type 4). Thorough investigations have been launched to interpret this lack of efficacy against

Table of Contents

serotype 2 in the specific epidemiological context of Thailand. Furthermore, large scale phase III efficacy studies with 31,000 volunteers are ongoing in several Latin American and Southeast Asian countries. These studies will generate important additional data in a broader population and in a variety of epidemiological settings to demonstrate vaccine efficacy against the four circulating dengue virus serotypes. Results are expected in the second half of 2014. Transmission and vaccination models have already demonstrated the significant impact vaccination with a dengue vaccine having the efficacy levels observed in the Phase IIb study could have on morbidity.

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. Toxoids have been used as the basis of a number of highly successful licensed vaccines. 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.

Rotavirus 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. 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 starting in 2014.

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 III study was initiated in July, 2013, in South Africa in infants.

Pseudomonas aeruginosa In February 2010, Sanofi Pasteur entered an agreement with KaloBios Pharmaceuticals, for the development of a Humaneered® antibody fragment to both treat and prevent *Pseudomonas aeruginosa* (*Pa*) infections. Most serious *Pa* infections occur in hospitalized and critically or chronically ill patients. Sanofi Pasteur acquired worldwide rights for all disease indications related to *Pa* infections except cystic fibrosis and bronchiectasis, which Sanofi Pasteur has the option to obtain at a later date. KaloBios has already completed phase I clinical trials and a small proof of concept phase II clinical trial. Sanofi Pasteur is developing a new formulation of antibody fragments. Completion of the Phase I study in healthy adult volunteers is expected in 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. An NIH-sponsored phase I trial was initiated in October 2013.

B.5.4 R&D expenditures for late stage development

Expenditures on research and development amounted to €4,770 million in 2013, comprising €4,087 million in the Pharmaceuticals segment, €518 million in Human Vaccines and €165 million in Animal Health. Research and development expenditures were the equivalent of about 14.5% of net sales in 2013, compared to about 14.1% in 2012, 14.4% in 2011 and 14.1% in 2010. 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

Edgar Filing: Sanofi - Form 20-F

Table of Contents

despite a greater proportion of products being in late stage development. Preclinical research in the pharmaceutical segment amounted to €951 million in 2013 compared to €1,037 million in 2012, €1,113 million in 2011 and €1,037 million in 2010. Of the remaining €3,136 million relating to clinical development in the Pharmaceuticals segment (€3,181 million in 2012, €2,989 million in 2011 and €2,848 million in 2010), 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) compounds in the Pharmaceuticals segment, we set out below the date at which this compound entered into Phase III development, information concerning any compound patent in the principal markets for innovative pharmaceutical products (the United States, European Union and Japan) as well as comments regarding significant future milestones that are reasonably determinable at this date. Because the timing of such milestones typically depends on a number of factors outside of our control (such as the time to validate study protocols and recruit subjects, the speed with which endpoints are realized, as well as the substantial time taken by regulatory review) it is frequently not possible to provide such estimates, and any such estimates as are given should be understood to be indicative only. See also "Item 3. Key Information D. Risk Factors Risks Relating to Our Business".

Phase III	Entry into Phase III(1)	Compound Patent Term(2)			Comments
		U.S.	E.U.	Japan	
Lyxumia® (lixisenatide) ⁽³⁾⁽⁴⁾ (AVE0010)	May 2008 ⁽⁵⁾	2020	2020	2020	Dossier approved in Europe in February 2013 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
Alirocumab (SAR236553) (REGN727)	July 2012	2029	2029	2029	Phase III program ongoing in hypercholesterolemia
Lemtrada ⁽⁴⁾ (alemtuzumab) (GZ402673)	September 2007	2015 Regulatory exclusivity: N/A	expired	expired	Dossier approved in Europe in September 2013 for the treatment of relapsing forms of Multiple Sclerosis. In the U.S. Complete Response Letter received from the FDA in December 2013. Sanofi is preparing its appeal.
U300	December 2011	2014 Protection extended to 2015, by pediatric extension.	2014 Protection extended to 2015, by pediatric extension.	2014	Phase III program ongoing; submission expected in the second quarter of 2014
Cerdelga (eliglustat) (GZ385600)	September 2009	2022	2022	2022	Dossier submitted in U.S. and Europe in September 2013 for the treatment of Gaucher Disease type 1
sarilumab (SAR153191)	August 2011	2028	2027	2027	Phase III program in the treatment of Rheumatoid Arthritis ongoing

(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 the following additional factors in mind.

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 " 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., aflibercept). 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 geographic region for 2013, 2012, and 2011 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 for full year 2013, 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.

Genzyme's sales are included from the acquisition date (April 1, 2011).

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 33.3% of our 2013 net sales, the largest contribution to net sales of any region. We are the leading healthcare company in emerging markets. In 2013, sales in emerging markets grew by 4.4% at constant exchange rates. Asia and Middle East recorded double-digit sales growth in 2013. Sales in BRIC (Brazil, Russia, India and China) countries account for 34% of Emerging Markets sales. Sales in China and Russia were up 18.6% and 12.0% respectively. In 2013, sales in Africa and the Middle East each exceeded €1 billion.

The United States represents 31.7% of our net sales; we rank twelfth with a market share of 3.3% (3.7% in 2012). Sales in the U.S. were down 0.7% at constant exchange rates in 2013.

Western Europe represents 23.8% of our net sales; we are the leading pharmaceutical company in France where our market share is 8.7% (9.3% in 2012), and we rank fourth in Germany with a 4.5% market share. In 2013, sales in Western Europe were down 5.6% at constant exchange rates.

Other countries represent 11.3% of our net sales; our market share in Japan is 3.3% (3.5% in 2012). Full-year 2013 sales in Japan were down 4.3% at constant exchange rates.

A breakdown of our sales by geographic market is presented in "Item 5. Operating and Financial Review and Prospects Results of Operations Year Ended December 31, 2013 Compared with Year Ended December 31, 2012."

Edgar Filing: Sanofi - Form 20-F

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

Table of Contents

exception of CHC products, these drugs are ordinarily dispensed to patients by pharmacies upon presentation of a doctor's prescription.

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 medical 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. As of December 31, 2013, we had a global sales force of 33,509 representatives: 8,281 in Europe (including 3,691 in Eastern Europe), 4,771 in the United States, and 20,457 in the rest of the world.

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 geographic 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 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.

Our Animal Health products are sold and distributed through various channels, depending on each country's legislation for veterinary products. Merial takes into account each country's specific characteristics and sells either to veterinaries, chemists, or via wholesalers. In the case of epizootics, 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.

Our CHC business competes with multinational corporations such as Johnson & Johnson, Bayer, Pfizer, Novartis, and GlaxoSmithKline as well as local players, especially in emerging markets.

Table of Contents

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, including Merck (outside Europe), GlaxoSmithKline, Pfizer (Wyeth), Novartis and Johnson & Johnson (Crucell). 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 our Animal Health business, we compete primarily with international companies like Zoetis, Merck and Elanco in both production and companion animals; with Boehringer Ingelheim in production animals; with Boehringer Ingelheim mainly in the vaccines segment; with Novartis and Bayer for pets, particularly for parasiticides; and with Virbac, Ceva and Vetoquinol, French companies with global presence, for pharmaceuticals and/or 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" above). 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 related 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 up to 30% in some countries. However, in markets where powerful regulatory controls are in place, counterfeit drugs are estimated to represent less than 1% of market value.

B.6.3. Regulatory Framework

B.6.3.1 Overview

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

Table of Contents

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. An example of these efforts is the Common Technical Document (CTD), which is a format used for product applications in ICH, with only local or regional adaptation.

In 2013, 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.

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. Recognising the need to engage actively with other harmonisation initiatives, representatives from five Regional Harmonisation's 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, Czech Republic, 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, orphans, 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 proved 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.

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, cancers, 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

Table of Contents

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.

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

Since its introduction in the second quarter of 2012 the PRAC has initiated reviews of marketed products (by class or on *ad hoc* basis) through various procedures. 38 Sanofi products underwent PRAC review from July 2012 to October 2013, generating 10 labeling variations (up to November 2013; two additional variations are ongoing). In only one case for Sanofi (Myolastan®) 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. 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. These amendments also include other aspects: clarification of the scope and strengthened safety-referral procedures in the E.U.; improved coordination and facilitation of swift action and extension of assessment, for the benefit of public health; the scope of translation exemptions to include cases of severe issues of availability, including shortages of medicines, in order to facilitate the availability of medicines across the E.U.; and extension of the mandatory scope of the medicines subject to additional monitoring.

Table of Contents

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 required PASS and PAES can be properly implemented as required, either in the frame of a RMP (Risk Management Plan) or following a Health Authority request.

The Pharmacovigilance legislation also introduces a new periodic safety report to be prepared by the pharmaceutical companies. This is no longer 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. Sanofi has fully implemented the new report since January 2013.

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 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 current review time for an ANDA exceeds 30 months. The ANDA pathway in the United States can only be used for generics of drugs approved under the FD&C Act.

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 1, 2014, no sponsor has submitted a 351k application to the FDA for review.

The FDASIA, signed into law on July 9, 2012, expands the FDA's authority and strengthens its ability to safeguard and advance public health by giving the FDA the authority to collect user fees from industry to fund reviews of innovator drugs, medical devices, generic drugs and biosimilar biological products; promoting innovation to speed patient access to safe and effective products; increasing stakeholder involvement in FDA processes; and enhancing the safety of the drug supply chain. The FDA has established a three-year implementation plan, which is planned to be updated on a monthly basis.

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 off-label indications with high medical needs. The pharmaceutical companies concerned are required to conduct submission based on available documentation within six months or start a clinical trial for registration within one year after the official development request of the off label

Table of Contents

indications. For unproven drugs with high medical needs, clinical trials in Japanese patients are generally required. Otherwise, NHI prices of all products of the company would be reduced dramatically.

Based on the reform of the NHI price system finalized on December 25, 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). 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 plant or animal tissues, 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 November 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). However, starting in 2011 and continuing in 2013, the EMA initiated a revision of the majority of the existing biosimilar guidelines (general over-arching guidelines, quality, non-clinical and clinical guidelines, comments on which had to be submitted to the EMA by end of 2013, as well as immunogenicity and product-related guidelines for recombinant insulin and LMWH).

The major update in the revised over-arching biosimilar guideline is the opportunity to use a version of the reference product sourced outside the EEA provided bridging data are generated by the applicant. This important change will help facilitate the global development of biosimilars and will come into force via the revision of the over-arching biosimilar guideline, expected in 2014.

Table of Contents

While the EMA has adopted a balanced approach for all biosimilars, allowing evaluation on a case-by-case basis in accordance with relevant biosimilar guidelines, the EMA has expressed some willingness to simplify the pathway in very specific circumstances. For a very simple biological fully characterized on the quality level, a biosimilar could be authorized based on a bioequivalence study combined only with an extensive quality package. 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 2013, the European Commission granted marketing authorisations for the first monoclonal-antibody biosimilar. This approval was considered a landmark decision by the EMA, proving that the biosimilar concept can be successfully applied to complex molecules such as monoclonal antibodies and that extrapolation of multiple indications is possible.

Since February 2012, the FDA has published for consultation four draft scientific guidance documents for biosimilar development. All four of these guidance documents remain in draft format.

At the December 2013 FDA-CMS meeting, the FDA acknowledged that the agency has had the equivalent of pre-NDA "meetings" in the biosimilar space.

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 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 Medical Devices

Currently in the E.U., there is no pre-market authorisation 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 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 proposed texts are currently being discussed in the European Parliament and in the Council.

The position of the European Parliament Committee on the Environment, Public Health and Food Safety (ENVI) passed a vote on September 25, 2013, and 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 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.

B.6.3.4 Generic drugs

In the E.U., the number of positive opinions by centralized procedure for generics is unchanged year-on-year (16 in 2013). 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.

Table of Contents

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.

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

The NHI price system will be reformed in Japan in fiscal year 2014, including a new special price reduction rule for long-listed drugs. The new rule would 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 would be introduced in April 2014.

Under the new price system, NHI prices of first generics (currently set at 70%) would be set at 60% of the price of the originator product, while a 50% rule would be applied to oral first generics when more than 10, with the same ingredients, obtain listing.

In addition, a 10% "precursor premium" would 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.6.3.5 OTC drugs

In the E.U., one product has had a prescription-to-OTC switch approved through Centralized Procedure since May, 2009.

In the United States, FDA approved two first-in-class prescription-to-OTC switches in 2013, one of which was Sanofi's Nasacort® Allergy 24HR.

The FDA's Nonprescription Drug Safe Use Regulatory Expansion (NSURE) Initiative was launched to explore regulatory approaches to expanding the nonprescription drug market but the timeline for implementation may be longer than some anticipated.

In Japan, the J-MHLW drug safety committee meeting held on December 20, 2013 decided 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 will give 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 will have to be categorized as products that require pharmacist consultations when purchasing.

Under the new plan, the J-MHLW will require 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.

Table of Contents

From a regulatory perspective, ambitious initiatives have been undertaken by the major regulatory authorities.

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

In June 2013, the EMA released a draft policy on publication and access to clinical-trial data.

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.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Pharmaceutical Research and Manufacturers of America (PhRMA) have strengthened their long-standing commitment to enhancing public health by endorsing joint "Principles for Responsible Clinical Trial Data Sharing". Under the new commitments, biopharmaceutical companies will dramatically increase the amount of information available to researchers, patients, and members of the public. On January 2, 2014 Sanofi announced its commitment to expanding access to its clinical trial data.

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

Regarding transparency regarding Health Care Professionals (HCP), there is no common harmonized approach in the E.U. For transparency purpose, there is an increased external scrutiny of interactions between pharmaceutical companies and HCPs at national level with legal provisions or with Healthcare Industry voluntary undertakings (Pharma Code) in some countries (such as United Kingdom, Denmark, France, Portugal or Slovakia).

The EFPIA released 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". The compliance with this new Disclosure Code has become an obligation for EFPIA's memberships, who are required to transpose this Code into their national codes in full by 31 December 2013.

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

B.6.3.7 Other new legislation proposed or pending implementation

Clinical trials regulation: a proposal for a regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use, repealing Directive 2001/20/EC, was first released in July 2012.

On December 20, 2013, the Council of the E.U. endorsed a compromise agreement, reached by the Council, the European Parliament and the European Commission. The move opens the way to the regulation's final approval before the parliamentary elections in May 2014.

Edgar Filing: Sanofi - Form 20-F

One of the main objectives behind a new proposal for clinical trials regulation by the European Commission was the impact on the competitiveness of the European life sciences industry caused by changes to the conditions of the

Table of Contents

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.

While the final text has not been released yet, the following major points are known:

The timeline for approving a clinical trial proposal was 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.

Falsified medicines: implementation of Directive 2011/62/EU: The European Union has reformed the rules for importing active substances for medicinal products for human use into the E.U. As of January 2, 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 Harmonisation" ICH Q7. As of 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.

Implementation of Directive 2011/62/EU was expected by July 2, 2013. To date 17 of the 27 Member States have yet to transpose the directive in to national law.

A major uncertainty was expected regarding potential temporary drug shortages in the E.U. in cases where manufacturers were unable to supply the required documentation. At end 2013, no shortages of medicines from innovator or generic companies associated with the Falsified Medicines Directive had been identified, largely due to measures taken by companies to avoid importation problems.

In the U.S., on November 28, 2013, President Obama signed into law H.R. 3204, the Drug Quality and Security Act (DQSA). The legislation introduces a federal track-and-trace system for medicines with serial numbers added to individual packs and (non-mixed) cases within four years of the legislation being adopted, and electronic tracing of production through the supply chain mandated within 10 years.

It also strengthens licensure requirements for wholesale distributors and third-party logistics providers, and requires the FDA to maintain a database of wholesalers that will be available to the public through its website.

The law also boosts oversight of compounding pharmacies that make drugs to order, with the FDA getting greater powers to oversee large-volume or 'outsourcing' compounders without individual prescriptions.

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 in fiscal year 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 would launch a pilot program this fiscal year, which would run through to the end of fiscal year 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 fiscal year 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 of the 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 E.U., electronic submission for marketing authorization and variation applications has already been in place for many years. To allow secure submission over the internet for all types of eCTD applications for human medicines, the EMA launched the eSubmission Gateway; this was followed by the eSubmission web client, launched in January, 2013. From March, 2014, the use of the eSubmission Gateway or web client will become mandatory for all eCTD submissions through the centralized procedure, order to improve efficiency and decrease costs for applicants.

The EMA will extend the use of eSubmission Gateway and web client to paediatric submissions, veterinary medicines and referral procedures in the near future.

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.

Significant recent pricing events and trends include:

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, while increased mandated rebates will have a deleterious effect on the net value of products in these segments of the market.

In Europe, the financial crisis of recent years seems to have stabilised. The long-anticipated Value-Based Pricing system in the UK has not led to considerable changes from previous framework agreements. Instead, a new edition of the Pharmaceutical Price Regulation Scheme has been approved, while certain evaluation criteria used by the National Institute for Health and Clinical Excellence (NICE) are to be revised in 2014. In Germany, the price freeze implemented under the law on the restructuring of the pharmaceutical market (AMNOG) and scheduled to finish at the end of 2013 has been temporarily extended so that debates can take place to renew the measure for the medium term. However, the mandatory rebate has been reduced from 16% to 6% as scheduled.

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 anticipated to be a subject for scrutiny in the future. Among the large emerging markets, India has finally implemented price control. Also, instances of positions taken against innovative product patents have multiplied and compulsory licensing has again been considered with a wider therapeutic scope. Russia continues to widen its programme of pilot insurance schemes and reforms to its Essential Drugs List price controls are expected in 2014, while legislation favours national production. National production is also a theme of policy in Brazil.

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

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.

Table of Contents

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

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

B.7. Patents, Intellectual Property and Other Rights

Patent Protection

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

active ingredients;

pharmaceutical formulations;

product manufacturing processes;

intermediate chemical compounds;

therapeutic indications/methods of use;

delivery systems; and

enabling technologies, such as assays.

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

Additionally, the product may benefit from the protection of patents obtained during development or after the product's initial marketing approval. The protection a patent affords the related product depends upon the type of patent and its scope of coverage, and may also vary from country to country. In Europe for instance, applications for new patents may be submitted to the European Patent Office (EPO), an intergovernmental organization which centralizes filing and prosecution. As of December 2013, an EPO patent application may cover the 38 European Patent Convention member states, including all 27 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 13 Member States including France, Germany, and the United Kingdom. As of the date of this document only Austria has ratified.

Edgar Filing: Sanofi - Form 20-F

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.

Table of Contents

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 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 or generic brands if they are perceived to be equivalent or superior products". In some cases, it is possible to continue to obtain commercial benefits from product manufacturing trade secrets or from other types of patents, such as patents on processes, intermediates, structure, formulations, methods of treatment, indications or delivery systems. Certain categories of products, such as traditional vaccines and insulin, have been historically relatively less reliant on patent protection and may in many cases have no patent coverage, although it is increasingly frequent for novel vaccines and insulins to be patent protected. See " Focus on Biologics" below. 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.

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-

Table of Contents

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"

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"), for example, Lantus® received FDA grant of 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 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 marketing 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 " Pharmaceutical Products Main Pharmaceutical Products". Concerning animal health products, Merial's intellectual property coverage is described above (see " Animal Health: Merial"). In the discussion of patents below, we 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.

Edgar Filing: Sanofi - Form 20-F

Table of Contents

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.

Lantus® (insulin glargine)

U.S. Compound: August 2014, protection extended to February 2015 by Pediatric Extension ⁽¹⁾	E.U. Compound: November 2014 in most of Western Europe extended until May 2015 by Pediatric Extensions	Japan Compound: November 2014
--	--	---

(1)

A patent infringement suit was filed by Sanofi against Eli Lilly on January 30, 2014 in the United States. The suit was triggered by Eli Lilly's submission to FDA of an NDA (505(b)(2) New Drug Application) seeking approval to sell an insulin glargine drug product. The suit resulted in a stay during which the FDA cannot approve Eli Lilly's NDA. The stay is expected to expire the earlier of (i) a court decision favorable to Eli Lilly or (ii) June 2016.

Apidra® (insulin glulisine)

U.S. Compound: June 2018 Later filed patent: 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
--	---	---

Jevtana® (cabazitaxel)

U.S. Compound: March 2021 Later filed patents: coverage ranging through December 2025 Regulatory exclusivity: June 2015	E.U. Compound: March 2016 Later filed patents: coverage ranging through September 2024 to March 2025 with SPC granted in some EU countries Regulatory exclusivity: March 2021	Japan Compound: March 2016 (patent term extension to be determined once product is approved in Japan) Later filed patents: coverage ranging through September 2024 Regulatory exclusivity: to be determined upon approval of a product in Japan
---	---	---

Lovenox® (enoxaparin sodium)

U.S. Compound: no compound patent coverage Generics on the market	E.U. Compound: expired	Japan Compound: expired Regulatory exclusivity: January 2016
--	----------------------------------	---

Table of Contents

Plavix® (clopidogrel bisulfate)

<p>U.S. Compound: expired Generics on the market Aprovel® (irbesartan)</p>	<p>E.U. Generics on the market</p>	<p>Japan Compound: expired Regulatory exclusivity: expired</p>
--	---	---

<p>U.S. Compound: expired Generics on the market Multaq® (dronedarone hydrochloride)</p>	<p>E.U. Compound: expired Generics on the market</p>	<p>Japan Compound: March 2016 Regulatory exclusivity: April 2016</p>
--	---	---

<p>U.S. Compound: July 2016 with PTE Later filed patent: formulation (June 2018) Regulatory exclusivity: July 2014 Stilnox® (zolpidem tartrate)</p>	<p>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</p>	<p>Japan Compound: expired</p>
--	---	---

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

Depakine® (sodium valproate)

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

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

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 Later filed patents: coverage ranging through January 2016</p>
---	---	---

(1) *See "Item 8 A. Consolidated Financial Statements and Other Financial Information Patents Allegra® Patent Litigation" of this annual report for further information.*

Table of Contents

Actonel® (risedronate sodium)⁽¹⁾

<p>U.S. Compound: protection extended to June 2014 by Pediatric extension Later filed patents: coverage ranging through June 2018</p>	<p>E.U. Compound: expired Later filed patents: coverage ranging through June 2018</p>	<p>Japan Compound: expired</p>
--	---	---

(1) *On October 30, 2009, Procter & Gamble Pharmaceuticals (P&G) sold its pharmaceutical business to Warner Chilcott (WCRX) which became the successor to P&G in rights and interests for the Actonel® alliance and now holds the NDA and the patents for this product in the United States. We commercialize Actonel® with WCRX. See "Item 5 Financial Presentation of Alliances".*

Amaryl® (glimepiride)

<p>U.S. Compound: expired Insuman® (human insulin)</p>	<p>E.U. Compound: expired</p>	<p>Japan Compound: expired</p>
--	--	---

<p>U.S. Compound: N/A Fabrazyme® (agalsidase beta)</p>	<p>E.U. Compound: N/A</p>	<p>Japan Compound: N/A</p>
--	--------------------------------------	---------------------------------------

<p>U.S. Compound: N/A Later filed patents: coverage ranging through September 2015 Biologics Regulatory Exclusivity: April 2015 Cerezyme® (imiglucerase)</p>	<p>E.U. Compound: N/A</p>	<p>Japan Compound: N/A Later filed patents: expired Orphan regulatory exclusivity: expired</p>
--	--------------------------------------	--

<p>U.S. Compound: expired Lumizyme® / Myozyme® (alglucosidase alpha)</p>	<p>E.U. Compound: N/A</p>	<p>Japan Compound: N/A</p>
--	--------------------------------------	---------------------------------------

<p>U.S. Compound: N/A Later filed patents: coverage ranging through February 2023 Orphan Drug Exclusivity: expired Biologics Regulatory Exclusivity: April 2018 Renagel® (sevelamer hydrochloride)</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>
--	---	---

<p>U.S. Compound: N/A Later filed patent: coverage ranging through September 2014</p>	<p>E.U. Compound: N/A Later filed patent: August 2014 SPC coverage to January 2015 in certain EU countries</p>	<p>Japan Compound: N/A Later filed patent: August 2014 PTE protection to December 2016</p>
--	--	--

Edgar Filing: Sanofi - Form 20-F

Table of Contents

Renvela® (sevelamer carbonate)

<p>U.S. Compound: N/A Later filed patent: coverage ranging through September 2014</p>	<p>E.U. Compound: N/A Later filed patent: August 2014</p> <p>SPC coverage to January 2015 in certain EU countries SPC coverage to August 2019 in certain countries (Austria, Greece, Italy and Luxembourg)</p>	<p>Japan Compound: N/A Later filed patent: August 2014</p>
--	---	---

Synvisc® (hyaline G-F 20)

<p>U.S. Compound: expired <i>Synvisc-One® (hyaline G-F 20)</i></p>	<p>E.U. Compound: N/A</p>	<p>Japan Compound: expired</p>
--	--------------------------------------	---

<p>U.S. Compound: expired <i>Lyxumia® (lixisenatide)</i></p>	<p>E.U. Compound: N/A</p>	<p>Japan Compound: expired</p>
--	--------------------------------------	---

<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 pending for compound patent and two device patents Regulatory Exclusivity: June 2021</p>
--	--	--

Zaltrap® (afibercept)

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

<p>U.S. Compound: October 2014 (May 2019 if PTE is granted) Regulatory Exclusivity: September 2017 <i>Aldurazyme® (laronidase)</i></p>	<p>E.U. Compound: expired</p>	<p>Japan Compound: expired</p>
--	--	---

<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>
--	--	--

Table of Contents

Mozobil® (plerixafor)

<p>U.S. Compound: N/A Later filed patents: ranging through July 2023 Orphan Regulatory Exclusivity: December 2015</p>	<p>E.U. Compound: N/A Later filed patents: ranging through July 2022 Regulatory Exclusivity: July 2019</p>	<p>Japan Compound: N/A Later filed patents: ranging through July 2022</p>
--	---	--

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 Later filed patent: September 2027 (pending)</p>	<p>Japan Compound: expired Later filed patent: September 2027</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 Eloxatin® in Europe, 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

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 " Focus on Biologics" 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.

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

Table of Contents

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.

The accelerated ANDA-type procedures are potentially applicable to many, but not all, of the products we manufacture. See " Focus on Biologics" and " Regulation" below. We seek to defend our patent rights vigorously in these cases. Success or failure in the assertion of a given patent against a competing product is not necessarily predictive of the future success or failure in the assertion of the same patent *ou 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".

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 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 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 of quality and distribution. Our production process consists of three principal stages: the manufacture of active pharmaceutical ingredients, the transformation of these 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 product throughout the production cycle. In some cases, however, we rely on third parties for the manufacture and supply of certain active ingredients and medical devices. 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 Alza. These 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".

Table of Contents

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 North America, 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 2013, the new influenza vaccine production plant at Shenzhen was approved by the Chinese authorities (CFDA).

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®, Zactran®, Previcox®) and a broad range of vaccines for different animal species (dogs, cats, horses, ruminants, pigs and fowl). A number of pharmaceutical products are subcontracted (Heartgard®, Eprinex®) but almost all veterinary vaccines are manufactured at its own plants. Merial's dedicated animal health industrial operations cover all activities, from the purchase of raw materials through to the delivery of the finished product, meeting customer needs through a reliable and flexible offering that meets quality expectations. There are 18 production sites spread across nine countries.

All of our pharmaceutical and vaccine facilities are 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, Holmes Chapel, and Fawdon, the latter due to close in 2015); in Ireland (Waterford); in Germany (Frankfurt); in Hungary (Veresegyhaz); in Italy (Anagni); and in the United States (Saint Louis and Chattanooga). 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.

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

Our Animal Health facilities in Athens, Worthington, Gainesville, Berlin and Raleigh 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.

On May 24, 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 Genzyme's 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. Genzyme has itself retained an expert to monitor and oversee the implementation of the remediation workplan. This workplan

Edgar Filing: Sanofi - Form 20-F

was submitted to the FDA in April 2011 and accepted by the FDA in January 2012, and 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

Table of Contents

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 five years. To date, all requirements of the consent decree, including all requirements of the workplan, have been met by Genzyme.

In March 2012, modifications to the workplan were submitted to the FDA to take account of planned changes in manufacturing operations for Fabrazyme® and Cerezyme® at the Allston facility. These modifications were accepted by the FDA. In addition, the U.S. facility at Framingham was approved by the FDA and the EMA in January 2012 for the production of Fabrazyme® (agalsidase beta). Production of the Fabrazyme® active substance at the Allston factory ended in 2012.

In July 2012, Sanofi Pasteur received a warning letter from the FDA following routine inspections conducted at its facilities in Toronto (Canada) and Marcy l'Étoile (France). Sanofi Pasteur is working actively with the FDA to implement a series of immediate and ongoing measures to address the issues raised in the warning letter and to further strengthen its production tools and quality systems.

In June and September 2013, follow-up inspections took place at the Marcy l'Étoile and Toronto facilities respectively. Though significant progress in quality systems was reported by the U.S. authorities at the time of the inspections, Sanofi Pasteur decided to strengthen and accelerate its improvement plan in the third quarter of 2013.

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.

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

Table of Contents

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 the 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 2013.

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.

Table of Contents

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, Brazil, 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 Rochester, Cincinnati, 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 Gaessio 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 Harbor, 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. Rehabilitation studies and an NRD assessment are underway in a similar project in Portland, Oregon. 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 2013, Sanofi spent € 52 million on rehabilitating sites previously contaminated by soil or groundwater pollution. During the year ended December 31, 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 €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 due to the multiple factors involved, such as the complexity of operational or previously operational sites, the nature of claims received, the rehabilitation techniques considered, the planned timetable for rehabilitation, and the outcome of discussions with national regulatory authorities or other potentially responsible parties, as in the case of multiparty sites. Given the long industrial history of some of our sites and the legacy obligations 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 has not been subject in 2013 to liabilities for non-compliance with current HSE laws and regulations that could be expected to significantly jeopardize its activities, financial situation or operating income. We also believe that we are in substantial compliance with current HSE laws and regulations and that all the environmental permits required to operate our facilities have been obtained. Regular HSE audits (43 in 2013) 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, 81 specialized audits covering contractors (72) or biosafety (9) and 164 loss prevention technical visits were carried out by our teams in 2013.

Sanofi has implemented a worldwide master policy on health, safety and the environment to promote the health and well-being of the employees and contractors working on its sites and respect for the environment. We consider this master policy to be an integral part of our commitment to social responsibility. In order to implement this master policy, 78 rules (policies) have been drawn up in the key fields of HSE management, Good HSE Practices, safety in the workplace, process safety, industrial hygiene, health in the workplace and protection of the environment.

Health

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

Table of Contents

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 annual implementation of HSE progress plans. In addition, 54 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 2013, 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 2013, we reduced carbon dioxide emissions caused by our sales representation car fleet by 10% versus 2012 due to the policy of using energy efficient cars as well as a reduction in

Table of Contents

the number of cars. Measured against the benchmark year for our new targets (2010), direct and indirect emissions from our production and research facilities (excluding vehicle fleets) have fallen by 11.0% 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 of subsidiaries. The table below sets forth our significant subsidiaries and affiliates as of December 31, 2013. 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 or Affiliate	Date of Incorporation	Country of Incorporation	Principal Activity	Financial and Voting Interest
Aventis Inc.	07/01/1998	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 Ltd	08/01/1997	United Kingdom	Animal Health	100%
Merial S.A.S.	02/25/1941	France	Animal Health	100%
Sanofi-Aventis Amérique du Nord S.A.S.	09/20/1985	France	Pharmaceuticals	100%
Sanofi-Aventis Deutschland GmbH	06/30/1997	Germany	Pharmaceuticals	100%
Sanofi-Aventis Europe S.A.S.	07/15/1996	France	Pharmaceuticals	100%
Sanofi-Aventis U.S. LLC	06/28/2000	United States	Pharmaceuticals	100%
Sanofi Pasteur	02/08/1989	France	Vaccines	100%
Sanofi Pasteur Inc.	01/18/1977	United States	Vaccines	100%
Sanofi Winthrop Industrie	12/11/1972	France	Pharmaceuticals	100%

Since 2009, we have transformed our Group through numerous acquisitions (see Item 4A "History and Development of the Company"), in particular those of Genzyme in April 2011 and Merial in September 2009. The financial effects of the Genzyme acquisition are presented in Note D.1.3. to our consolidated financial statements, included in this annual report at Item 18. The financial effects of the Merial acquisition are

Edgar Filing: Sanofi - Form 20-F

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. We have also entered into worldwide marketing arrangements. Two of our major products (Plavix® and Aprovel®) are marketed through an alliance with BMS, Actonel® is marketed through an alliance with Warner Chilcott (acquired by Actavis), and Zaltrap® is marketed through an alliance with Regeneron. See "Item 5 Financial Presentation of 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 Ltd

Table of Contents

and Merial S.A.S. (Animal Health); these entities define strategic priorities and coordinate R&D efforts. To fulfill this role, these entities subcontract R&D work to subsidiaries that have the necessary resources. They also license patents, manufacturing know-how and trademarks to certain French and foreign subsidiaries. In these cases, the licensee subsidiaries manufacture and distribute 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. (France), Sanofi-Aventis Deutschland GmbH (Germany), Sanofi-Aventis U.S. LLC and Genzyme Corporation (United States);

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

Animal Health: Merial Ltd (United Kingdom) 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". These assets are mainly held by Sanofi Pasteur, Genzyme Corporation, Sanofi Chimie, Sanofi-Aventis Deutschland GmbH, Sanofi Pasteur Inc. and Sanofi Winthrop Industrie.

D. Property, Plant and Equipment

D.1. Overview

Our headquarters are located in Paris, France. See " 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 of all our support functions, plus operational representatives from our subsidiaries and the Group.

A breakdown of these 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.

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. These 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 and development and production facilities, either freehold or under finance leases with a purchase option exercisable at 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 the continuing evolution of our Industrial Affairs department in support of our new business model. As a result, since June 2013 the Industrial Affairs department has been responsible for all production and quality operations within the Group. The department focuses on the needs of customers and the quality of service, the sharing of lean manufacturing practices, the development of a common culture committed to quality, and the sharing of expertise within technology platforms, particularly in biologics and injectables.

Edgar Filing: Sanofi - Form 20-F

Table of Contents

We carry out our industrial production at 112 sites in 41 countries (including 37 sites in emerging markets):

82 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 2013, we produced the following quantities:

Pharmaceuticals: 3,153 million boxes produced and packaged (3,758 including outsourced production);

Vaccines: 476 million containers prepared (including outsourced production); and

Animal Health: 550 million doses of vaccines for all species other than avian, 90 billion doses of avian vaccines, and 68 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 these facilities with regard to environmental, health, safety and security matters, quality compliance and capacity utilization. For more information about our property, plant and equipment, see Note D.3 to our consolidated financial statements, included at Item 18 of this annual report and "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).

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

France: Ambarès (Aprovel®, Depakine®, Multaq®), Aramon (irbesartan), Compiègne (Arava®, Orelox®, Magne B6®), Le Trait (Lovenox®), Lyon Gerland (Thymoglobulin®, Celsior®), Maisons-Alfort (Lovenox®), Neuville-sur-Saône (which discontinued its traditional chemicals activities at end 2013 with the transfer of dronedarone production to the Sisteron site), Quetigny (Stilnox®, Plavix®), Sisteron (clopidogrel bisulfate, dronedarone, zolpidem tartrate), Tours (Stilnox®, Aprovel®, Xatral®), Vitry-sur Seine (docetaxel/ aflibercept);

Germany: Frankfurt (insulins, Ramipril, Lantus®, Tritace®, oncology, Taxotere®, Eloxatine®, medical devices, Apidra®);

Ireland: Waterford (Myozyme®, Lumizyme®, Cholestagel®, Thymoglobulin®, Renagel®, Renvela®, and Cerezyme®);

Italy: Scoppito (Tritace®, Amaryl®) and Anagni (Depakine®, Fasturtec®, Rifa antibiotic family);

United Kingdom: Dagenham (Taxotere® and Eloxatine®, production of which was transferred to Frankfurt in Germany after closure of the site in June 2013), Fawdon (Plavix®, Aprovel®), Haverhill (sevelamer hydrochloride API (Renagel®), sevelamer carbonate API (Renvela®), Cerezyme®, Fabrazyme®, Thyrogen®, Myozyme®, etc), and Holmes Chapel (Nasacort®, Flutiform®);

Edgar Filing: Sanofi - Form 20-F

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 11 production sites and works with more than 20 subcontractors to manufacture 22 commercial products over a broad range of technological platforms.

Genzyme's sites are as follows:

Belgium: Geel (A1 alpha glucosidase: Myozyme®/Lumizyme®);

Table of Contents

United States: Allston (Cerezyme®), Framingham (Fabrazyme®, Myozyme®, Thyrogen®, Seprafilm®, hyaluronic acid), Cambridge (Carticel®, Epicel®, MACI® (Matrix-induced Autologous Chondrocyte Implantation), Ridgefield (Synvisc®, Hectorol®, Mozobil®, Jonexa®, Prevelle®), Woburn (LeGoo®), and Lynnwood, Washington (Leukine®); and

Denmark: Copenhagen (MACI®).

Industrial Sites: Vaccines (Sanofi Pasteur)

The headquarters of our Vaccines division, Sanofi Pasteur, are 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, is intended to gradually replace the chemicals activity on the site, which was discontinued at the end of 2013, by vaccine production from 2014 onwards.

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

Industrial Sites: Animal Health (Merial)

Merial has 18 industrial sites in nine different countries, 15 R&D sites, 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), St-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: dedicated facilities for Merial's avian vaccines at Berlin (Maryland), Gainesville (Georgia) and Raleigh (North Carolina), dedicated facility for mammal viral and bacterial vaccines at Athens (Georgia), and dedicated facility for autogenous bovine and swine vaccines at Worthington (Minnesota); and

Edgar Filing: Sanofi - Form 20-F

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 above.

In Animal Health, research and development activities are conducted at 15 sites.

Table of Contents

D.3. Acquisitions, Capital Expenditures and Divestitures

The carrying amount of our property, plant and equipment at December 31, 2013 was €10,182 million. During 2013, we invested €1,082 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 2011, 2012 and 2013 are described in Notes D.1. ("Impact of changes in the scope of consolidation"), D.2. ("Merical"), 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, 2013, our firm commitments in respect of future capital expenditures amounted to €324 million. The principal sites involved were: for the Pharmaceuticals segment, the industrial facilities at Frankfurt (Germany), Framingham and Allston (United States), Vertolaye (France), and in Hungary; and for the Vaccines segment, the facility at Swiftwater (United States).

In the medium term and assuming no changes in the scope of consolidation, we expect to invest on average €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.

Our principal ongoing investments are described below. During 2013, our industrial network actively contributed to the development of our seven growth platforms: Emerging Markets, Diabetes Solutions, Consumer Health Care, Genzyme and Other Innovative Products (all of which are part of our Pharmaceuticals segment), Vaccines, and Animal Health.

Pharmaceuticals

In our **Diabetes Solutions** growth platform, the Frankfurt site – the principal manufacturing center for Sanofi Diabetes products – is being equipped with a new aseptic processing area that uses isolator technology to significantly improve the aseptic filling process and improve productivity. This investment will be operational in 2016. The Frankfurt site also celebrated the production of its billionth SoloSTAR® insulin pen on World Diabetes Day in November 2013. In February 2013, Sanofi announced it was investing €44 million in Genzyme's biotechnology campus in Waterford, Ireland. In particular, Sanofi will be investing in filling facilities for Lantus®. Subject to regulatory approval, Lantus® should go into commercial production in Waterford in 2017.

The Sanofi Diabetes industrial network is also expanding its footprint in emerging markets, both in Russia with the Orel site, which is now Sanofi's second largest insulin pen production site after Frankfurt, and in China (Beijing), where a new facility inaugurated in 2012 has begun assembly and packaging of SoloSTAR®, the pre-filled injection system for Lantus®. Finally in order to incorporate Shantha (India) into Sanofi's injectables platform, a certain number of technologies for manufacturing Insuman® insulin are currently being transferred from the Frankfurt site to the Indian site so that it can handle filling and packaging for the local market.

Our industrial pharmaceutical operations for the **Consumer Health Care** platform are based on a network of 10 production sites spread over four growth hubs: in Europe, with the Lisieux (France) factories producing Doliprane®, Origgio (Italy), Cologne (Germany) and Rzeszow (Poland); in Asia, where the new consumer products facility at Hangzhou in China (production capacity: 3 billion pills) has been operational since the beginning of 2013, as well as the Tangshan (China) and Virginia (Australia) sites; in South America, with the Suzano (Brazil) site; and in the United States, with the Chattem site, which in September 2013 launched the over-the-counter antacid Roloids® product from its Chattanooga (Tennessee) production facility (which in 2012 led preparations for the U.S. launch of the pediatric oral suspension formulation of Allegra®). In 2013, the industrial development teams also continued making an active contribution to consumer health care product launches, expanding our presence in this highly competitive market.

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

Edgar Filing: Sanofi - Form 20-F

rejection.

In March 2013, a bioproduction platform was launched to develop synergies between Pharmaceuticals, Sanofi Pasteur, Genzyme, Meril and the Biotherapeutics businesses. This platform will enable Sanofi to build its

Table of Contents

presence in biotechnologies by taking advantage of transversal opportunities, in particular in the use of production capacity, development, technologies of the future in biotechnology, and skills management.

The development of our **Emerging Markets** platform is built on a network of over 30 regional and local industrial sites in 20 countries, supporting growth in these markets. In addition to our recent investments in China in Diabetes Solutions and CHC, a number of other projects are under way. In the Middle East, 2012 saw Sanofi lay the foundation stone for a facility in Saudi Arabia that will produce solid pharmaceutical formulations, which will be marketed from 2015. In Latin America, where we already have a large industrial footprint, the Brasilia plant has been operational since 2013, producing oral antibiotics and generic contraceptives, with potential capacity of 66 million units. In addition, after the acquisition of Genfar at end 2012, Sanofi is now the leading player in the Colombian pharmaceuticals market and in the generics market, with the Villa-Rica factory supporting the Sanofi production site at Cali.

In India since 2012, the Ankleshwar Pharma site in Gujarat State (India) has handled packaging and quality control through to release of the first commercial batches of **AllStar**, the first high-quality affordable insulin pen. The Goa site (India) invested to extend its solid formulation production capacity to around 2.5 billion pills a year. In Vietnam, Sanofi announced in March 2013 that it was investing \$75 million in the construction of a new factory to produce specialty pharmaceuticals and CHC products from 2015.

In Algeria, where Sanofi has been operating for over 20 years, the foundation stone of the new Sidi Abdellah factory was laid in September 2013. This site, which will be the largest Sanofi industrial complex in the Africa/Middle East territory, will mainly produce dry and liquid formulations, and will also host a distribution center. It will have production and distribution capacity of 100 million units per annum, or around 80% of the volumes distributed by Sanofi in Algeria.

During 2013, our Pharmaceuticals segment continued to roll out the economic performance improvement plan launched in 2011. Based on its Sanofi Manufacturing System, the plan is intended to deliver performance standards commensurate with the diversity of our pharmaceuticals businesses and markets, and to meet the industrial challenges ahead to 2020. Our Industrial Affairs department is constantly adapting the network of industrial sites to market needs, as a result of which a number of sites are in the process of sale or closure, such as Kansas City in 2015 (United States), Dagenham in 2013 and Fawdon in 2015 (United Kingdom), Romainville in 2013, and the traditional chemicals business in Neuville-sur-Saône in 2013 (France).

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 Framlington Biologics site, based at 74 New York Avenue, has started construction of a new factory to increase purification capacity for production of Fabrazyme® representing an investment of \$83 million.

Vaccines (Sanofi Pasteur)

Sanofi Pasteur is undergoing a major investment phase, particularly the new dedicated dengue fever vaccine facility at Neuville (France), which produced its first batches in 2014. Two new dedicated influenza vaccine facilities are in the start-up phase: Shenzhen (China), approved by the Chinese authorities (CFDA) at end 2013, and Ocoyoacac (Mexico). Ocoyoacac was approved by the Mexican authorities at the start of 2012, had a successful first influenza vaccination season in Mexico in 2013, and is currently doubling its capacity for 2014. In response to observations made by the FDA during routine inspections conducted in 2012 in Toronto (Canada) and Marcy l'Etoile (France), Sanofi Pasteur initiated and stepped up a compliance program to address the quality issues identified.

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). In order to support the future growth of avian and other vaccines in the Chinese market, Merial has invested \$70 million in a new site in the Nanchang high-tech development zone, which was inaugurated in October 2013. In Brazil at the Paulinia site, Merial is adapting its industrial facilities for the production of the new product **NexGard** (to be governed by European Union Good Manufacturing Practices and approved by the FDA).

Table of Contents

Innovation and culture of industrial excellence

In 2013 Sanofi highlighted industrial innovation by organizing its fifth annual round of innovation trophies, centered on patient needs, industrial performance and citizen entrepreneurship.

In addition, the investment in an innovative biosynthesis process at the Saint-Aubin-Lès-Elbeuf and Vertolaye sites in France is entering the final phase before start-up and production, with the certification/approval of the numerous items of fermentation and extraction plant which will improve Sanofi's international competitiveness in the production of corticosteroids.

The Chemistry and Biotechnology teams were awarded the 2013 industry prize by the Chemistry Society of France for developing an innovative industrial process for manufacturing artemisinin, used as the basis for anti-malarial drugs. Finally, the development teams won the Good Design Award, one of the most important industrial design prizes, giving worldwide recognition for Lyxumia® and its AllStar and JuniorSTAR® insulin pens.

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 been carrying out a review of our office space master plan for the Greater Paris area since 2009.

This review will result in all our Group support functions and operating divisions being housed on a smaller number of sites (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) is currently under construction on the old site (Gentilly Val De Bièvre). The foundation stone was laid at end 2012, with completion expected in early 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, marks the Group's transformation symbolically.

A new Master Plan, initiated at end 2011, which defines the Group's medium-term office space requirements in the Lyon agglomeration, is in the implementation phase. A first off-plan lease was signed in early 2013 covering some of the "Pooled Services" functions, due to be delivered in March 2015 by its owner, Plastic Omnium. A second lease will be signed in early October 2014 for 2016, covering the corporate functions of Merial and Sanofi Pasteur via the sale of an existing freehold site and the off-plan reconstruction of the Group's first energy-positive building in France. The Master Plan aims to align the new sites on the Paris Master Plan, involving buildings with environmental certification, accompanied by a reduction in overall occupancy costs and work space in line with the new Corporate Charter.

An office space integration project covering the real estate portfolio of Genzyme and Merial, begun in 2011, is operative in 50 countries covering 540,000m². At end 2013, 44 sites had been integrated.

Other Master Plans were initiated at end 2012 to define office space real estate strategy, the first in the Cambridge (Massachusetts, USA) agglomeration, the second in Frankfurt (Germany). Operational implementation had not begun at end 2013. Integration of Genzyme's activities in the United States will enable office space use to be redefined in that city.

Item 4A. 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, 2013.

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.

2013 Overview

During 2013, we continued to follow the strategic direction that we established 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.

Our full-year results for 2013 were, until August, negatively impacted by the residual effects of the loss of exclusivity in the United States of a number of our historical flagship products in the previous year: Avapro® in March 2012, Plavix® in May 2012, and Eloxatin® in August 2012. Despite temporary difficulties for our Generics business in Brazil, a slowdown in the Chinese pharmaceutical market, temporary supply limitations for our Pentacel® and Adacel® vaccines in the United States and strong competition for our Frontline® product in Animal Health, our net sales growth has nevertheless moved back into positive territory since September 2013, which marked the end of the patent cliff related to some of our major products. In a tough economic climate and against a backdrop of pressure by governments to cut healthcare costs, we have been able to limit the drop in our net sales and profitability thanks to the performance of our growth platforms and rigorous cost control.

Our net sales for the year were €32,951 million, 5.7% lower than in 2012 (0.5% at constant exchange rates, see definition at " Presentation of Net Sales" below), reflecting the €1.3 billion of net sales lost through competition from generics (see " Impacts from generic competition" below) but also good performances from our Diabetes Solutions, Genzyme and Emerging Markets growth platforms. The year also saw a number of new product launches stemming from our research efforts including Zaltrap® (metastatic colorectal cancer), Lyxumia® (type 2 diabetes), and Aubagio® and Lemtrada (multiple sclerosis) in Europe, and Kynamro (homozygous familial hypercholesterolemia) in the United States.

Our other revenues fell by €655 million (64.9%) year-on-year, mainly as a result of the loss of license revenues under the worldwide alliance with Bristol-Myers Squibb (BMS) on Plavix® and Aprovel®. The restructuring of the alliance between Sanofi and BMS, announced in October 2012 following the loss of exclusivity for Plavix® and Avapro®/Avalide® in many major markets, took effect on January 1, 2013. Under the new agreement, BMS returned to us our rights to Plavix® and Avapro®/Avalide® worldwide, with the exception of the United States and Puerto Rico for Plavix®, thereby giving us exclusive control over these products and their commercialization.

The ongoing realignment of our resources, combined with favorable exchange rate effects, helped reduce further our research and development expenses by 2.8% and our selling and general expenses by 3.7%. Our business net income was €6,687 million, down 17.5% from 2012, while our business earnings per share were €5.05, down 17.8% from 2012. This year-on-year fall includes the effect of exchange rates, which was negative overall. 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.

Net income attributable to equity holders of Sanofi amounted to €3,717 million, down 24.0% from 2012. Basic earnings per share were €2.81, down 24.3% from 2012; diluted earnings per share for 2013 were €2.78 (24.5% lower).

During 2013, we continued our policy of targeted acquisitions and of alliances in research and development. In Consumer Health Care, we acquired the worldwide rights to the Rolaid® brand via our Chattem subsidiary in January 2013. In Generics, we completed the acquisition of Colombian pharmaceutical company Genfar S.A., a

Table of Contents

significant player in its home country and throughout Latin America generally, in March 2013. In Animal Health, Merial acquired the animal health division of Dosch Pharmaceuticals Pvt Ltd in India in June 2013. We also entered into various alliances and licensing deals to extend or strengthen our existing research fields.

As of December 31, 2013, we had reduced our debt, net of cash and cash equivalents to €6.0 billion (compared with €7.7 billion as of December 31, 2012). A dividend of €2.80 per share in respect of the 2013 financial year, representing a payout equivalent to 55% of our business net income, will be submitted for approval by the shareholders at the Annual General Meeting of May 5, 2014.

Our operations generate significant cash flow. We recorded €6,954 million of net cash provided by operating activities in 2013 compared to €8,171 million in 2012. During 2013, we paid out €3.6 billion in dividends. With respect to our financial position, we ended 2013 with our debt, net of cash and cash equivalents (see definition at "Liquidity and Capital Resources" below) at €6,043 million (2012: €7,719 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 10.6% at the end of 2013 compared to 13.4% at the end of 2012. See "Liquidity and Capital Resources" below.

Impacts from generic competition

Some of our flagship products continued to experience sales erosion in 2013 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, 2013 and 2012 (see "Results of Operations Year Ended December 31, 2013 Compared with Year Ended December 31, 2012") shows that in 2013, generic competition led to a loss of €1.3 billion of net sales on a reported basis (or €1.3 billion at constant exchange rates). The table below sets forth the impact by product.

<i>(€ million)</i> Product	2013 Reported	2012 Reported	Change on a reported basis	Change on a reported basis (%)
Plavix® Western Europe	257	307	(50)	-16.3%
Aprovel® Western Europe	338	557	(219)	-39.3%
Taxotere® Western Europe	22	53	(31)	-58.5%
Eloxatin® U.S.	19	718	(699)	-97.4%
Lovenox® U.S.	187	319	(132)	-41.4%
Plavix® U.S. ⁽¹⁾	5	76	(71)	-93.4%
Aprovel® U.S. ⁽¹⁾	17	45	(28)	-62.2%
Taxotere® U.S.	42	53	(11)	-20.8%
Ambien® U.S.	88	85	+3	+3.5%
Xatral® U.S.	3	20	(17)	-85.0%
Nasacort® U.S.	7	21	(14)	-66.7%

Edgar Filing: Sanofi - Form 20-F

Xyzal® U.S.	6	6		
Allegra® U.S.	(3)	(1)	(2)	
Total	988	2,259	(1,271)	-56.3%

(1)

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

We expect the erosion caused by generic competition to continue in 2014, with a negative impact on net income. Products susceptible to the effects of such competition in 2014 include:

those for which new generic competition can reasonably be expected in 2014 based on expiration dates, patents or other regulatory or commercial exclusivity: Renagel®/Renvela® in the United States and Europe;

Table of Contents

those which already faced generic competition as of January 1, 2013, but whose sales can reasonably be expected to be subject to further sales erosion in 2014: Plavix® and Aprovel® in Europe; Lovenox®, Ambien® and Taxotere® in the United States; and Allegra®, Amaryl®, Myslee® and Taxotere® in Japan.

In 2013, the aggregate consolidated net sales of these products in countries where generic competition currently exists or is expected in 2014 were €2,260 million (€848 million in the United States, €728 million in Europe and €684 million in Japan). This 2013 figure includes Renagel®/Renvela® sales of €531 million in the U.S. and €133 million in Western Europe. 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, 2013, December 31, 2012 and December 31, 2011 have been significantly affected by our August 2004 acquisition of Aventis and certain subsequent transactions, mainly our acquisition of Genzyme on April 4, 2011. 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 (€1,199 million in 2013, €1,489 million in 2012, and €1,788 million in 2011). The Genzyme business combination has given rise to significant amortization of intangible assets (€930 million in 2013, €976 million in 2012 and €705 million in 2011) and impairment of intangible assets (€665 million in 2013, €25 million in 2012 and €119 million in 2011).

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, 2013, 2012 and 2011, 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."

Table of Contents

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".

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 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. in Europe.

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. In particular, this segment included our interest in the Yves Rocher group (see note D.6. to our consolidated financial statements included at Item 18 of this annual report).

Inter-segment transactions are not material.

Business Operating Income of Segments

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.

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

the amounts reported in the line items "Fair value remeasurement of contingent consideration liabilities", "Restructuring costs" 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;

the share 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; and

restructuring costs relating to associates and joint ventures are eliminated.

Edgar Filing: Sanofi - Form 20-F

Table of Contents

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

<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	(8,517)	(1,776)	(689)		(10,982)
Research and development expenses	(4,087)	(518)	(165)		(4,770)
Selling and general expenses	(7,361)	(588)	(653)		(8,602)
Other operating income and expenses	421	3	(1)	26	449
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	7,887	909	502	26	9,324

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	(7,650)	(609)	(669)	(1)	(8,929)
Other operating income and expenses	134	(7)	3	18	148
Share of profit/(loss) of associates and joint ventures	432	(1)	(7)		424
Net income attributable to non-controlling interests	(171)		(1)		(172)
Business operating income	9,601	1,157	673	17	11,448

(1)

Includes the impact of applying the revised IAS 19 (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, 2011⁽¹⁾.

<i>(€ million)</i>	Pharmaceuticals	Vaccines	Animal Health	Other	Total
Net sales	27,890	3,469	2,030		33,389
Other revenues	1,622	25	22		1,669
Cost of sales	(8,340)	(1,400)	(649)		(10,389)
Research and development expenses	(4,082)	(562)	(144)		(4,788)
Selling and general expenses	(7,351)	(541)	(615)	(1)	(8,508)
Other operating income and expenses	29		(7)	24	46
Share of profit/(loss) of associates and joint ventures	1,088	1		13	1,102
Net income attributable to non-controlling interests	(246)		(1)		(247)
Business operating income	10,610	992	636	36	12,274

(1)

Includes the impact of applying the revised IAS 19 (see Note A.2.2. to our consolidated financial statements included at Item 18 of this annual report).

Table of Contents

The following table (in accordance with paragraph 28 of IFRS 8) reconciles our Business Operating Income to our Income before tax and associates and joint ventures for the years ended December 31, 2013, 2012 and 2011:

<i>(€ million)</i>	2013	2012(1)	2011(1)
Business Operating Income	9,324	11,448	12,274
Share of profit/(loss) of associates and joint ventures ⁽²⁾	(85)	(424)	(1,102)
Net income attributable to non-controlling interests ⁽³⁾	162	172	247
Amortization of intangible assets	(2,914)	(3,291)	(3,314)
Impairment of intangible assets	(1,387)	(117)	(142)
Fair value remeasurement of contingent consideration liabilities	314	(192)	15
Expenses arising from the impact of acquisitions on inventories ⁽⁴⁾	(8)	(23)	(476)
Restructuring costs	(300)	(1,141)	(1,314)
Other gains and losses and litigation ⁽⁵⁾			(327)
Operating Income	5,106	6,432	5,861
Financial expense	(612)	(751)	(744)
Financial income	109	93	140
Income before tax and associates and joint ventures	4,603	5,774	5,257

- (1) *Includes the impact of applying the revised IAS 19 (see Note A.2.2. to our consolidated financial statements included at Item 18 of this annual report).*
- (2) *Excluding restructuring costs of associates and joint ventures and expenses arising from the impact of acquisitions on associates and joint ventures.*
- (3) *Excluding the portion attributable to non-controlling interests of the adjustments shown in the table above.*
- (4) *This line comprises the workdown of inventories remeasured at fair value at the acquisition date.*
- (5) *See Note D.28. 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.

Edgar Filing: Sanofi - Form 20-F

Our management uses business net income to manage and to evaluate our performance, and we believe it is appropriate to disclose this non-GAAP financial measure, as a supplement to our IFRS reporting, in order to assist investors in analyzing the factors and trends affecting our business performance. Our management also intends to use business net income as the basis for proposing the dividend policy for the Group. Accordingly, management believes that an investor's understanding of trends in our dividend policy is enhanced by disclosing business net income.

We have also decided to report "business earnings per share". Business earnings per share is a specific non-GAAP financial measure, which we define as business net income divided by the weighted average number of shares outstanding. Our management intends to give earnings guidance based on business earnings per share. We also present business earnings per share on a diluted basis.

Business net income is defined as "Net income attributable to equity holders of Sanofi", determined under IFRS, excluding (i) amortization of intangible assets; (ii) impairment of intangible assets; (iii) fair value remeasurement of contingent consideration liabilities; (iv) other impacts associated with acquisitions (including impacts of acquisitions on associates and joint ventures); (v) restructuring costs (including restructuring costs relating to associates and joint ventures); (vi) other gains and losses, and litigation; (vii) the tax effect related to the items listed in (i) through (vi); as well as (viii) the effects of major tax disputes, the tax on dividends distributed to Sanofi shareholders starting in 2013, and as an exception for 2011, the retroactive effect (2006-2010) on the tax liability resulting from the agreement signed on December 22, 2011 by France and the United States on transfer prices (APA-Advance Pricing Agreement), for which the amount is deemed to be significant; and (ix) the share of non-controlling interests in items (i) through (viii). Items (i), (ii), (iii), (v) and (vi) correspond to those reported in the income statement line items

Edgar Filing: Sanofi - Form 20-F

Table of Contents

"Amortization of intangible assets", "Impairment of intangible assets", "Fair value remeasurement of contingent consideration liabilities", "Restructuring costs" and "Other gains and losses, and litigation", as defined in Notes B.19. and B.20. to our consolidated financial statements.

The following table reconciles our business net income to our Net income attributable to equity holders of Sanofi for the years ended December 31, 2013, 2012 and 2011:

<i>(€ million)</i>	2013	2012(1)	2011(1)
Business net income	6,687	8,101	8,748
(i) Amortization of intangible assets	(2,914)	(3,291)	(3,314)
(ii) Impairment of intangible assets	(1,387)	(117)	(142)
(iii) Fair value remeasurement of contingent consideration liabilities	314	(192)	15
(iv) Expenses arising from the impact of acquisitions on inventories ⁽²⁾	(8)	(23)	(476)
(v) Restructuring costs	(300)	(1,141)	(1,314)
(vi) Other gains and losses, and litigation ⁽³⁾			(327)
(vii) Tax effects on the items listed above, comprising:	1,480	1,580	1,905
<i>amortization of intangible assets</i>	939	1,159	1,178
<i>impairment of intangible assets</i>	527	42	37
<i>fair value remeasurement of contingent consideration liabilities</i>	(85)	2	34
<i>expenses arising from the impact of acquisitions on inventories</i>	2	7	143
<i>restructuring costs</i>	97	370	399
<i>other gains and losses, and litigation</i>			114
(iv)/(ix) Other tax items ⁽⁴⁾	(109)		577
(x) Share of items listed above attributable to non-controlling interests	4	3	6
(iv)/(v) Restructuring costs and expenses arising from the impact of acquisitions on associates and joint ventures ⁽⁵⁾	(50)	(31)	(32)
Net income attributable to equity holders of Sanofi	3,717	4,889	5,646

(1) *Includes the impact of applying the revised IAS 19 (see Note A.2.2. to our consolidated financial statements included at Item 18 of this annual report).*

(2) *This line comprises the workdown of inventories remeasured at fair value at the acquisition date.*

(3)

See Note D.28. to our consolidated financial statements included at Item 18 of this annual report.

- (4) In 2013, this line item corresponds to the tax on dividends distributed to Sanofi shareholders. In 2011, this line item includes €349 million relating to the effect of the Franco-American Advance Pricing Agreement (APA), and a €228 million reduction in deferred tax liabilities on remeasurements of intangible assets of Merial as a result of changes in tax legislation in the United Kingdom.
- (5) This line shows the portion of major restructuring costs incurred by associates and joint ventures, and expenses arising from the impact of acquisitions on associates and joint ventures (workdown of acquired inventories, amortization and impairment of intangible assets, and impairment of goodwill).

The following table sets forth the calculation of our business net income for the years ended December 31, 2013, 2012 and 2011:

<i>(€ million)</i>	2012	2012(1)	2011(1)
Business operating income	9,324	11,448	12,274
Financial income and expenses	(503)	(658)	(604)
Income tax expense	(2,134)	(2,689)	(2,922)
Business net income	6,687	8,101	8,748

- (1) *Includes the impact of applying the revised IAS 19 (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. We believe that excluding these non-cash charges

Table of Contents

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, 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) 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. 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 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. More recently, 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

Edgar Filing: Sanofi - Form 20-F

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.

Table of Contents

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 in the periods following the closing of the acquisition.

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 2013, 2012 and 2011. 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.

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, 2013 Compared with Year Ended December 31, 2012 Net Sales" and at " Results of Operations Year Ended December 31, 2012 Compared with Year Ended December 31, 2011 Net Sales" below.

Financial Presentation of Alliances

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

The financial impact of the alliances on the Company's income statement is described in " Results of Operations Year Ended December 31, 2013 Compared with Year Ended December 31, 2012" and " Year Ended December 31, 2012 Compared with Year Ended December 31, 2011", in particular in " Net sales", " Other Revenues", " Share of Profit/Loss of Associates and Joint Ventures" and " Net Income Attributable to Non-Controlling Interests".

Table of Contents

Alliance Arrangements with Bristol-Myers Squibb (BMS)

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

Initial Alliance Agreement

Under the terms of the initial alliance agreement, there are three principal marketing arrangements that are used:

Co-marketing. Under the co-marketing system, each company markets the products independently under its own brand names. We record our own sales and related costs in our consolidated financial statements.

Exclusive Marketing. Under the exclusive marketing system, one company has the exclusive right to market the products. We record our own sales and related costs in our consolidated financial statements.

Co-promotion. Under the co-promotion system, the products are marketed through the alliance arrangements (either by contractual arrangements or by separate entities) under a single brand name. The accounting treatment of the co-promotion agreement depends upon who has majority ownership and operational management in that territory, as discussed below.

The initial alliance arrangements include two royalty streams that are 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 earn an adjustable discovery royalty on part of Aprovel®/Avapro®/Karvea®/Karvezide® and Plavix®/Iscover® sold in alliance countries regardless of the marketing system. The discovery royalty earned in territories under operational management of BMS is reflected in our consolidated income statement in "Other revenues."

Development Royalty. In addition to the discovery royalty, we and BMS are 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®.

We record development royalties paid to BMS in our consolidated income statement as an increase to our cost of sales in countries where we consolidate sales of the products. We record development royalties that we receive as "other revenues" in countries where BMS consolidates sales of the products.

Under the initial alliance arrangements, there are two territories, one under our operational management and the other under the operational management of BMS. The territory under our operational management consists of Europe and most of Africa and Asia, while the territory under the operational management of BMS consists of the rest of the world (excluding Japan). In Japan, Aprovel® has been marketed jointly by Shionogi Pharmaceuticals and Dainippon Sumitomo Pharma Co. Ltd since June 2008. Our alliance with BMS does not cover distribution rights to Plavix® in Japan, which is marketed by Sanofi.

Territory under our operational management. In the territory under our operational management, the marketing arrangements and recognition of operations by the Group are as follows:

we use the co-promotion system for most of the countries in Western Europe for Aprovel®/Avapro®/Karvea®/Karvezide® and Plavix®/Iscover® and for certain Asian countries for Plavix®/Iscover®. We record 100% of all alliance revenues and expenses in our consolidated financial statements. We also record, as selling and general expenses, payments to BMS for the cost of BMS's personnel involved in the promotion of the products. BMS's share of the operating income of the alliances is recorded as "non-controlling interests";

Edgar Filing: Sanofi - Form 20-F

we use the co-marketing system in Germany, Spain and Greece for both Aprovel®/Avapro®/Karvea®/Karvezide® and Plavix®/Iscover® and in Italy for Aprovel®/Avapro®/Karvea®/Karvezide®; and

we have the exclusive right to market Aprovel®/Avapro®/Karvea®/Karvezide® and Plavix®/Iscover® in Eastern Europe, Africa, the Middle East, and certain Asian countries (excluding Japan); we have the exclusive right to market Aprovel® in Scandinavia and Ireland, and Plavix® in Malaysia.

Table of Contents

Territory under BMS operational management. In the territory under BMS operational management, the marketing arrangements and recognition of operations by the Group are as follows:

we use the co-promotion system in the United States, Canada and Puerto Rico, where the products are sold through the alliances under the operational management of BMS. With respect to Avapro® (the brand name used in the United States for Aprovel®) and Plavix®, we record our share of the alliance's operating income under "Share of profit/loss of associates and joint ventures". We also record payments from BMS for the cost of our personnel in connection with the promotion of the product as a deduction from our selling and general expenses;

we use the co-marketing system in Brazil, Mexico, Argentina and Australia for Plavix®/Iscover® and Aprovel®/Avapro®/Karvea®/Karvezide® and in Colombia for Plavix®/Iscover®; and

we have the exclusive right to market the products in certain other countries of Latin America.

In countries where the products are marketed by BMS on a co-marketing basis, or through alliances under the operational management of BMS, we also earn revenues from the sale of the active ingredients for the products to BMS or such entities, which we record as "Net sales" in our consolidated income statement.

Revised 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 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® 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.

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*".

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 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.

Edgar Filing: Sanofi - Form 20-F

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 is recognized in the line item "Other operating expenses", a component of operating income.

Table of Contents

Under the terms of the same agreement, Regeneron agreed to repay 50% of the development costs initially funded by Sanofi. Contractually, this amount represents 5% of the residual repayment 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.

The agreement also stipulates milestone payments to be made by Sanofi on receipt of specified marketing approvals for Zaltrap® in the United States, within the European Union and in 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. On February 5, 2013, the European Commission granted marketing authorization in the European Union for Zaltrap®. 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.

In Japan, Sanofi will develop and commercialize Zaltrap®, with Regeneron entitled to receive a royalty.

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

In November 2007, Sanofi and Regeneron signed additional agreements for the discovery, development and commercialization of fully human therapeutic antibodies. In November 2009, the agreements were broadened and the term extended. Under the 2009 agreements Sanofi committed to funding Regeneron's discovery and pre-clinical development of fully human therapeutic antibodies, 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 an option to license for further development any antibodies discovered by Regeneron that attain Investigational New Drug (IND) status.

If such an option is exercised, Sanofi would be primarily responsible for funding, and would co-develop the antibody with Regeneron. Sanofi and Regeneron would share co-promotion rights and profits on sales of the co-developed antibodies. Development costs for the drug candidate would be shared between the companies, with Sanofi generally funding these costs up front, except that following receipt of the first positive Phase III trial results for a co-developed drug candidate, subsequent Phase III trial-related costs for that drug candidate would be shared 80% by Sanofi and 20% by Regeneron. Once a product begins to be marketed, Regeneron would progressively repay out of its profits 50% of the development costs borne by Sanofi for all antibodies licensed by Sanofi. However, Regeneron would not be required to apply more than 10% of its share of the profits from collaboration products in any calendar quarter towards reimbursing Sanofi for these development costs. Under the terms of the collaboration agreement, Sanofi may also be required to make milestone payments based on aggregate sales of antibodies. In 2013, seven antibodies were in clinical development, two of which were in Phase III.

If Sanofi does not exercise its licensing option for an antibody under development, Sanofi would be entitled to receive a royalty once the antibody begins to be marketed.

Investor Agreement

On January 11, 2014, Regeneron, Sanofi and some of its subsidiaries (collectively "Sanofi") agreed to amend and restate the original investor agreement, dated as of December 20, 2007, as amended in its entirety and entered into the Amended and Restated Investor Agreement (the "Amended Investor Agreement"). The Amended Investor Agreement was amended to, among other things, provide Sanofi with the right to nominate a single independent director to the Regeneron's Board of Directors upon reaching 20% ownership of the Company's then outstanding shares of Class A Stock, par value \$0.001 per share and Common Stock (together the "Capital Stock") and to extend the term of the lock-up obligations. Sanofi retains its right to acquire up to 30% of the Capital Stock. The Amended Investor Agreement also provides Sanofi with the right to receive certain information as may be reasonably agreed upon by the parties that will facilitate Sanofi's ability to account for their investment in the Company using the equity method of accounting under International Financial Reporting Standards.

Subsequently Sanofi has determined to purchase, directly or through its subsidiaries, additional shares of Common Stock to increase its beneficial ownership to approximately 20.5% of the Common Stock outstanding. Sanofi made no commitment in terms of the timing of such transactions, which will depend on market conditions including the price and availability of shares of Common Stock, and on such other factors considered relevant to Sanofi.

Table of Contents

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

Our agreement with Warner Chilcott ("the Alliance Partner") covers the worldwide development and marketing arrangements of Actonel®, except Japan for which we hold no rights. Until October 30, 2009, this agreement was between Sanofi and Procter & Gamble Pharmaceuticals (P&G). Since the sale by P&G of its pharmaceutical business to Warner Chilcott on October 30, 2009, Actonel® has been marketed in collaboration with Warner Chilcott. The local marketing arrangements may take various forms.

Co-promotion, whereby sales resources are pooled but only one of the two parties to the alliance agreement (Sanofi or the Alliance Partner) invoices product sales. Co-promotion is carried out under contractual agreements and is not based on any specific legal entity. The Alliance Partner sells the product and incurs all of the related costs in France and Canada. This co-promotion scheme formerly included Germany, Belgium and Luxembourg until December 31, 2007, the Netherlands until March 31, 2008, and the United States and Puerto Rico until March 31, 2010. We recognize our share of revenues under the agreement in our income statement as a component of operating income in the line item "Other operating income". Since April 1, 2010, we have received royalties from the Alliance Partner on sales made by the Alliance Partner in the United States and Puerto Rico. In the secondary co-promotion territories (the United Kingdom until December 31, 2008, Ireland, Sweden, Finland, Greece, Switzerland, Austria, Portugal and Australia), we sell the product and recognize all the revenues from sales of the product along with the corresponding expenses. The share due to the Alliance Partner is recognized in "Cost of sales";

Co-marketing, which applies in Italy, whereby each party to the alliance agreement sells the product in the country under its own brand name, and recognizes all revenues and expenses from its own operations in its respective income statement. Each company also markets the product independently under its own brand name in Spain, although Spain is not included in the co-marketing territory;

Warner Chilcott only territories: the product has been marketed by the Alliance Partner independently in Germany, Belgium and Luxembourg since January 1, 2008, in the Netherlands since April 1, 2008, in the United Kingdom since January 1, 2009 and in the United States and Puerto Rico since April 1, 2010. We recognize our share of revenues under the alliance agreement in "Other operating income"; and

Sanofi only territories: we have exclusive rights to sell the product in all other territories. We recognize all revenues and expenses from our own operations in our income statement, but in return for these exclusive rights we pay the Alliance Partner a royalty based on actual sales. This royalty is recognized in "Cost of sales".

In 2010, Sanofi and Warner Chilcott began negotiations on the future of their alliance arrangements. In an arbitration proceeding, an arbitration panel decided on July 14, 2011 that the termination by Warner Chilcott of an ancillary agreement did not lead to the termination of the Actonel® Alliance. Pursuant to this decision, the alliance will remain in effect until January 1, 2015.

In October 2013, Warner Chilcott and Sanofi 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 definitive lump-sum of \$125 million.

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 2013, we earned 31.7% of our net sales in the United States. 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 decrease 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 alliance with BMS in the United States, which is under the operational management of BMS, as described at "Financial Presentation of Alliances Alliance arrangements with Bristol-Myers Squibb" above.

Edgar Filing: Sanofi - Form 20-F

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".

Table of Contents

Divestments

In 2013, Sanofi sold its U.S. commercial rights to 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 Cosmétique Yves Rocher, in line with the Group's desire to focus on strategic activities.

In December 2011 Sanofi sold the Dermik dermatology business to Valeant Pharmaceuticals International Inc., for €321 million (see Note D.1.3. to our consolidated financial statements included at Item 18 of this annual report).

Acquisitions

The principal acquisitions during 2013 are described below:

In January 2013, Sanofi (via Chattem) completed the acquisition of the worldwide rights to the Rolaid® brand from the McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. Rolaid® 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.1.1. to our consolidated financial statements included at Item 18 of this annual report.

In June 2013, Meril 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 strengthened its presence in biosurgery by acquiring a 100% equity interest in Pluomed, Inc. (Pluomed), an American medical devices company. Pluomed 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, Meril completed the acquisition of Newport Laboratories, a privately held company based in Worthington, Minnesota (United States), which is 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.

The principal acquisitions during 2011 are described below:

In February 2011, Sanofi completed the acquisition of 100% of the share capital of BMP Sunstone Corporation (BMP Sunstone), a pharmaceutical company that is developing a portfolio of branded pharmaceutical and healthcare products in China. See Note D.1.3. to our consolidated financial statements included at Item 18 of this annual report.

In April 2011, Sanofi acquired Genzyme Corporation (Genzyme), a major biotechnology company headquartered in Cambridge, Massachusetts (United States), with primary areas of focus in rare diseases, renal endocrinology, oncology and biosurgery. The transaction was completed in accordance with the terms of the public exchange offer at a price of \$74 in cash plus the issuance to Genzyme shareholders of one contingent value right (CVR) per share. The total purchase price amounted to €14.8 billion. The purchase price allocation is disclosed in Note D.1.3. to our consolidated financial statements included at Item 18 of this annual report.

In October 2011, Sanofi acquired Topaz Pharmaceuticals Inc. (Topaz), a U.S. pharmaceutical research company that developed an innovative anti-parasitic product for treating head lice. An upfront payment of \$35 million was made on completion of the transaction. According to the agreement, future milestone payments may be made upon market approval and depending on the achievement of sales targets.

Edgar Filing: Sanofi - Form 20-F

See Note D.1.3. to our consolidated financial statements included at Item 18 of this annual report.

In November 2011, Sanofi acquired the business of Universal Medicare Private Limited (Universal), a major producer of nutraceuticals in India. The acquisition price amounted to €83 million. See Note D.1.3. to our consolidated financial statements included at Item 18 of this annual report.

Table of Contents

In December 2011, Sanofi co-invested in Warp Drive Bio, an innovative start-up biotechnology company, along with two venture capital firms, Third Rock Ventures (TRV) and Greylock Partners. Warp Drive Bio is an innovative biotechnology company, focusing on proprietary genomic technology to discover drugs of natural origin. Sanofi and TRV / Greylock have invested in Warp Drive Bio at parity.

Results of Operations***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	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	(10,990)	(33.4%)	(11,098)	(31.8%)
Gross profit	22,316	67.7%	24,859	71.1%
Research & development expenses	(4,770)	(14.5%)	(4,905)	(14.0%)
Selling & general expenses	(8,602)	(26.1%)	(8,929)	(25.6%)
Other operating income	691		562	
Other operating expenses	(242)		(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	5,106	15.5%	6,432	18.4%
Financial expenses	(612)		(751)	
Financial income	109		93	
Income before tax and associates and joint ventures	4,603	14.0%	5,774	16.5%
Income tax expense	(763)		(1,109)	
Share of profit/(loss) of associates and joint ventures	35		393	

Edgar Filing: Sanofi - Form 20-F

Net income	3,875	11.8%	5,058	14.5%
Net income attributable to non-controlling interests	158		169	
Net income attributable to equity holders of Sanofi	3,717	11.3%	4,889	14.0%
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		3.71	
Diluted earnings per share (in euros)	2.78		3.68	

(1)

Includes the impact of applying the revised IAS 19 (see Note A.2.2. to our consolidated financial statements included at Item 18 of this annual report).

Table of Contents**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 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%

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.

Edgar Filing: Sanofi - Form 20-F

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

Edgar Filing: Sanofi - Form 20-F

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	Change at constant exchange rates
Product	Indication	2013 Reported	2012 Reported	reported basis	
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%
Lyxumia®	Diabetes	9			
Other products		49	36	+36.1%	+38.9%
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			
Other prescription 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 advanced 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 consists of treatments for rare diseases, and treatments for multiple sclerosis (Aubagio® and Lemtrada®). The 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.

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 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.

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

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 advanced 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).

(1)

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

Edgar Filing: Sanofi - Form 20-F

Table of Contents

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.

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> Product	2013 Reported	2012 Reported	Change on a reported basis	Change at constant exchange rates
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.

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.

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 2013:

<i>(€ million)</i> 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
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%
Lyxumia®	6						3	
Other products	45	+50.0%		-100.0%	2		2	
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%
Other products	39	+14.7%	99	+5.2%	39	+13.9%	67	+8.0%

Edgar Filing: Sanofi - Form 20-F

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(4)	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 prescription 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 of 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 Frontline® and 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</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 **Frontline® / 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).

Table of Contents

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).

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

<i>(€million)</i> 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
Frontline® and other 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	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:

<i>(€million)</i>	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%

Edgar Filing: Sanofi - Form 20-F

<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%
<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 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, an increase of 4.4% at constant exchange rates. Growth was slowed by temporary difficulties in the Generics business in Brazil, but was mainly driven 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

Table of Contents

totalled €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 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 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 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 €22,316 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.

Table of Contents

Selling and General Expenses

Selling and general expenses totaled €8,602 million, versus €8,929 million in 2012, a reduction of €327 million or 3.7%. These expenses represented 26.1% of net sales, versus 25.6% in 2012.

The Pharmaceuticals segment recorded a reduction of €289 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 €242 million (versus €414 million in 2012).

Overall, other operating income and expenses represented net income of €449 million in 2013, versus net income of €148 million in 2012. This €301 million rise 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).

Table of Contents

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.

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 €5,106 million for 2013, versus €6,432 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 "3. Consolidated Balance sheet" 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).

Gains on disposals of non-current financial assets totaled €50 million (versus €37 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 €4,603 million in 2013, versus €5,774 million in 2012, a fall of 20.3%.

Income Tax Expense

Income tax expense represented €763 million in 2013, versus €1,109 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

Table of Contents

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 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 €3,875 million in 2013, versus €5,058 million in 2012.

Net Income Attributable to Non-Controlling Interests

Net income attributable to non-controlling interests was €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 €3,717 million, versus €4,889 million in 2012.

Basic earnings per share for 2013 was €2.81, 24.3% lower than the 2012 figure of €3.71, 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 €2.78 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 €9,324 million in 2013, 18.6% lower than in 2012 (€11,448 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	2012	Change
Pharmaceuticals	7,887	9,601	-17.9%
Vaccines	909	1,157	-21.4%
Animal Health	502	673	-25.4%
Other	26	17	+52.9%
Business operating income	9,324	11,448	-18.6%

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.

Business net income totaled €6,687 million in 2013, versus €8,101 million in 2012, a fall of 17.5%; it represented 20.3% of net sales, against 23.2% in 2012.

Table of Contents**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.

Year Ended December 31, 2012 Compared with Year Ended December 31, 2011

The consolidated income statements for the years ended December 31, 2012 and December 31, 2011 break down as follows:

(under IFRS) <i>(€ million)</i>	2012(1)	as % of net sales	2011(1)	as % of net sales
Net sales	34,947	100.0%	33,389	100.0%
Other revenues	1,010	2.9%	1,669	5.0%
Cost of sales	(11,098)	(31.8%)	(10,865)	(32.5%)
Gross profit	24,859	71.1%	24,193	72.5%
Research & development expenses	(4,905)	(14.0%)	(4,788)	(14.3%)
Selling & general expenses	(8,929)	(25.6%)	(8,508)	(25.5%)
Other operating income	562		319	
Other operating expenses	(414)		(273)	
Amortization of intangible assets	(3,291)		(3,314)	
Impairment of intangible assets	(117)		(142)	
Fair value remeasurement of contingent consideration liabilities	(192)		15	
Restructuring costs	(1,141)		(1,314)	
Other gains and losses, and litigation			(327)	
Operating income	6,432	18.4%	5,861	17.6%
Financial expenses	(751)		(744)	
Financial income	93		140	
Income before tax and associates and joint ventures	5,774	16.5%	5,257	15.7%
Income tax expense	(1,109)		(440)	

Edgar Filing: Sanofi - Form 20-F

Share of profit/(loss) of associates and joint ventures	393		1,070	
Net income	5,058	14.5%	5,887	17.6%
Net income attributable to non-controlling interests	169		241	
Net income attributable to equity holders of Sanofi	4,889	14.0%	5,646	16.9%
Average number of shares outstanding (million)	1,319.5		1,321.7	
Average number of shares outstanding after dilution (million)	1,329.6		1,326.7	
Basic earnings per share (in euros)	3.71		4.27	
Diluted earnings per share (in euros)	3.68		4.26	

(1)

Includes the impact of applying the amended IAS 19 (see Note A.2.2. to our consolidated financial statements included at Item 18 of this annual report).

Our consolidated income statements include the results of the operations of Genzyme from April 2011. In order to help investors gain a better understanding of our performances, in the narrative discussion of certain income statement line items ("net sales", "research & development expenses", and "selling & general expenses"), we include non-consolidated 2011 first-quarter data for Genzyme in additional analyses.

Table of Contents**Net Sales**

Net sales for the year ended December 31, 2012 amounted to €34,947 million, up 4.7% on 2011. Exchange rate movements had a favorable effect of 4.2 points, mainly reflecting the appreciation of the U.S. dollar against the euro, and to a lesser extent the appreciation of the yen and the yuan. At constant exchange rates and after taking account of changes in structure (mainly the consolidation of Genzyme from April 2011), net sales rose by 0.5% year-on-year.

The following table sets forth a reconciliation of our reported net sales for the years ended December 31, 2012 and December 31, 2011 to our net sales at constant exchange rates:

<i>(€ million)</i>	2012	2011	Change
Net sales	34,947	33,389	+4.7%
Effect of exchange rates	(1,400)		
Net sales at constant exchange rates	33,547	33,389	+0.5%

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

The following table breaks down our 2012 and 2011 net sales by business segment:

<i>(€ million)</i>	2012 Reported	2011 Reported	Change on a reported basis	Change at constant exchange rates
Pharmaceuticals	28,871	27,890	+3.5%	-0.4%
Vaccines	3,897	3,469	+12.3%	+5.7%
Animal Health	2,179	2,030	+7.3%	+3.1%
Total	34,947	33,389	+4.7%	+0.5%

Net Sales by Product - Pharmaceuticals segment

Net sales generated by our Pharmaceuticals segment were €28,871 million in 2012, up 3.5% on a reported basis but down 0.4% at constant exchange rates. The year-on-year change (increase of €981 million) reflects the positive effect of exchange rates (€1,082 million) on the one hand, and the following impacts at constant exchange rates on the other hand:

the positive impact of consolidating Genzyme from April 2011 (non-consolidated sales of €733 million were generated by Genzyme in the first quarter of 2011);

the performance of growth platforms (€1,381 million);

the negative effects of generic competition (mainly on sales of Lovenox®, Taxotere® and Eloxatin® in the United States, and of Taxotere®, Plavix® and Aprovel® in Western Europe), totaling €1,345 million;

Edgar Filing: Sanofi - Form 20-F

the ending of the co-promotion agreement with Teva on Copaxone® and the divestiture of the Dermik business in 2011 (negative effects of €559 million); and

other impacts (negative effects of €311 million), including the negative impact of austerity measures in the European Union.

On a constant structure basis and at constant exchange rates (which primarily means including the non-consolidated sales of Genzyme for the first quarter of 2011 and excluding sales of Copaxone® for the whole of 2011), net sales for the Pharmaceuticals segment fell by 0.6% in 2012.

Our flagship products (Lantus® and Apidra®, Cerezyme®, Myozyme® / Lumizyme®, Fabrazyme®, Aubagio®, Multaq®, Jevtana®, Mozobil®, Zaltrap®, Lovenox®, Renagel® / Renvela®, Allegra®, Stilnox® / Ambien® / Myslee®, Synvisc® / Synvisc-One®, Taxotere® and Eloxatin®) are discussed below. Sales of Plavix® and Aprovel® are discussed further below under " Worldwide Presence of Plavix® and Aprovel®".

Table of Contents

The following table breaks down our 2012 and 2011 net sales for the Pharmaceuticals segment by product:

<i>(€ million)</i>				Change on a reported basis	Change at constant exchange rates
Product	Indication	2012 Reported	2011 Reported		
Lantus®	Diabetes	4,960	3,916	+26.7%	+19.3%
Apidra®	Diabetes	230	190	+21.1%	+16.8%
Amaryl®	Diabetes	421	436	-3.4%	-8.0%
Insuman®	Diabetes	135	132	+2.3%	+3.0%
Other products		36	10	+260.0%	+250.0%
Total: Diabetes	Diabetes	5,782	4,684	+23.4%	+16.7%
Eloxatin®	Colorectal cancer	956	1,071	-10.7%	-17.3%
Taxotere®	Breast, lung, prostate, stomach, and head & neck cancer	563	922	-38.9%	-41.9%
Jevtana®	Prostate cancer	235	188	+25.0%	+20.2%
Thymoglobulin®(1)	Organ rejection	193	128		
Zaltrap®	Colorectal cancer	25			
Mozobil®(1)	Hematologic malignancies	96	59		
Other products(1)		326	261		
Total: Oncology(1)		2,394	2,629	-8.9%	-14.3%
Cerezyme®(1)	Gaucher disease	633	441		
Myozyme®/Lumizyme®(1)	Pompe disease	462	308		
Fabrazyme®(1)	Fabry disease	292	109		
Aldurazyme®(1)	Mucopolysaccharidosis	150	100		
Other products(1)		241	164		
Sub-total: Rare diseases(1)		1,778	1,122		

Edgar Filing: Sanofi - Form 20-F

Aubagio®	Multiple sclerosis	7			
Sub-total: Multiple sclerosis		7			
Total: Genzyme(1)		1,785	1,122		
Plavix®	Atherothrombosis	2,066	2,040	+1.3%	-4.6%
Lovenox®	Thrombosis	1,893	2,111	-10.3%	-12.0%
Aprovel®/CoAprovel®	Hypertension	1,151	1,291	-10.8%	-13.3%
Renagel®/Renvela®(1)	Hyperphosphatemia	653	415		
Allegra®	Allergic rhinitis, urticaria	553	580	-4.7%	-9.5%
Stilnox®/Ambien®/Myslee®	Sleep disorders	497	490	+1.4%	-4.5%
Depakine®	Epilepsy	410	388	+5.7%	+3.1%
Synvisc®/Synvisc-One®(1)	Arthritis	363	256		
Tritace®	Hypertension	345	375	-8.0%	-8.3%
Multaq®	Atrial fibrillation	255	261	-2.3%	-8.0%
Lasix®	Edema, hypertension	210	213	-1.4%	-3.8%
Targocid®	Bacterial infections	198	200	-1.0%	-2.5%
Orudis®	Rheumatoid arthritis, osteoarthritis	184	158	+16.5%	+15.8%
Cordarone®	Arrhythmia	163	160	+1.9%	-2.5%
Xatral®	Benign prostatic hypertrophy	130	200	-35.0%	-37.0%
Actonel®	Osteoporosis, Paget's disease	134	167	-19.8%	-21.6%
Other prescription products		4,853	5,738	-15.4%	-17.4%
Total: Other prescription products(1)		14,058	15,043	-6.5%	-9.6%
Consumer Health Care		3,008	2,666	+12.8%	+9.9%
Generics		1,844	1,746	+5.6%	+5.0%
Total Pharmaceuticals		28,871	27,890	+3.5%	-0.4%

(1) *In 2011, net sales of Genzyme products were recognized from the acquisition date (April 2011).*

Table of Contents

Diabetes division

Net sales for the Diabetes division amounted to €5,782 million, up 16.7% at constant exchange rates, driven by strong growth for Lantus®.

Lantus® posted a 19.3% increase in net sales at constant exchange rates in 2012 to €4,960 million, driven by very strong growth in the United States (up 22.0% at €3,087 million); in Emerging Markets (up 25.4% at €793 million), especially in China (up 35.9%) and Latin America (up 32.3%); and in Japan (up 22.0%). In Western Europe, growth was a more modest 5.3% at constant exchange rates.

Net sales of the rapid-acting insulin analog **Apidra®** advanced by 16.8% (at constant exchange rates) to €230 million in 2012, buoyed by the product's performance in Emerging Markets (up 37.8%).

Amaryl® saw net sales fall by 8.0% at constant exchange rates to €421 million, mainly as a result of competition from generics in Japan (down 31.7%, at €125 million), and in spite of 11.4% growth in Emerging Markets to €263 million.

Oncology business

Net sales for the Oncology business were €2,394 million, down 14.3% at constant exchange rates.

Net sales of **Eloxatin®** fell by 17.3% at constant exchange rates to 956 million in 2012, reflecting the loss of exclusivity in the United States on August 9, 2012, which had been expected.

Taxotere® reported a fall in net sales of 41.9% at constant exchange rates, to €563 million. The product faced competition from generics in Western Europe (down 72.5%) and the United States (down 80.2%). Emerging Markets sales amounted to €270 million, down 11.2% at constant exchange rates.

Jevtana® posted net sales of €235 million in 2012, up 20.2% at constant exchange rates, boosted by product launches in various countries in Western Europe (€91 million, up 104.5% at constant exchange rates) and in Emerging Markets.

Zaltrap®, launched in the United States and Puerto Rico at the end of August 2012, generated net sales of €25 million for the year.

Mozobil® reported net sales of €96 million, up 19.7% on a constant structure basis and at constant exchange rates (i.e., including non-consolidated sales generated by Genzyme in the first quarter of 2011).

Jevtana®, Zaltrap® and Mozobil®, along with Multaq® (see " Other pharmaceutical products" below), form the "Other Innovative Products" growth platform. This platform generated net sales of €611 million in 2012.

Genzyme business

The Genzyme business consists of products used to treat rare diseases, and products for the treatment of multiple sclerosis (Aubagio® and the experimental agent Lemtrada). Because Genzyme's net sales have been consolidated from the acquisition date (i.e. the start of April 2011), the 2011 consolidated net sales of the Genzyme business do not include sales for the first quarter of 2011. On a constant structure basis and at constant exchange rates, i.e. after including non-consolidated net sales for the first quarter of 2011, the net sales of the Genzyme business rose by 16.9% in 2012 to € 1,785 million.

Table of Contents

The following table breaks down our 2012 and 2011 net sales for the Genzyme business by product:

<i>(€ million)</i>				Change on a constant structure basis and at constant exchange rates
Product	Indication	2012 Reported	2011 Reported	
Aubagio®	Multiple sclerosis	7		
Sub-total: Multiple sclerosis		7		
Cerezyme® ⁽¹⁾	Gaucher disease	633	441	+6.0%
Myozyme®/Lumizyme® ⁽¹⁾	Pompe disease	462	308	+11.4%
Fabrazyme® ⁽¹⁾	Fabry disease	292	109	+96.4%
Aldurazyme® ⁽¹⁾	Mucopolysaccharidosis	150	100	+9.8%
Other rare disease products ⁽¹⁾		241	164	+6.1%
Sub-total: Rare diseases⁽¹⁾		1,778	1,122	+16.4%
Total: Genzyme⁽¹⁾		1,785	1,122	+16.9%

(1) *In 2011, net sales of Genzyme products were recognized from the acquisition date (April 2011).*

Cerezyme® recorded net sales growth of 6.0% on a constant structure basis and at constant exchange rates, to €633 million (+0.9% in Western Europe, at €215 million; +6.3% in the United States, at €166 million). Production continued to improve during the year, enabling normal doses to be delivered to patients in the product's principal markets.

Net sales of **Myozyme®/Lumizyme®** were up 11.4% on a constant structure basis and at constant exchange rates at €462 million (+10.4% in Western Europe, at €257 million; +6.9% in the United States, at €117 million).

Fabrazyme® reported a 96.4% surge in net sales on a constant structure basis and at constant exchange rates, to €292 million. This increase was due mainly to the resumption of production at the new facility at Framingham (United States) in March 2012, enabling full doses to be supplied in all markets where the product is approved for sale.

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

In multiple sclerosis, **Aubagio®** was launched in the United States in October 2012, and recorded fourth-quarter net sales of €7 million.

Other pharmaceutical products

Lovenox® recorded a fall in net sales of 12.0% at constant exchange rates to €1,893 million in 2012, as a result of competition from generics in the United States, where sales slipped by 53.1% (at constant exchange rates) to €319 million. Sales generated outside the United States

Edgar Filing: Sanofi - Form 20-F

accounted for 83.1% of worldwide net sales and rose by 5.5% at constant exchange rates to €1,574 million, driven by Emerging Markets (up 11.6% at constant exchange rates at €615 million). Sanofi also launched its own generic version of Lovenox® in the United States, sales of which are recognized in the Generics business.

Net sales of **Renagel®/Renvela®** rose by 13.0% on a constant structure basis and at constant exchange rates (i.e. including non-consolidated sales generated by Genzyme in the first quarter of 2011) to €653 million, on a fine performance in the United States (up 19.2% on a constant structure basis and at constant exchange rates).

Synvisc®/Synvisc-One® reported sales growth of 4.0% on a constant structure basis and at constant exchange rates (including non-consolidated sales generated by Genzyme in the first quarter of 2011) to €363 million, driven mainly by the Synvisc-One® franchise in the United States (€302 million, up 5.7% on a constant structure basis and at constant exchange rates).

Net sales of the **Ambien®** range fell by 4.5% at constant exchange rates to €497 million, reflecting competition from generics of Ambien® CR in the United States and Western Europe and the introduction of generic versions of Myslee® in Japan during the second half of 2012.

Table of Contents

Allegra® reported a decline in net sales as a prescription medicine (down 9.5% at constant exchange rates) to €553 million, reflecting lower prices in Japan (down 15.2% at constant exchange rates, at € 423 million). This product is sold over the counter in the United States, and has also been available over the counter in Japan since November 2012. Sales over the counter are recognized in the Consumer Health Care business. In August 2012 three generic versions of Allegra® were approved by the regulatory authorities in Japan; since February 2013, Allegra® as a prescription medicine has been subject to generic competition in this country.

Net sales of **Multaq®** fell by 8.0% at constant exchange rates to €255 million, due to the effect of restrictions placed on the product's indication during the second half of 2011.

Net sales of **Copaxone®** (reported under the line item "Other prescription products") amounted to €24 million, versus €436 million in 2011, down 94.7% (at constant exchange rates), reflecting the ending of the co-promotion agreement with Teva in all territories in the first quarter of 2012. Since the transfer of Copaxone® to Teva, we no longer recognize net sales of the product. Instead, for the two years following the transfer we are entitled to receive a payment representing 6% of net sales, which we recognize under the income statement line item "Other revenues".

Consumer Health Care business

Net sales for the **Consumer Health Care** business rose by 9.9% at constant exchange rates in 2012, to €3,008 million. This figure includes revenues generated from the acquisitions made in 2011 (primarily BMP Sunstone in China, and the nutraceuticals business of Universal Medicare in India).

In Emerging Markets, net sales advanced by 19.9% at constant exchange rates to €1,478 million. In the United States, sales growth was modest (up 2.2% at constant exchange rates, at €606 million) compared with 2011; this reflects the fact that in the early part of 2011, distributors were building up inventories of the over-the-counter (OTC) version of Allegra®, launched in March 2011. Excluding Allegra® OTC, growth in the United States reached 6.2% at constant exchange rates. Allegra® OTC was also launched in Japan in November 2012.

Generics business

The **Generics** business reported net sales of €1,844 million in 2012, a rise of 5.0% at constant exchange rates. The business was boosted by sales growth in the United States (up 42.4% at constant exchange rates, at €272 million), where we launched our own authorized generic versions of Lovenox® and Aprovel®. In Emerging Markets, net sales fell slightly (down 2.7% at constant exchange rates) to €1,045 million, due to the impact of tougher competition and disruptions in the Brazilian market.

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 2012:

<i>(€million)</i>		Change at constant exchange rates		Change at constant exchange rates		Change at constant exchange rates		Change at constant exchange rates
Product	Western Europe(1)		United States		Emerging Markets(2)		Rest of the world(3)	
Lantus®	778	+5.3%	3,087	+22.0%	793	+25.4%	302	+20.6%
Apidra®	78	+14.7%	73	+3.1%	51	+37.8%	28	+30.0%
Amaryl®	28	-12.5%	3	-25.0%	263	+11.4%	127	-32.6%
Insuman®	98	-4.9%	1		37	+27.6%	(1)	
Other products	30	+190.0%	3				3	
Total: Diabetes	1,012	+4.3%	3,167	+21.5%	1,144	+22.5%	459	+0.2%
Eloxatin®	13	-65.8%	718	-18.0%	153	-10.5%	72	+3.1%
Taxotere®	53	-72.5%	53	-80.2%	270	-11.2%	187	-10.7%
Jevtana®	91	+104.5%	109	-23.7%	33	+153.8%	2	
Thymoglobulin®(4)	29		98		50		16	
Zaltrap®			24				1	
Mozobil®(4)	30		56		7		3	
Other products(4)	75		183		45		23	
Total: Oncology	291	-23.7%	1,241	-19.8%	558	0.0%	304	-1.7%
Cerezyme®(4)	215		166		190		62	
Myozyme®/Lumizyme®(4)	257		117		55		33	
Fabrazyme®(4)	52		152		41		47	
Aldurazyme®(4)	58		26		47		19	
Other products(4)	34		96		36		75	
Sub-total Rare diseases(4)	616		557		369		236	

Edgar Filing: Sanofi - Form 20-F

Aubagio®			7					
Sub-total Multiple sclerosis			7					
Total: Genzyme(4)	616		564		369		236	
Plavix®	307	-25.8%	76*	-62.2%	799	+5.5%	884	+13.4%
Lovenox®	854	+1.9%	319	-53.1%	615	+11.6%	105	+2.1%
Aprovel®/CoAprovel®	557	-26.4%	45*	-8.2%	395	+2.5%	154	+17.5%
Renagel®/Renvela®(4)	128		451		53		21	
Allegra®	11	-15.4%	(1)	-133.3%	120	+21.2%	423	-15.1%
Stilnox®/Ambien®/Myslee®	46	-13.2%	85	-4.9%	70	+7.7%	296	-5.5%
Depakine®	143	-3.4%			251	+7.9%	16	-6.3%
Synvisc®/Synvisc-One®(4)	20		302		24		17	
Tritace®	150	-11.8%			180	-1.1%	15	-37.5%
Multaq®	46	-31.8%	200	+0.5%	8	0.0%	1	-25.0%
Lasix®	79	-3.7%	3	0.0%	62	+7.0%	66	-12.7%
Targocid®	86	-9.5%			90	-3.3%	22	+53.8%
Orudis®	51	+6.3%			129	+20.8%	4	
Cordarone®	28	-9.7%			76	+7.4%	59	-9.8%
Xatral®	45	-24.1%	20	-74.7%	62	-6.3%	3	0.0%
Actonel®	33	-38.9%			66	-16.7%	35	-5.7%
Other prescription products	1,900	-27.0%	585	-20.5%	1,731	-4.6%	637	-11.4%
Total: Other prescription products(4)	4,484	-19.2%	2,085	-18.7%	4,731	+2.6%	2,758	-2.5%
Consumer Health Care	666	+2.2%	606	+2.2%	1,478	+19.9%	258	-2.1%
Generics	500	+11.5%	272	+42.4%	1,045	-2.7%	27	-29.4%
Total pharmaceuticals	7,569	-9.9%	7,935	+0.9%	9,325	+7.8%	4,042	-0.3%

(1)

Edgar Filing: Sanofi - Form 20-F

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.*
- (4) *In 2011, net sales of Genzyme products were recognized from the acquisition date (April 2011).*
- * *Sales of active ingredient to the entity majority-owned by BMS in the United States.*

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

Net sales for the Vaccines segment amounted to €3,897 million in 2012, up 12.3% on a reported basis and 5.7% at constant exchange rates.

The following table presents the 2012 and 2011 sales of our Vaccines segment by range of products:

<i>(€million)</i>	2012 Reported	2011 Reported	Change on a reported basis	Change at constant exchange rates
Polio/Pertussis/Hib Vaccines (including Pentacel® and Pentaxim®)	1,184	1,075	+10.1%	+5.0%
Influenza Vaccines (including Vaxigrip® and Fluzone®)	884	826	+7.0%	-0.2%
Meningitis/Pneumonia Vaccines (including Menactra®)	650	510	+27.5%	+18.0%
Adult Booster Vaccines (including Adacel®)	496	465	+6.7%	0.0%
Travel and Other Endemics Vaccines	364	370	-1.6%	-4.9%
Other Vaccines	319	223	+43.0%	+31.8%
Total Vaccines	3,897	3,469	+12.3%	+5.7%

Polio/Pertussis/Hib vaccines saw net sales increase by 5.0% at constant exchange rates to €1,184 million. This rise reflects a strong performance in Japan (€239 million, up 140.9% at constant exchange rates, mainly due to the successful launch of Imovax® in September 2012) and a good performance in Emerging Markets (€495 million, up 5.7% at constant exchange rates), but also a drop in net sales in the United States (down 25.1% at constant exchange rates, at €374 million) due to supply limitations for Pentacel® and Adacel® following a temporary shutdown in production at Sanofi Pasteur.

Net sales of **Influenza** vaccines were flat (down 0.2% at constant exchange rates), at €884 million. In the United States, net sales fell by 5.5% at constant exchange rates, to €466 million; in Emerging Markets, net sales rose by 5.1% at constant exchange rates, to €317 million.

Meningitis/Pneumonia vaccines posted net sales of €650 million, up 18.0% at constant exchange rates, driven by a strong performance from Menactra® (€564 million, up 21.8% at constant exchange rates). Growth was especially strong in Emerging Markets (up 52.9% at constant exchange rates, at €165 million) and in the United States (up 10.5% at constant exchange rates, at €473 million).

Net sales of **Adult Booster** vaccines were unchanged year-on-year (at constant exchange rates), at €496 million.

Net sales of **Travel and Other Endemics** vaccines fell by 4.9% (at constant exchange rates) to €364 million, hit by a temporary shutdown in production of the Theracys®/Immucyst® and BCG vaccines.

In addition to the Vaccines activity reflected in our consolidated net sales, sales of Sanofi Pasteur MSD, our joint venture with Merck & Co., Inc. in Europe, amounted to €845 million in 2012, up 6.8% on a reported basis. Sales generated by Sanofi Pasteur MSD are not included in our consolidated net sales. The main growth drivers were the performance of Gardasil® (up 13.6% on a reported basis, at €206 million) and sales of the travel and endemics vaccines franchise.

Table of Contents

The following table presents the 2012 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>	55	+52.8%	374	-25.1%	495	+5.7%	260	+105.0%
Influenza Vaccines <i>(inc. Vaxigrip® and Fluzone®)</i>	79	+2.6%	466	-5.1%	317	+5.1%	22	+16.7%
Meningitis/Pneumonia Vaccines <i>(inc. Menactra®)</i>	4	+33.3%	473	+10.5%	165	+52.9%	8	-38.5%
Adult Booster Vaccines <i>(inc. Adacel®)</i>	59	-22.4%	372	+0.9%	45	+50.0%	20	-5.0%
Travel and Other Endemics Vaccines	21	-12.5%	96	-1.1%	201	-4.8%	46	-8.5%
Other Vaccines	9	-46.7%	277	+46.6%	18	0.0%	15	-25.0%
Total Vaccines	227	-2.2%	2,058	-0.7%	1,241	+9.1%	371	+48.9%

(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 Western Europe and the United States, net sales fell slightly (by 2.2% and 0.7% at constant exchange rates, respectively). In Emerging Markets, most of the rise in sales (9.1% at constant exchange rates) was generated in Latin America and China. The Rest of the World region reported strong growth (48.9% at constant exchange rates), due mainly to the performance of Imovax® in Japan.

Net Sales Animal Health segment

Edgar Filing: Sanofi - Form 20-F

The Animal Health segment achieved net sales of €2,179 million in 2012, up 3.1% at constant exchange rates (7.3% on a reported basis), driven by the performance in Emerging Markets and the first-time consolidation of the net sales of Newport Laboratories ("Newport").

The following table presents the 2012 and 2011 sales of our Animal Health segment by range of products:

<i>(€million)</i>	2012 Reported	2011 Reported	Change on a reported basis	Change at constant exchange rates
Companion animals	1,372	1,277	+7.4%	+1.9%
Production animals	807	753	+7.2%	+5.1%
Total Animal Health	2,179	2,030	+7.3%	+3.1%
<i>Of which Frontline® and other fipronil-based products</i>	775	764	+1.4%	-3.4%
<i>Of which Vaccines</i>	730	662	+10.3%	+7.6%
<i>Of which Avermectin</i>	423	372	+13.7%	+7.8%
<i>Of which Other products</i>	251	232	+8.2%	+3.9%

Net sales for the **companion animals** franchise rose by 1.8% at constant exchange rates to €1,372 million. Erosion in sales of the **Frontline®/fipronil** range of products was limited to 3.4% at constant exchange rates (€775 million) despite competitive pressure in the United States (down 7.8% at constant exchange rates, at €411 million), thanks to good performances in Emerging Markets (up 10.5%, at €93 million).

Net sales for the **production animals** franchise were 5.1% higher at constant exchange rates, at €807 million. These figures include the contribution from Newport from April 2012 onwards.

Table of Contents

The following table breaks down net sales of our Animal Health segment by product and by geographical region in 2012:

(€ 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
Frontline® and other fipronil-based products	208	-0.5%	411	-7.8%	93	+10.5%	63	-3.3%
Vaccines	181	-7.7%	152	+11.1%	375	+14.2%	22	+31.3%
Avermectin	62	-4.7%	223	+15.8%	65	+10.0%	73	-2.8%
Other products	88	-2.2%	94	+1.1%	46	+27.8%	23	0.0%
Total Animal Health	539	-3.8%	880	+1.4%	579	+14.0%	181	+0.6%

(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.

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 2012 and 2011 net sales by region:

(€ million)	2012 Reported	2011 Reported	Change on a reported basis	Change at constant exchange rates
United States	10,873	9,957	+9.2%	+0.7%
Emerging Markets ⁽¹⁾	11,145	10,133	+10.0%	+8.3%
<i>Of which Eastern Europe and Turkey</i>	<i>2,721</i>	<i>2,666</i>	<i>+2.1%</i>	<i>+2.1%</i>
<i>Of which Asia (excl. Pacific region)</i>	<i>2,841</i>	<i>2,416</i>	<i>+17.6%</i>	<i>+10.1%</i>

Edgar Filing: Sanofi - Form 20-F

<i>Of which Latin America</i>	3,435	3,111	+10.4%	+11.3%
<i>Of which Africa</i>	1,018	949	+7.3%	+8.3%
<i>Of which Middle East</i>	1,001	872	+14.8%	+12.2%
Western Europe ⁽²⁾	8,335	9,130	-8.7%	-9.3%
Rest of the World ⁽³⁾	4,594	4,169	+10.2%	+2.5%
<i>Of which Japan</i>	3,274	2,865	+14.3%	+6.6%
Total	34,947	33,389	+4.7%	+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 were up 0.7% at constant exchange rates (but fell by 2.8% after including Genzyme in the first quarter of 2011) to €10,873 million. The year-on-year change reflected strong performances from Lantus® and from the Genzyme and Generics businesses (including our own generic version of Lovenox®), but also the impact of generics of Taxotere®, Lovenox® and Eloxatin®.

In Emerging Markets, net sales reached €11,145 million, up 8.3% at constant exchange rates (or 7.2% after including Genzyme for the first quarter of 2011). In China, net sales were €1,249 million, up 15.0% at constant exchange rates, on a strong performance from Plavix® and Lantus®. In Brazil, net sales increased by 7.7% at constant exchange rates to €1,530 million, boosted by the Consumer Health Care business and the contribution from Genzyme, although growth was hampered by a slowdown in sales of generics. The Africa and Middle East zones topped the billion-euro mark for the first time (€1,018 million and €1,001 million, respectively). Sales in Russia reached €851 million, up 13.6% at constant exchange rates, driven by the Consumer Health Care and Generics businesses and also by Lantus®, Plavix® and Lovenox®.

Table of Contents

Net sales in Western Europe fell by 9.3% at constant exchange rates to €8,335 million, hampered by the transfer of the Copaxone® business to Teva; by competition from generics of Taxotere® (down 72.5% at constant exchange rates), Aprovel® (down 26.4% at constant exchange rates) and Plavix® (down 25.8% at constant exchange rates); and by the impact of austerity measures implemented by European governments. After including Genzyme for the first quarter of 2011 and excluding Copaxone®, net sales fell by 7.5% at constant exchange rates.

In the Rest of the World region, net sales totaled €4,594 million, up 2.5% at constant exchange rates (or 0.8% after including Genzyme sales for the first quarter of 2011). In Japan, net sales were €3,274 million (up 6.6% at constant exchange rates, or 4.7% after including Genzyme sales for the first quarter of 2011); positive factors included strong performances from Plavix® (up 16.0% at constant exchange rates, at €837 million) and from the Polio/Pertussis/Hib vaccines franchise (up 140.9% at constant exchange rates at €239 million, driven by the successful launch of Imovax®), while negative factors included erosion in sales of Allegra® (down 15.2% at constant exchange rates, at €423 million) and the impact of bi-annual price cuts.

Worldwide Presence of Plavix® and Aprovel®

Two of our leading products Plavix® and Aprovel® were discovered by Sanofi and jointly developed with BMS under an alliance agreement. In all territories except Japan, these products are sold either by Sanofi or by BMS in accordance with the terms of this alliance agreement applicable in 2012 and 2011 (see " Financial Presentation of Alliances Alliance arrangements with Bristol-Myers Squibb" above). Plavix® and Aprovel® lost exclusivity in the U.S. on May 17, 2012 and March 30, 2012, respectively.

Worldwide sales of these two products in 2012 and 2011 are an important indicator because they facilitate a financial statement user's understanding and analysis of our consolidated income statement, particularly in terms of understanding our overall profitability in relation to consolidated revenues, and also facilitate a user's ability to understand and assess the effectiveness of our research and development efforts.

Also, disclosing sales made by BMS of these two products in 2012 and 2011 enables the users to have a clearer understanding of trends in different lines of our income statement, in particular the lines "*Other revenues*", where we record royalties received on those sales (see " Other Revenues"); "*Share of profit/loss of associates and joint ventures*" (see " Share of Profit/Loss of Associates and Joint Ventures"), where we record our share of the profit/loss of entities included in the BMS Alliance and under BMS operational management; and "*Net income attributable to non-controlling interests*" (see " Net Income Attributable to Non-Controlling Interests"), where we record the BMS share of the profit/loss of entities included in the BMS Alliance and under our operational management.

On September 27, 2012, Sanofi and BMS restructured their alliance with effect from January 1, 2013 (see " Financial Presentation of Alliances Alliance arrangements with Bristol-Myers Squibb" above).

Table of Contents

The table below sets forth the worldwide sales of Plavix® and Aprovel® in 2012 and 2011, by geographic region:

(<i>€ million</i>)	2012			2011			Change on reported basis	Change at a constant exchange rates
	Sanofi(2)	BMS(3)	Total	Sanofi(2)	BMS(3)	Total		
Plavix®/Iscover®(1)								
Europe	424	29	453	530	44	574	-21.1%	-21.2%
United States		1,829	1,829		4,759	4,759	-61.6%	-63.7%
Other countries	1,613	89	1,702	1,370	286	1,656	+2.8%	-4.6%
Total	2,037	1,947	3,984	1,900	5,089	6,989	-43.0%	-46.2%
Aprovel®/Avapro® /Karvea®/Avalide®(4)								
Europe	527	99	626	694	130	824	-24.0%	-24.3%
United States	24	110	134		374	374	-64.2%	-66.5%
Other countries	521	91	612	451	156	607	+0.8%	-5.1%
Total	1,072	300	1,372	1,145	660	1,805	-24.0%	-26.6%

(1)

Plavix® is marketed under the trademarks Plavix® and Iscover®.

(2)

Net sales of Plavix® consolidated by Sanofi, excluding sales to BMS (€86 million in 2012 and €208 million in 2011). Net sales of Aprovel® consolidated by Sanofi, excluding sales to BMS (€111 million in 2012 and €150 million in 2011).

(3)

Translated into euros by Sanofi using the method described in Note B.2. "Foreign currency translation" to our consolidated financial statements included at Item 18 in this annual report.

(4)

Aprovel® is marketed under the trademarks Aprovel®, Avapro®, Karvea® and Avalide®.

Worldwide sales of Plavix®/Iscover® fell by 46.2% at constant exchange rates in 2012 to €3,984 million, under the impact of competition from generics in the United States and Europe. In the United States, where the product lost exclusivity on May 17, 2012, sales (consolidated by BMS) were down 63.7% at constant exchange rates, at €1,829 million. In Europe, net sales of Plavix® fell by 21.2% at constant exchange rates, to €453 million. In the Other Countries region, net sales were down 4.6% at constant exchange rates; this reflected the entry of generics into the Canadian market (where sales, consolidated by BMS, dipped by 76.1% at constant exchange rates to €50 million), but also the continuing success of the product in Japan and China where net sales (consolidated by Sanofi) reached €837 million (up 16.0% at constant exchange rates) and

€371 million (up 20.6% at constant exchange rates), respectively.

Worldwide sales of Aprovel®/Avapro®/Karvea®/Avalide® in 2012 amounted to €1,372 million, a decline of 26.6% at constant exchange rates, reflecting loss of exclusivity in the United States on March 30, 2012 and competition from generics in most Western European countries. In Japan and China, net sales (consolidated by Sanofi) came to €101 million (up 47.0% at constant exchange rates) and €138 million (up 17.3% at constant exchange rates), respectively.

Other Revenues

Other revenues, which mainly comprise royalty income under licensing agreements contracted in connection with ongoing operations, fell by 39.5% to €1,010 million (versus €1,669 million in 2011).

The decrease was mainly due to lower licensing revenue under the worldwide alliance with BMS on Plavix® and Aprovel®, which totaled €532 million in 2012 versus €1,275 million in 2011 (down 58.1% on a reported basis), due largely to the loss of exclusivity in the United States for Aprovel® (on March 30, 2012) and Plavix® (on May 17, 2012). However, the appreciation of the U.S. dollar against the euro had a favorable impact on other revenues, as did the recognition in 2012 of a €45 million payment from BMS relating to the Avalide® supply disruption in the United States during 2011.

This line also includes royalty income of €171 million from Amgen relating to a worldwide license contracted on the product Enbrel®. Royalties received on U.S. sales represented a significant portion of this income in 2012 and will contractually end in February 2013.

Table of Contents

Gross Profit

Gross profit amounted to €24,859 million in 2012 (71.1% of net sales), versus €24,193 million in 2011 (72.5% of net sales). This represents an increase of 2.8% in gross profit, but a fall of 1.4 points in the gross margin ratio.

The gross margin ratio for the Pharmaceuticals segment slipped by 3.0 points to 72.9%, reflecting a lower level of royalty income (-2.6 points) and a deterioration in the ratio of cost of sales to net sales (-0.4 of a point); this latter trend was mainly attributable to the adverse impact of generics (mainly of Taxotere® in the United States), partially offset by productivity gains and lower raw materials prices for heparins.

The gross margin ratio for the Vaccines segment fell by 1.1 point to 59.3%.

The gross margin ratio for the Animal Health segment improved by 0.2 of a point to 69.3%.

In addition, consolidated gross profit for 2012 was adversely affected by a €23 million expense (0.1 of a point) arising from the workdown of acquired inventories remeasured at fair value in connection with the acquisition of Genzyme. In 2011, this expense was €476 million (1.4 points), out of which €473 million were related to the acquisition of Genzyme.

Research and Development Expenses

Research and development (R&D) expenses totaled €4,905 million (versus €4,788 million in 2011), representing 14.0% of net sales (versus 14.3% in 2011). Overall, R&D expenses rose by €117 million, or 2.4% on a reported basis. After including Genzyme's costs for the first quarter of 2011, R&D expenses were virtually stable year-on-year. In addition, the amount of R&D expenses reported for 2012 was adversely affected by the appreciation of the U.S. dollar against the euro.

R&D expenses for the Pharmaceuticals segment increased by €121 million, up 3.0% on a reported basis. After including Genzyme's costs for the first quarter of 2011, R&D expenses were virtually stable year-on-year, reflecting our ongoing transformation initiatives and the rationalization of the project portfolio.

R&D expenses for the Vaccines segment fell by €24 million to €538 million (down 4.3% on a reported basis), due mainly to trends in the cost of clinical trials on the dengue fever vaccine and various influenza-related projects.

In the Animal Health segment, R&D expenses rose by €20 million (up 13.9% on a reported basis) versus 2011.

Selling and General Expenses

Selling and general expenses amounted to €8,929 million, compared with €8,508 million in 2011, an increase of €421 million or 4.9% on a reported basis. The ratio of selling and general expenses to net sales was virtually unchanged year-on-year at 25.6% (25.5% in 2011). After including Genzyme's costs for the first quarter of 2011, selling and general expenses were up around 1.8% year-on-year. In addition, the amount reported for 2012 was adversely affected by the appreciation of the U.S. dollar against the euro.

In the Pharmaceuticals segment, selling and general expenses increased by €299 million, or 4.1% on a reported basis. After including Genzyme's costs for the first quarter of 2011, selling and general expenses for the segment were virtually stable year-on-year. This trend reflects tight cost control (especially in mature regions) and the effect of synergies unlocked by the integration of Genzyme, and was achieved in spite of ongoing investment in our growth platforms and the launch costs incurred on Zaltrap® and Aubagio®.

Selling and general expenses for the Vaccines segment rose by €68 million (up 12.6% on a reported basis), due partly to adverse trends in the U.S. dollar/euro exchange rate and partly to increased promotional investments.

In the Animal Health segment, selling and general expenses increased by €54 million (up 8.8% on a reported basis), reflecting adverse trends in the U.S. dollar/euro exchange rate and higher promotional costs on the companion animals franchise.

Other Operating Income and Expenses

In 2012, other operating income amounted to €562 million (versus €319 million in 2011), and other operating expenses to €414 million (versus €273 million in 2011).

Table of Contents

Overall, other operating income and expenses represented net income of €148 million in 2012, compared with €46 million in 2011. This increase was mainly due to the favorable outcome of litigation relating to a license.

This line item also includes a net operational foreign exchange loss of €41 million, against €5 million in 2011.

Amortization of Intangible Assets

Amortization charged against intangible assets amounted to €3,291 million in 2012, versus €3,314 million in 2011. The year-on-year reduction of €23 million was mainly due to:

reductions: a fall in amortization charged against intangible assets recognized on the acquisition of Aventis (€1,489 million in 2012, versus €1,788 million in 2011), as some products reached the end of their life cycles in the face of competition from generics;

increases: amortization charges generated by intangible assets recognized on the acquisition of Genzyme in the second quarter of 2011 (€981 million over 12 months in 2012, versus €709 million over 9 months in 2011).

Impairment of Intangible Assets

This line showed impairment losses of €117 million against intangible assets in 2012, compared with €142 million in 2011. The impairment losses recognized in 2012 relate mainly to the discontinuation of R&D projects in the Pharmaceuticals segment, in particular some development programs in oncology.

In 2011, the impairment losses related mainly to (i) the discontinuation of a Genzyme research project; (ii) certain Zentiva generics, following a downward revision of sales projections; and (iii) the discontinuation of a joint project with Metabolex in diabetes. This line also included a reversal of impairment losses on Actonel®, recognized following confirmation of the terms of the collaboration agreement with Warner Chilcott (see Note C.3. to our consolidated financial statements included at Item 18 of this annual report).

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 an expense of €192 million in 2012, compared with a net gain of €15 million in 2011. This item mainly relates to the contingent value rights (CVRs) issued in connection with the Genzyme acquisition, and to contingent consideration payable to Bayer as a result of an acquisition made by Genzyme prior to the latter's acquisition by Sanofi (see Note D.18. to our consolidated financial statements included at Item 18 of this annual report).

Restructuring Costs

Restructuring costs amounted to €1,141 million in 2012, versus €1,314 million in 2011, and relate primarily to measures announced in connection with the major transformation program that we initiated in 2009 to adapt our structures to the challenges of the future.

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.

In 2011, these costs reflected the transformation and reorganization of our R&D operations, measures taken to adapt our industrial facilities in Europe, adjustments to our sales forces in the United States and Europe, the implementation of multi-country organizations in Europe, and the integration of Genzyme entities worldwide.

Other Gains and Losses, and Litigation

Nothing was recognized on this line in 2012.

Edgar Filing: Sanofi - Form 20-F

In 2011, this line item included a net expense of €327 million, mainly comprising (i) a €519 million backlog of depreciation and amortization expense that was not charged against the property, plant and equipment and intangible assets of Merial from September 18, 2009 through December 31, 2010 because these assets were classified as held for sale or exchange during that period in accordance with IFRS 5 (see Note D.8.2. to the consolidated financial statements included at Item 18 of this annual report); (ii) a gain of €210 million arising from damages received in connection with a Plavix® patent; and (iii) the impact of the divestiture of the Dermik dermatology business (see Note D.28. to our consolidated financial statements).

Table of Contents

Operating Income

Operating income totaled €6,432 million for 2012, versus €5,861 million for 2011, an increase of 9.7%.

Financial Income and Expenses

Net financial expense for 2012 was €658 million, compared with €604 million for 2011, an increase of €54 million.

Financial expenses directly related to our debt, net of cash and cash equivalents (see definition at "Liquidity and Capital Resources" below) were €349 million in 2012 compared to €325 million in 2011. This increase was due to a reduction in financial income resulting from a lower average rate of return on cash.

Because the average level of debt and the average rate of interest on debt were relatively stable year-on-year, financial expenses were virtually unchanged in 2012.

Impairment losses on investments and financial assets amounted to €30 million in 2012 (versus €58 million in 2011). In 2012, these losses related primarily to available-for-sale financial assets; in 2011, they related mainly to Greek government bonds (€49 million, versus €6 million in 2012).

Gains on disposals of non-current financial assets amounted to €37 million in 2012, compared with €25 million in 2011. The 2011 figure included the effect of the change in consolidation method for the investment in Société Financière des Laboratoires de Cosmétologie Yves Rocher following loss of significant influence (see Note D.6. to our consolidated financial statements). In August 2012, Sanofi sold this investment.

The effect of the unwinding of discount on provisions was €87 million in 2012 (versus €83 million in 2011), and the net financial foreign exchange loss was €17 million in 2012 (versus a net gain of €10 million in 2011).

Income before Tax and Associates and Joint Ventures

Income before tax and associates and joint ventures for 2012 was €5,774 million in 2011, versus €5,257 million in 2011, an increase of 9.8%.

Income Tax Expense

Income tax expense amounted to €1,109 million in 2012, versus €440 million in 2011.

Income tax expense in 2011 included a significant reduction in the deferred tax liability relating to the remeasurement of the intangible assets of Merial in response to changes in tax rates and legislation (primarily in the United Kingdom) and the effect of the Franco-American Advance Pricing Agreement (APA) for the period from 2006 through 2011 (see Note D.30. to our consolidated financial statements).

These effects did not impact income tax expense for 2012. However, the rise in income tax expense during the year was limited by the favorable effects of differential income tax rates applicable to our foreign subsidiaries (including the impact of an Advance Pricing Agreement (APA) with the Japanese authorities covering the period from 2012 through 2014), and also by the settlement of tax audits and the effects of some items becoming time-barred.

This item includes positive tax effects arising from (i) the amortization of intangible assets, totaling €1,159 million in 2012 (versus €1,178 million in 2011, including the impact of the Merial backlog, see "Other Gains and Losses, and Litigation" above) and (ii) restructuring costs (€370 million in 2012, versus €399 million in 2011).

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 25.5% in 2012, versus 27.0% in 2011. The difference relative to the standard corporate income tax rate applicable in France (34.4%) was mainly due to royalty income being taxed at a reduced rate in France, and to the differential in tax rates applied to profits of our foreign subsidiaries.

Share of Profit/Loss of Associates and Joint Ventures

Edgar Filing: Sanofi - Form 20-F

The share of profit/loss of associates and joint ventures in 2012 was €393 million, versus €1,070 million in 2011. This line mainly includes our share of after-tax profits from territories managed by BMS under the Plavix® and Avapro® alliance, which fell by 60.7% to €420 million (versus €1,070 million in 2011). The decline in our share was

Table of Contents

mainly attributable to a 61.6% 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 €5,058 million in 2012, compared with €5,887 million in 2011.

Net Income Attributable to Non-Controlling Interests

Net income attributable to non-controlling interests totaled €169 million in 2012, against €241 million in 2011. This line mainly comprises the share of pre-tax profits paid to BMS from territories managed by Sanofi (€149 million, versus €225 million in 2011); this year-on-year fall was directly related to increased competition from generics of clopidogrel (Plavix®) in Europe.

Net Income Attributable to Equity Holders of Sanofi

Net income attributable to equity holders of Sanofi was €4,889 million in 2012, versus €5,646 million in 2011.

Basic earnings per share for 2012 was €3.71, 13.1% lower than the 2011 figure of €4.27, based on an average number of shares outstanding of 1,319.5 million in 2012 (1,321.7 million in 2011). Diluted earnings per share for 2012 was €3.68, compared to €4.26 for 2011, based on an average number of shares outstanding after dilution of 1,329.6 million in 2012 and 1,326.7 million in 2011.

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 for 2012 was €11,448 million, compared to €12,274 million in 2011 (down 6.7%). The table below shows trends in business operating income by business segment for 2012 and 2011:

<i>(€million)</i>	2012	2011	Change
Pharmaceuticals	9,601	10,610	-9.5%
Vaccines	1,157	992	+16.6%
Animal Health	673	636	+5.8%
Other	17	36	-52.8%
Business operating income	11,448	12,274	-6.7%

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.

Business net income totaled €8,101 million in 2012 versus €8,748 million in 2011 (down 7.4%), and represented 23.2% of net sales compared with 26.2% in 2011.

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).

Edgar Filing: Sanofi - Form 20-F

Business earnings per share for 2012 were €6.14 versus €6.62 in 2011, down 7.3%, based on an average number of shares outstanding of 1,319.5 million in 2012 (1,321.7 million in 2011). Diluted business earnings per share for 2012 were €6.09 versus €6.59 in 2011, down 7.6%, based on an average number of shares outstanding of 1,329.6 million in 2012 and 1,326.7 million in 2011.

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 reduced our net debt during 2013 and 2012, whereas in 2011 our debt increased significantly to finance the acquisition of Genzyme.

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, 2013, our debt, net of cash and cash equivalents stood at €6,043 million versus €7,719 million as of December 31, 2012 and €10,859 million as of December 31, 2011. 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, 2013, our gearing ratio stood at 10.6% of our net equity versus 13.4% as of December 31, 2012 and 19.3% as of December 31, 2011.

Consolidated Statement of Cash Flows

The table below shows our summarized cash flows for the years ended December 31, 2013, 2012 and 2011:

<i>(€ million)</i>	2013	2012	2011
Net cash provided by / (used in) operating activities	6,954	8,171	9,319
Net cash provided by / (used in) investing activities	(1,273)	(1,587)	(14,701)
Net cash provided by / (used in) financing activities	(3,726)	(4,351)	2,893
Impact of exchange rates on cash and cash equivalents	(79)	24	1
Net change in cash and cash equivalents (decrease) / increase	1,876	2,257	(2,341)

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, 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).

Edgar Filing: Sanofi - Form 20-F

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

Table of Contents

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).

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.

Year Ended December 31, 2012 Compared with Year Ended December 31, 2011

Net cash provided by operating activities amounted to €8,171 million in 2012, compared with €9,319 million in 2011. Operating cash flow before changes in working capital was €8,503 million, versus €9,834 million in 2011. This decrease was largely attributable to erosion in revenues from the territories managed by BMS under the alliance on Plavix® and Avapro®, due to competition from generics in the United States. This revenue erosion was reflected in a reduced share of after-tax profits from these territories (€420 million, versus €1,070 million in 2011) and lower license revenue from the worldwide alliance with BMS on Plavix® and Aprovel®/Avapro® (€532 million in 2012, versus €1,275 million in 2011).

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, 2012 Compared with Year Ended December 31, 2011". 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.

Working capital requirements rose by €332 million in 2012, after an increase of €515 million in 2011. The increase during 2012 was mainly attributable to an increase in inventories (€445 million, including €315 million for reconstituting inventories at the Genzyme business).

Net cash used in investing activities amounted to €1,587 million in 2012, versus €14,701 million in 2011.

Acquisitions of property, plant and equipment and intangible assets totaled €1,612 million (2011: €1,782 million). The main items were investments in industrial and research facilities (€1,324 million, versus €1,394 million in 2011) and contractual payments for intangible rights under license and collaboration agreements (€293 million, versus €245 million in 2011).

Acquisitions of investments in the period amounted to €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. In 2011, acquisitions of investments amounted to €13,616 million; after including assumed liabilities and commitments, they totaled €14,079 million, and mainly comprised the acquisitions of Genzyme (€13,602 million) and BMP Sunstone (€374 million).

After-tax proceeds from disposals (€358 million) related to divestitures of financial assets (in particular, our equity interests in Société Financière des Laboratoires de Cosmétologie Yves Rocher and Handok), and to disposals of various items of property, plant and equipment and intangible assets. In 2011, proceeds from disposals came to €359 million, mainly generated by the divestiture of the Dermik dermatology business (€321 million).

Table of Contents

Financing activities generated a net cash outflow of €4,351 million in 2012, compared with a net cash inflow of €2,893 million in 2011. The 2012 figure includes €615 million of debt repayments (net change in short-term and long-term debt), as compared with net external debt raised of €5,283 million in 2011; it also includes the Sanofi dividend payout of €3,487 million (versus €1,372 million in 2011).

After the impact of exchange rates and of the cash and cash equivalents of Merial, the net change in cash and cash equivalents in 2012 was an increase of €2,257 million, compared with a decrease of €2,341 million in 2011.

Consolidated Balance Sheet and Debt

Total assets stood at €96,065 million as of December 31, 2013, versus €100,409 million a year earlier, a decrease of €4,344 million.

Debt, net of cash and cash equivalents (see definition above) was €6,043 million as of December 31, 2013, versus €7,719 million as of December 31, 2012. The table below shows our financial position for the years ended December 31, 2013, 2012 and 2011:

<i>(€ million)</i>	2013	2012	2011
Long-term debt	10,414	10,719	12,499
Short-term debt and current portion of long-term debt	4,176	3,812	2,940
Cash and cash equivalents	(8,257)	(6,381)	(4,124)
Related interest rate and currency derivatives	(290)	(431)	(456)
Debt, net of cash and cash equivalents	6,043	7,719	10,859

Our gearing ratio (debt, net of cash and cash equivalents as a proportion of total equity) fell from 13.4% in 2012 to 10.6% in 2013. Analyses of debt as of December 31, 2012 and December 31, 2011, 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, 2013 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 €57,014 million as of December 31, 2013, versus €57,466 million as of December 31, 2012. The net year-on-year decrease in equity was attributable primarily to:

increases: our net income for the year ended December 31, 2013 (€3,723 million) and the effects of share-based payment plans (€1,236 million);

decreases: the dividend payout to our shareholders in respect of the 2012 financial year (€3,638 million) and repurchases of our own shares (€1,641 million).

As of December 31, 2013, we held 3.6 million of our own shares, recorded as a deduction from equity and representing 0.27% of our share capital.

Goodwill and Other intangible assets (€52,529 million in total) decreased by €5,736 million, mainly reflecting:

decreases: amortization and impairment losses recognized during the period (€4,475 million), and currency translation differences on assets denominated in foreign currencies (€1,766 million, mainly relating to the U.S. dollar);

increases: the impact of the Genfar and Dosch acquisitions (€199 million), and acquisitions of other intangible assets (€310 million).

Provisions and other non-current liabilities (€8,735 million) decreased by €2,308 million, due mainly to a net decrease in provisions for pensions and other long-term employee benefits of €1,217 million (primarily as a result of actuarial gains on defined-benefit plans, contributions paid into pension funds, and plan settlements) and to transfers to other current liabilities (€682 million).

Table of Contents

Net deferred tax liabilities (€906 million) fell by €647 million year-on-year. This reflects a reduction caused by reversals of deferred tax liabilities relating to the remeasurement of acquired intangible assets (€1,459 million), but also an increase associated with provisions for pensions (€281 million) and accrued expenses (€271 million).

Current and non-current liabilities related to business combinations and to non-controlling interests were €542 million lower year-on-year at €908 million. This reduction reflects the impact of fair value remeasurements to the contingent value rights (CVRs) issued in connection with the Genzyme acquisition and to the contingent consideration payable to Bayer as a result of an acquisition made by Genzyme prior to the latter's acquisition by Sanofi, plus the reversal of contingent consideration relating to the BiPar and TargeGen acquisitions (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 2013, we held cash and cash equivalents amounting to €8,257 million, substantially all of which were held in euros (see Note D.13. to our consolidated financial statements). As at December 31, 2013, €573 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 section " 3.1.8. 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 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 2012, 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 Spain due to payments received. The total consolidated amount of trade receivables overdue by more than 12 months which primarily consists of amounts due from public-sector customers fell from €276 million as of December 31, 2011 to €161 million as of December 31, 2012 due to payments received (see Note D.10. to our consolidated financial statements included at Item 18 of this annual report).

During 2013, 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 Italy and Greece. Over the Group as a whole, the amount of trade receivables overdue by more than 12 months which primarily consists of amounts due from public-sector bodies around the world rose from €161 million as of December 31, 2012 to €168 million as of December 31, 2013 (see Note D.10. to our consolidated financial statements).

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). In 2013, Sanofi purchased an additional 10,928,075 CVRs (for a total consideration of approximately \$9 million). As of December 31, 2013, 238,275,333 CVRs were outstanding out of 291,313,510 issued at the time of the Genzyme acquisition.

At year-end 2013, 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 €10.0 billion at December 31, 2013. For a discussion of our treasury policies, see "Item 11. Quantitative and Qualitative Disclosures about Market Risk."

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

Off-Balance Sheet Arrangements / Contractual Obligations and Other Commercial Commitments

We have various contractual obligations and other commercial commitments arising from our operations. Our contractual obligations and our other commercial commitments as of December 31, 2013 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.

Table of Contents

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, 2013 <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⁾	15,688	4,372	3,681	2,611	5,024
Operating lease obligations	1,265	257	356	224	428
Finance lease obligation ⁽²⁾	78	18	33	23	4
Irrevocable purchase commitments ⁽³⁾ given	3,189	1,707	800	385	297
received	(237)	(151)	(64)	(3)	(19)
Research & development license agreements Future service commitments ⁽⁴⁾	569	150	253	142	24
Potential milestone payments ⁽⁵⁾	1,589	100	174	171	1,144
Obligations relating to business combination ⁽⁶⁾	4,416	28	583	480	3,325
Firm commitment related to the BMS agreement ⁽⁷⁾	75			75	
Estimated benefit payments on unfunded pensions and post employment benefits ⁽⁸⁾	1,039	54	110	119	756
Total contractual obligations and other commitments	27,671	6,535	5,926	4,227	10,983
Undrawn general-purpose credit facilities	10,021	3,020		7,001	

(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.1. 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 €268 million in 2013.*

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

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

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

Table of Contents

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 below. Milestone payments relating to development projects under these agreements amounted to €1.4 billion in 2013. These exclude projects in the research phase (€3.8 billion in 2013, €5.0 billion in 2012) and payments contingent upon the attainment of sales targets once a product is on the market (€3.6 billion in 2013, €4.7 billion in 2012).

In May 2011, Sanofi signed a license agreement with Glenmark Pharmaceuticals S.A. (Glenmark), a subsidiary of Glenmark Pharmaceuticals Limited India, for the development and commercialization of GBR500, a novel monoclonal antibody for the treatment of Crohn's disease and other chronic autoimmune diseases.

In June 2010, Sanofi signed an exclusive global collaboration and license agreement with Ascenta Therapeutics, a U.S. biopharmaceutical company, on a number of molecules that could restore apoptosis (cell death) in tumor cells.

At the end of April 2010, Sanofi signed a license agreement with Glenmark for the development and commercialization of novel agents to treat chronic pain. Those agents are vanilloid receptor (TRPV3) antagonist molecules, including a first-in-class clinical compound, GRC 15300, which is currently in Phase I clinical development.

In April 2010, Sanofi signed a global license agreement with CureDM Group Holdings, LLC for Pancreate, a novel human peptide which could restore a patient's ability to produce insulin and other pancreatic hormones in both type 1 and 2 diabetes.

In December 2009, Sanofi and the U.S. biotechnology company Alopexx Pharmaceuticals LLC simultaneously signed (i) a collaboration agreement, and (ii) an option for a license on an antibody for the prevention and treatment of infections originating in the bacterium that causes plague and other serious infections.

In May 2009, Sanofi signed a global license agreement with Exelixis, Inc. for XL147 and XL765, and simultaneously signed an exclusive research collaboration agreement for the discovery of inhibitors of Phosphoinositide-3-Kinase (PI3K) for the management of malignant tumors. On December 22, 2011, Sanofi and Exelixis, Inc. agreed to end this collaboration agreement.

May 2009, Sanofi signed a collaboration and licensing agreement with Kyowa Hakko Kirin Co., Ltd, under which Sanofi obtained the worldwide rights to the anti-LIGHT fully human monoclonal antibody. This anti-LIGHT antibody is expected to be first-in-class in the treatment of ulcerative colitis and Crohn's disease.

In November 2007, Sanofi signed a collaboration agreement with Regeneron to discover, develop and commercialize fully human therapeutic antibodies. This agreement was broadened, and its term extended, on November 10, 2009. Under the terms of the development agreement, Sanofi committed to fund the discovery and pre-clinical development costs of Regeneron's antibody research program until 2017 (see Note C.2. to our consolidated financial statements included at Item 18 of this annual report). Once a product begins to be marketed, Regeneron will repay out of its profits (provided they are sufficient) half of the development costs borne by Sanofi. As of December 31, 2013, the balance of the development costs initially funded by Sanofi amounted to €1.3 billion.

In September 2003, Sanofi signed a collaboration agreement in oncology with Regeneron Pharmaceuticals Inc. (Regeneron) to develop the Vascular Endothelial Growth Factor (VEGF) Trap program. Under the terms of the agreement, Sanofi will pay 100% of the development costs of the VEGF Trap. Once a VEGF Trap product starts to be marketed, Regeneron will repay 50% of the development costs (originally paid by Sanofi) in accordance with a formula based on Regeneron's share of the profits.

Edgar Filing: Sanofi - Form 20-F

Sanofi has also entered into the following major agreements, which are currently in a less advanced research phase:

In November 2012, Sanofi and the U.S. biotechnology company Selecta Biosciences signed a collaboration agreement to identify and develop food allergy treatments using a technology based on nanoparticles.

Since acquiring Genzyme in April 2011, the Group has had a commitment to Isis Pharmaceuticals Inc. under a collaboration agreement signed in January 2008. This agreement granted an exclusive license to develop and commercialize mipomersen, a treatment in an advanced development phase for the treatment of severe familial hypercholesterolemia.

Table of Contents

In December 2010: Sanofi signed a global licensing and patent transfer agreement with Ascendis Pharma (Ascendis) on the proprietary Transcon Linker and Hydrogel Carrier technology developed by Ascendis for precise, time-controlled release of therapeutic active ingredients into the body. The agreement will enable Sanofi to develop, manufacture and commercialize products combining this technology with active molecules for the treatment of diabetes and related disorders.

Also in December 2010, Sanofi entered into an alliance with Avila Therapeutics Inc. (Avila) to discover target covalent drugs for the treatment of cancers, directed towards six signaling proteins that are critical in tumor cells. Under the terms of the agreement, Sanofi will have access to Avila's proprietary Avilomics® platform offering "protein silencing" for these pathogenic proteins.

In June 2010, Sanofi entered into an alliance with Regulus Therapeutics Inc. to discover, develop and commercialize novel micro-RNA therapeutics, initially in fibrosis. Sanofi also received an option which if exercised would provide access to the technology to develop and commercialize other micro-RNA based therapeutics, beyond the first four targets.

At the end of April 2010, Sanofi signed a license agreement with Glenmark Pharmaceuticals S.A. for the development and commercialization of novel agents to treat chronic pain. These are vanilloid receptor (TRPV3) antagonist molecules, including ERC 15300, a first-in-class clinical compound.

At the end of September 2009, Sanofi and Merrimack Pharmaceuticals Inc. signed an exclusive global licensing and collaboration agreement covering the MM-121 molecule for the management of solid tumors.

In July 2013, Sanofi decided to discontinue the project on novel classes of antibiotics derived from the RX-04 and Rib-X program, and to terminate its research agreement with Rib X Pharmaceuticals, Inc.

In September 2013, Sanofi decided to discontinue the project to identify novel targets in oncology for the development of new therapeutic agents directed towards these targets and their associated biomarkers, and to end its collaboration with the Belfer Institute of Applied Cancer Science at Dana-Farber Cancer Institute (DFCI).

In November 2013, Sanofi decided to discontinue the project relating to an exclusive global licensing option with Oxford BioTherapeutics for three existing antibodies, plus a research and collaboration agreement to discover and validate new targets in oncology.

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 2013.

In February 2014, pursuant to the "Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits", Sanofi Pasteur and the WHO signed a "Standard Material Transfer Agreement" (SMTA 2). This bilateral agreement stipulates that Sanofi Pasteur will, during declared pandemic periods, (i) donate 7.5% of its real-time production of pandemic vaccines against any strain with potential to cause a pandemic, and (ii) reserve a further 7.5% of such production on affordable terms. This agreement cancels and replaces all preceding commitments to donate pandemic vaccines to the WHO.

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

Edgar Filing: Sanofi - Form 20-F

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.

Table of Contents

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". 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

Table of Contents

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.

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.

Item 6. Directors, Senior Management and Employees

A. Directors and Senior Management

The offices of Chairman and Chief Executive Officer have been separated since January 1, 2007. The annual evaluations conducted since that date have indicated that this governance structure is appropriate to the Group's current configuration. This arrangement was therefore continued 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 considers that this governance structure is appropriate in the Group's current context.

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.

The Chairman being an independent director, the Board of Directors has not deemed it necessary to appoint a lead independent director, since this role has been broadly assumed by Serge Weinberg.

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 the Shareholders' General Meeting and within the limits set by the Board of Directors.

The Chief Executive Officer must be no more than 65 years old.

Table of Contents

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. 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

The Company is administered by a Board of Directors, currently comprising sixteen members.

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.

Each year, the Board of Directors conducts a review to ensure that there is an appropriate balance in its composition and 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.

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 the director 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, independent directors are required:

not to be an employee or corporate officer of the Company, or a corporate officer of a related company;

not to be a customer, supplier, or investment banker or corporate banker of the Company;

not to have close family ties with any corporate officer of the Company;

not to have acted as auditor for the Company over the course of the last five years;

not to 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, a discussion as to the independence of the current directors took place during the meeting of the Board of Directors of October 29, 2013. Of the sixteen 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: Uwe Bicker, Robert Castaigne, Lord Douro, Jean-René Fourtou, Claudie Haigneré, Fabienne Lecorvaisier, Suet-Fern Lee, Carole Piwnica, Klaus Pohle, Gérard Van Kemmel and Serge Weinberg.

Edgar Filing: Sanofi - Form 20-F

In particular, it was determined that the situation of Robert Castaigne had changed. Until 2012, Robert Castaigne had not been considered as an independent director due to his past links with the Total Group. 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 the Total Group four years ago.

Total passed below the threshold of 5% of our voting rights: notification of February 16, 2012. (Since that date, Total has ceased to have any equity interest in the Group.)

Table of Contents

Consequently, the Board of Directors considered that the links with Total no longer created a presumption of non-independence.

Moreover, contrary to the independence criteria set by the AFEP-MEDEF Code, the Board of Directors does not consider 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. Nevertheless a mechanical application of this criterion is not considered desirable as it does not take account of the diversity of situations.

Consequently, although this criterion is applied by the Board of Directors, it is not of itself a determining factor in making a decision as to a director's independence. The Board of Directors assesses the reality of each situation when making a decision. In the case of Robert Castaigne, the Board considers that this director has always demonstrated a questioning approach, which is fundamentally what the APEF-MEDEF criteria are seeking to check.

Finally, there was no other reason to determine that Robert Castaigne is not independent.

Consequently, the Board determined on this basis, at its meeting of May 4, 2012, that Robert Castaigne qualified as an independent director.

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 68% demonstrates that the Board in no way underestimates the importance of having a majority of independent directors in its governance.

In 2013, it was considered that the rules governing the office of the Chairman of the Board had changed, and they henceforth enabled the Board to consider the Chairman as an independent director in accordance with the continued assessment of the Board of Directors. Until 2013, Serge Weinberg had not been considered 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 considered 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 considered 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 links to 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.

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 2013. 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 independently of Sanofi.

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

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.

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.

Table of Contents

The latest three-year formal evaluation of the operating procedures of the Board and its committees took place in late 2012 – early 2013. The directors were heavily involved in the process, as demonstrated by the quality and the quantity of their responses. The Board indicated that it wished its contributions to be systematically acted upon and implemented.

The general appraisal of how the Board and its committees functioned was positive. The quality of the Audit Committee's work was particularly appreciated and acknowledged.

The evaluation showed that R&D performance monitoring was appreciated, and the directors expressed their wish that it should be continued and intensified. Directors would welcome a systematic *ex-post* assessment of acquisitions.

Since 2011, in response to needs expressed in the 2010 evaluation presentations from various Group activities have been given during Board meetings or Strategy Committee sessions. Directors requested more interactions with key Group managers. To satisfy this request, an annual business presentation program has been set up, systematically involving Group managers.

Presentations were given by the Executive Vice President Chief Financial Officer, Executive Vice President Legal Affairs and General Counsel, Vice President Global Compliance Officer, Executive Vice President Chief Strategy Officer, Senior Vice President Diabetes and Senior Vice President Zentiva.

Directors expressed their desire to get more information about human resources management and our main competitors' strategies. In 2013, directors were regularly kept informed of the work conducted by the Appointments and Governance Committee on the succession planning review, in particular concerning the replacement of Hanspeter Spek (President Global Operations) following his retirement. Each business activity presentation included an overview of the market and the competitive environment.

Concerning the composition of the Board, directors requested that the onboarding of more women be continued and that certain competencies be reinforced. This was achieved through the proposed appointment of Fabienne Lecorvaisier as a director.

On arrival, Fabienne Lecorvaisier received several days' training during which she acclimatized herself to the Company, its businesses, the health sector background and in particular the pharmaceutical industry.

Two strategic seminars took place in 2013: one in March on the Group research strategy in core disease areas, and a two-day seminar held in October in China which reviewed the development portfolio and the long range plan.

The annual discussion of the Board's operations during 2013 delivered an overall positive self-evaluation.

The Strategic Committee sessions centered on the R&D portfolio were perceived as having facilitated the Board's oversight of Sanofi's performance in research and development.

The directors also felt that their contacts with the Group's management had improved in both quality and frequency.

The recent changes in board composition were viewed favorably and the directors indicated a desire to see continued investment in pharmaceutical expertise.

The directors gave particularly positive feedback of their session in China, which they felt permitted them to better understand the context and the challenges of this country.

The directors highlighted the need to:

Reduce the number of board members after the current transitory period;

Institutionalize the Strategic Committee's review of all acquisition files before their presentation to the Board, as well as the Audit Committee's post hoc review of acquisitions; and

Spend more time on the competitive landscape and on discussions of the Company's challenges and strategic alternatives.

Composition of the Board of Directors as of December 31, 2013

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

Edgar Filing: Sanofi - Form 20-F

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 of Sanofi*, independent director

Member of the Supervisory Board of Schneider Electric*

Chairman of the Appointments and Governance Committee of Sanofi

Chairman of Weinberg Capital Partners

Chairman of the Strategy Committee of Sanofi

Chairman of Financière Piasa and Piasa Holding

Manager of Alret and Maremma

Director of VL Holding

Member of the Supervisory Board of Financière BFSA

Vice Chairman and Director of Financière Poinsetia and Financière Sasa

Weinberg Capital Partners' representative on the Board of Alliance Industrie and Sasa Industrie

In foreign companies

Edgar Filing: Sanofi - Form 20-F

None

None

Past directorships since 2009

None

In French companies

Chairman of the Board of Accor* (until 2009)

Director of Rasec (until 2010), of Fnac (until 2010), of Rothschild Concordia (until 2010) and of Team Partners Group (until 2011)

Member of the Supervisory Board of Rothschild & Cie (until 2010)

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

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

Member of the Supervisory Board of Amplitude Group and of Alfina (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**

Edgar Filing: Sanofi - Form 20-F

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

Table of Contents

Christopher Viehbacher	Date of birth:	March 26, 1960
135,442 shares	Nationality:	German and Canadian
	First elected:	December 2008
	Last reappointment:	May 2010
	Term expires:	2014

Directorships and appointments of Christopher Viehbacher

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

In French companies

None

Director and Chief Executive Officer of Sanofi*

Chairman of the Executive Committee and Head of Global Leadership Team of Sanofi

Member of the Strategy Committee of Sanofi

In foreign companies

Chairman of Genzyme (United States)

Chairman of European Federation of Pharmaceutical Industries and Associations (EFPIA, Belgium)

Member of Visitors of Fuqua School of Business, Duke University (United States)

Member of the Board of Business Roundtable (United States)

Member of the International Business Council, World Economic Forum (Switzerland)

Edgar Filing: Sanofi - Form 20-F

Chairman of the CEO Roundtable on Cancer (United States)

Past directorships since 2009

None	In French companies	None
	In foreign companies	

Chairman and Chief Executive Officer of Genzyme (United States, until 2011)

Member of Advisory Council of Center for Healthcare Transformation (United States, until 2010)

Chairman and member of the Board of Directors of Research America and Burroughs Wellcome Fund (United States, until 2011)

Chairman of the Board of Directors of PhRMA (United States, until 2012)

Vice Chairman of European Federation of Pharmaceutical Industries and Associations (EFPIA, Belgium, until June 2013)

Education and business experience

B.A. in Commerce from Queens University (Ontario-Canada); certified public accountant

Began his career at PricewaterhouseCoopers Audit

1988-2008	Various positions at the GSK group, including President Pharmaceutical Operations for North America
2004-2008	Member of the Cardinal Club (United States)

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 2009

None

In French companies

None

None

In foreign companies

President and Chief Executive Officer of L'Oréal USA
(United States, until 2009)

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
Since 2002	Member of L'Oréal* Executive Committee
Since 2010	Vice President General Manager Research and Innovation at L'Oréal*

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 2009

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 2010
	Term expires:	2014

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, Internal control and Risk Committee
	Vinci*:
	Director
	Member of the Audit Committee
	Member of the Remuneration Committee

In foreign companies

None	None
------	------

Past directorships since 2009

In French companies

None	None
------	------

Edgar Filing: Sanofi - Form 20-F

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)

142

Edgar Filing: Sanofi - Form 20-F

Table of Contents

Thierry Desmarest 1,017 shares	Date of birth: Nationality: First elected: Last reappointment: Term expires:	December 18, 1945 French February 2000 May 2011 2015
--	--	--

Directorships and appointments of Thierry Desmarest

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

In French companies

Director of Sanofi*

Total SA*:

Member of the Compensation Committee of Sanofi

Director and Honorary President

Member of the Appointments and Governance Committee of Sanofi

Chairman of the Nominating and Governance Committee

Member of the Strategy Committee of Sanofi

Member of the Compensation Committee

Member of the Strategy Committee

Chairman of *Fondation Total*

L'Air Liquide*:

Director

Edgar Filing: Sanofi - Form 20-F

Chairman of the Appointments and Governance Committee

Member of the Compensation Committee

Renault group:

Director of Renault SA*

Chairman of the International Strategy Committee of Renault SA

Member of the Remuneration Committee of Renault SA

Member of the Industrial Strategy Committee of Renault SA

Director of Renault SAS

Member of the Board of Directors of *l'Ecole Polytechnique* and
Chairman of *Fondation de l'Ecole Polytechnique*

Director of *Musée du Louvre*

In foreign companies

None

Bombardier Inc.* (Canada):

Edgar Filing: Sanofi - Form 20-F

Director

Past directorships since 2009

None **In French companies**

Chairman of the Board of Directors of Total SA* (until 2010)

None **In foreign companies**
Member of the Supervisory Board of Areva* (until 2010)

Bombardier Inc.* (Canada):

Member of the Appointments and Governance Committee (until 2013)

Member of the Human Resources and Compensation Committee (until 2013)

Education and business experience

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

Since 1981 Various positions at the Total* group including Chairman and Chief Executive Officer (1995-2007)
2000-2007 CEO and Chairman of the Board of Elf Aquitaine

Edgar Filing: Sanofi - Form 20-F

Table of Contents

Lord Douro 2,000 shares	Date of birth: Nationality: First elected: Last reappointment: Term expires:	August 19, 1945 British May 2002 May 2010 2014
-----------------------------------	--	--

Directorships and appointments of Lord Douro

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 Appointments and Governance Committee of Sanofi

Member of the Strategy Committee of Sanofi

None

In foreign companies

Chairman of Richemont Holdings UK Ltd (United Kingdom) and
Kings College London (United Kingdom)

Compagnie Financière Richemont AG* (Switzerland):

Director

Member of the Appointments Committee and of the Compensation
Committee

Member of the International Advisory Board of Abengoa SA*
(Spain)

RIT Capital* (United Kingdom):

Director

Chairman of the Remuneration Committee and the Conflicts Committee

Member of the Nominations Committee

Past directorships since 2009

None

In French companies

Pernod Ricard*:

Director (until 2011)

Member of the Compensation Committee and of the Appointments Committee (until 2010)

In foreign companies

None

Director of Abengoa Bioenergy (Spain, until 2011)

Advisor to Crédit Agricole CIB (United Kingdom, until 2012)

Director of GAM Worldwide (United Kingdom, until 2013)

Education and business experience

Edgar Filing: Sanofi - Form 20-F

Master of Arts from Oxford University

1979-1989	Member of the European Parliament
1995-2000	Chairman of Sun Life & Provincial Holdings Plc* (United Kingdom)
1993-2005	Chairman of Framlington Ltd (United Kingdom)
2003-2007	Commissioner of English Heritage (United Kingdom)

144

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

Current directorships and appointments

Outside the Sanofi Group

In French companies

Independent director of Sanofi*

Chairman of the Supervisory Board of Vivendi*

Member of the Compensation Committee of Sanofi

Member of the Appointments and Governance Committee of Sanofi

Member of the Strategy Committee of Sanofi

None

In foreign companies

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

Past directorships since 2009

None

In French companies

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

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*
2002-2005 Chairman and Chief Executive Officer of Vivendi*
2002-2008 Vice Chairman, Chairman then Honorary Chairman of the International Chamber of Commerce

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*

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 CGénial*

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 2009

In French companies

None

Counselor at the European Space Agency (until 2009)

Director and Chairman of the *Cité des Sciences et de l'Industrie* (until 2009)

Chairman of *Palais de la Découverte* (until 2009)

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 French government
2004-2005	Deputy Minister for European Affairs
2005-2009	Counselor at the European Space Agency (ESA)

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*)

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 2009

In French companies

None

Director of HSBC France (until 2012)

In foreign companies

None

Allianz AG* (Germany, until 2012):

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) and 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)

147

Edgar Filing: Sanofi - Form 20-F

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

Current directorships and appointments

Outside the Sanofi Group

In French companies

Independent director of Sanofi*

Air Liquide Group:

Member of the Audit Committee of Sanofi

Chief Executive Officer of Air Liquide Finance

Director of Air Liquide France Industries

Director of Air Liquide International

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 2009

None	In French companies	None
None	In foreign companies	

Director of Air Liquide Japon (since 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 2009

Edgar Filing: Sanofi - Form 20-F

In French companies

None

None

In foreign companies

None

Director of Richina Pacific Limited* (Bermuda, until 2009)

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

Senior Partner 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
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)
2010-2011	President of the Inter-Pacific Bar Association

Edgar Filing: Sanofi - Form 20-F

Table of Contents

Christian Mulliez	Date of birth:	November 10, 1960
1,444 shares	Nationality:	French
	First elected:	June 2004
	Last reappointment:	May 2010
	Term expires:	2014

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 Galderma Pharma (Switzerland)

Director of The Body Shop International (United Kingdom)

Past directorships since 2009

None

In French companies

None

None

In foreign companies

None

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***

Edgar Filing: Sanofi - Form 20-F

1984-2002 Various positions at Synthelabo and then at Sanofi-Synthelabo, including Vice President Finance

150

Edgar Filing: Sanofi - Form 20-F

Table of Contents

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

Directorships and appointments of Carole Piwnica

Within the Sanofi Group	Outside the Sanofi Group
<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

In foreign companies

None

Director of Naxos UK Ltd (United Kingdom)

Director of Big Red (United States)

Director of Elevance (United States)

Director of Amyris Inc.* (United States)

Past directorships since 2009

None

In French companies

None

None

In foreign companies

Edgar Filing: Sanofi - Form 20-F

Director of Toepfer GmbH (Germany, until 2010)

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

Member of the Ethical Committee of Monsanto* (United States, until 2009)

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*

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)

Edgar Filing: Sanofi - Form 20-F

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)

Edgar Filing: Sanofi - Form 20-F

Table of Contents

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

Directorships and appointments of Klaus Pohle

Within the Sanofi Group	Outside the Sanofi Group
<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 2009

None

In French companies

None

In foreign companies

None

DWS Investment GmbH, Frankfurt (Germany, until 2009):

Member of the Supervisory Board

Chairman of the Audit Committee

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

Edgar Filing: Sanofi - Form 20-F

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)

(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 2009

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 President EMEA then Europe Chairman

Changes in the Composition of the Board

The composition of the Board of Directors changed in 2013.

Fabienne Lecorvaisier was appointed as a Director of our Company at the Shareholders' General Meeting held on May 3, 2013. This appointment is in line with the Board of Directors' wish to increase the proportion of women on the Board but also to reinforce certain competencies, notably in finance. This appointment raises the number of female directors to four, i.e. 25% of the directors.

No mandate was up for renewal in 2013.

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.

Edgar Filing: Sanofi - Form 20-F

Table of Contents

Under current French legislation, and 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 in 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 has the following permanent members:

Christopher Viehbacher, 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 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

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. Unless otherwise indicated, each executive officer is a citizen of France.

Christopher Viehbacher

Chief Executive Officer

Chairman of the Executive Committee

Date of birth: March 26, 1960

Christopher Viehbacher was appointed as Chief Executive Officer on December 1, 2008, and is also a member of the Strategy Committee.

For additional information regarding his professional education and business experience see "Composition of the Board of Directors as of December 31, 2013" in "A. Directors and Senior Management" of this Item 6.

Christopher Viehbacher is a citizen of Germany and Canada.

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 posts 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 post 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.

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. 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 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-

Table of Contents

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 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 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.

Philippe Luscan is a citizen of France.

David 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.

Edgar Filing: Sanofi - Form 20-F

Table of Contents

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 has authored more than 40 articles and multiple book chapters.

Dr. Meeker joined Genzyme in 1994 as Medical Director to work on the Cystic Fibrosis Gene Therapy 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 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. Throughout her career within GEHC, Pascale Witz headed up a number of businesses. She was VP Information Technology and VP Six Sigma and Quality (2000-2001), General Manager, Nuclear Medicine & PET (2002-2004), VP Sales & Marketing Services (2005-2006), General Manager, Computed Tomography (2006-2007), VP & General Manager for the Global Interventional Business for France and U.S. (2008-2009). In 2009 she was appointed President & CEO of the medical diagnostics business. 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.

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 Collège 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

Table of Contents

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 has just been received as member of the U.S. National Academy of Engineering.

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

As of December 31, 2012, none of the members of the Executive Committee had their principal business activities outside of Sanofi.

The Executive Committee is assisted by the Global Leadership Team, which represents the principal functions of the Group. The Global Leadership Team is made up of the members of the Executive Committee and 35 additional senior managers.

B. Compensation

Compensation and pension 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 precise 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 " 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. 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 the Appointments and Governance Committee.

In accordance with our Board Charter and in close collaboration with the Senior Management, he 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 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 Appointments and Governance Committee or as chairman of the Strategy Committee.

Compensation awarded to Serge Weinberg

<i>(in euros)</i>	2013	2012	2011
Compensation payable for the year (details provided in the table below)	708,040	708,115	709,463
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	708,040	708,115	709,463
--------------	----------------	----------------	----------------

158

Table of Contents**Compensation payable and paid to Serge Weinberg**

<i>(in euros)</i>	2013		2012		2011	
	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 ⁽²⁾	N/A	N/A	N/A	N/A	N/A	35,625
Benefits in kind	8,040	8,040	8,115	8,115	9,463	9,463
Total	708,040	708,040	708,115	708,115	709,463	745,088

The amounts reported are gross amounts before taxes.

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

(2) Attendance fees were payable to Serge Weinberg from December 15, 2009 until May 17, 2010, i.e. until he became Chairman of the Board. Pursuant to the compensation policy applicable to corporate officers, he has not received directors' attendance fees since his appointment as Chairman of the Board of our Company.

On March 5, 2013, upon the recommendation of the Compensation Committee, the Board of Directors set the terms of the compensation of Serge Weinberg.

For 2013, his fixed compensation was maintained at an annual rate of €700,000.

He did not receive any variable compensation, stock options, or performance shares.

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

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

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 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.

Christopher Viehbacher

Christopher Viehbacher has held the office of Chief Executive Officer of Sanofi since December 1, 2008. He was an outside appointment and has never had an employment contract with Sanofi distinct from his current office.

The compensation policy of Christopher Viehbacher follows the same structures and principles as the Group compensation policy described later in this section of the report.

Edgar Filing: Sanofi - Form 20-F

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 performance and individual contribution and to maintain a balance between short-term performance and mid-long-term performance.

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

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

Table of Contents

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 has decided to maintain this policy and reinforce it 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.

The compensation of Christopher Viehbacher is 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 benefits from:

a top-up defined benefit pension plan;

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.

Table of Contents**Compensation, options and shares awarded to Christopher Viehbacher**

<i>(in euros)</i>	2013	2012	2011
Compensation payable for the year (details provided in the table below)	2,964,976	3,522,051	3,488,287
Value of stock subscription options awarded during the year ⁽¹⁾	2,884,800	2,020,800	2,364,000
Value of performance shares awarded during the year ⁽²⁾	2,798,550	1,938,300	1,282,500
Total	8,648,326	7,481,151	7,134,787

(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

<i>(in euros)</i>	2013		2012		2011	
	Payable	Paid	Payable	Paid	Payable	Paid
Fixed compensation ⁽¹⁾	1,260,000	1,260,000	1,250,000	1,250,000	1,200,000	1,200,000
Annual variable compensation ⁽²⁾	1,701,000	2,268,000	2,268,000	2,280,000	2,280,000	2,400,000
Exceptional compensation	0	0	0	0	0	0
Attendance fees	0	0	0	0	0	0
Benefits in kind	3,976	3,976	4,051	4,051	8,287	8,287
Total	2,964,976	3,531,976	3,522,051	3,534,051	3,488,287	3,608,287

The amounts reported are gross amounts before taxes.

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

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

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,

Edgar Filing: Sanofi - Form 20-F

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, 2013, upon the recommendation of the Compensation Committee, the Board of Directors established the terms of the compensation package for Christopher Viehbacher for 2013. His fixed compensation was maintained at €1,260,000 for 2013.

For 2013, the variable compensation of Christopher Viehbacher could have represented between 0% and 200% of his fixed compensation.

His variable compensation with respect to 2013 has been 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 four components: Business Net Income, development of the growth platforms, gross margin and cash flow;

improved performance in research and development (25%). This objective included net sales of new products, new product registration and developments in the product portfolio;

organizational structure of the Group and succession planning for key posts in the Group (15%). This objective covered the implementation of a Group organizational structure suited to its strategy, succession planning for key posts, and the transition in commercial operations after the retirement of Hanspeter Spek (President Global Operations);

corporate social responsibility (15%). This objective covered the environment, product quality and compliance.

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

Table of Contents

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

The Board considered that the financial targets were not fully attained, while all the other criteria concerning research and development, organizational structure and succession planning, and corporate social responsibility were fulfilled. On the basis of the foregoing, the Board of Directors fixed his variable compensation for 2013 at €1,701,000, i.e., 135% of the fixed portion of his compensation.

Christopher Viehbacher's 2013 variable compensation is to be paid in 2014.

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

At its meeting on 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 for 2014 is maintained at €1,260,000.

His variable compensation with respect to 2014 will be established on the basis of the same structure of objectives as in 2013: 45% based on operations, 25% based on R&D, 15% based on organizational structure and talent management, and 15% based on corporate social responsibility. Defined targets are set for each of these criteria.

For 2014, the variable compensation of Christopher Viehbacher may represent between 0% and 200% of his fixed compensation.

Stock options awarded to Christopher Viehbacher in 2013

Origin	Date of Board grant	Nature of options	Value (in €)	Number of options awarded in 2013	Exercise price (in €)	Exercise period
Sanofi	03/05/2013	Subscription options	2,884,800	240,000	72.19	03/06/2017 03/05/2023

On March 5, 2013, 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.

Edgar Filing: Sanofi - Form 20-F

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.

Table of Contents

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 the equity-based compensation in line with the medium-term performance, performance will be measured over three financial years.

The Board considers that these performance conditions are 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, 2013 was valued at €12.02, valuing the total benefit at €2,884,800.

The Board of Directors previously decided to limit the number of options that could be awarded to Christopher Viehbacher to 10% of the total limit approved by the Shareholders' General Meeting held on May 6, 2011 (1% of our share capital). The number of options awarded to Christopher Viehbacher in 2013 represents 1.81% of the total limit approved by the Shareholders' General Meeting held on May 6, 2011 (1% of our share capital) and 30.43% of the total award to all beneficiaries on March 5, 2013. The Board of Directors has 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).

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

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

In 2011, as part of its commitment to transparency, Sanofi undertook to publish in its annual report the level of attainment determined by the Board of Directors for performance conditions applicable to future equity-based compensation plans awarded to Christopher Viehbacher and the other members of the Executive Committee. The Board considers that disclosing the level of attainment allows our shareholders to better

Edgar Filing: Sanofi - Form 20-F

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 1, 2010, 275,000 subscription options were awarded to Christopher Viehbacher. All of these options were subject to a performance condition. The performance condition, which had to be fulfilled each financial year preceding the vesting of the shares (i.e. 2010, 2011, 2012, and 2013), was based on a ratio of adjusted net income excluding selected items (which was a non-GAAP financial measure used until the end of 2009) to net sales of at

Edgar Filing: Sanofi - Form 20-F

Table of Contents

least 18%. On February 5, 2014, the Board of Directors determined that the conditions had been met and that the 275,000 options would be exercisable subject to meeting the condition of continuing employment.

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 on 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 eleven pharmaceutical companies. These criteria were maintained because they align medium-term equity-based compensation with the strategy adopted by the Company.

This award is broken down as follows:

The performance criterion based on Business Net Income covers 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 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 options exercisable depends upon our position in comparison to the TSR for the other companies of this panel.

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.

Performance will be measured over three financial years.

The targets and the level of achievement for the internal criteria will be disclosed publicly at the end of the performance measurement period.

Christopher Viehbacher did not exercise any stock options in 2013.

As of the date of publication of this document, the total number of unexercised options held by Christopher Viehbacher represented 0.12% of the share capital as at December 31, 2013.

Performance shares awarded to Christopher Viehbacher in 2013

Origin	Date of Board award	Value (in €)	Number of performance shares awarded in 2013	Vesting date	Availability date
Sanofi	03/05/13	2,798,550	45,000	03/06/2016	03/06/2018

Edgar Filing: Sanofi - Form 20-F

On March 5, 2013, 45,000 performance shares were awarded to Christopher Viehbacher. The Compensation Committee, based on benchmarks for the compensation of chief executive officers in pharmaceutical companies, noted that Christopher Viehbacher's equity compensation was in the lower range and recommended increasing the number of performance shares granted. The Board of Directors therefore decided to increase his grant from 42,000 performance shares under the March 5, 2012 plan to 45,000 under the March 5, 2013 plan. 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. Each performance share awarded on March 5, 2013, was valued at €62.19, valuing the total benefit at €2,798,550.

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

Table of Contents

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 definitively acquired depends upon our position in comparison to the TSR for the other companies of this panel. Below the median, the corresponding performance shares will lapse.

In order to bring the equity-based compensation in line with the medium-term performance, performance will be measured over three financial years.

The Board considers that these performance conditions are 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.

The Board of Directors has 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 2013 represents 0.28% of this total limit approved by the Shareholders' General Meeting held on May 4, 2012 and 1.05% of the total award to all beneficiaries on March 5, 2013.

Performance shares awarded to Christopher Viehbacher

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

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.

Edgar Filing: Sanofi - Form 20-F

On March 5, 2014, 45,000 performance shares were awarded to Christopher Viehbacher. In compliance with the AFEF-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 on Total Shareholder Return ("TSR") in comparison to a reference set of eleven pharmaceutical companies. These criteria were maintained because they align medium-term equity-based compensation with the strategy adopted by the Company.

This award is broken down as follows:

The performance criterion based on Business Net Income covers 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.

Table of Contents

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 ultimately vesting depends upon our position in comparison to the TSR for the other companies of this panel.

Performance will be measured over three financial years.

The targets and the level of attainment of the internal criteria will be disclosed publicly at the end of the performance measurement period.

In making the 2014 award, the Board of Directors had to determine whether to make these awards contingent upon future share purchases. Taking into account the number of shares acquired at the outset of his mandate and the lock-up obligations applicable to shares obtained on exercise of stock options or disposition of performance shares, as well as share purchases made spontaneously by Christopher Viehbacher, the Board of Directors decided not to require him to acquire any further shares at his own expense. Indeed, of the 135,442 shares owned by Christopher Viehbacher, 40,442 have been acquired at his own expense.

As of the date of this annual report, the total number of performance shares awarded to Christopher Viehbacher represents 0.017% of our share capital as of December 31, 2013.

Performance shares awarded to Christopher Viehbacher which became available in 2013

65,000 performance shares that were awarded to Christopher Viehbacher on March 2, 2009 and vested on March 3, 2011, became available on March 4, 2013.

Pension arrangements for Christopher Viehbacher

Christopher Viehbacher is covered by the Sanofi top-up defined benefit pension plan (which has been called the Sanofi plan since the Company changed its name). The plan is offered to all employees of Sanofi and its French subsidiaries who meet the eligibility criteria specified in the plan rules. This plan was set up on October 1, 2008 as the final stage in the process of harmonizing the status of personnel across the French subsidiaries.

This top-up defined-benefit pension plan is offered to executives (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' 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, 538 executives were potentially eligible for this plan (6 retirees, 99 early retirees and 433 active employees) as of December 31, 2013.

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 Christopher Viehbacher 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.

Edgar Filing: Sanofi - Form 20-F

Because Christopher Viehbacher has pursued his career in different countries and in different groups, he has not continuously paid his contribution to the French compulsory industry schemes. Taking into account the award of ten years' service at his arrival and the five years spent at Sanofi, he has to date accumulated 15 years of service. As of

Table of Contents

today, the reference compensation being limited to 60x PASS (i.e. €2,221,920 in 2013), the maximum theoretical amount of the annuity is 22.5% of this amount, i.e. €499,932.

If Christopher Viehbacher were to leave at legal retirement age, he would have accumulated 28 years of service (the award of ten years' service at his arrival and 18 years of service since his arrival). His length of service would therefore be capped at 25 years pursuant to the Sanofi plan rules.

Furthermore, in order to receive this pension, Christopher Viehbacher would have to be entitled to benefit from compulsory industry schemes, which means that if he were to leave before the legal retirement age with full pension rights, he will lose the entire benefit of the Sanofi top-up defined-benefit pension.

In any event, this benefit was taken into account by the Board of Directors when setting his global compensation.

The admission of Christopher Viehbacher to this plan was approved by the Shareholders' General Meeting of April 17, 2009.

Commitments in favor of the Chairman and the Chief Executive Officer in office as of December 31, 2013

	Contract of employment	Top-up pension plan	Compensation or benefits payable or potentially payable on termination of office	Compensation payable under non-competition clause
Serge Weinberg	No	No	No	No
Christopher Viehbacher	No	Yes	Yes	No

In the event of his removal from office as Chief Executive Officer, Christopher Viehbacher would 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, subject to the performance criteria described below.

In accordance with article L. 225-42-1 of the French Commercial Code, payment of the termination benefit would be 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 (which was a non-GAAP financial measure used until the end of 2009) 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.

Edgar Filing: Sanofi - Form 20-F

The terms for the termination benefit entitlement of Christopher Viehbacher were approved by the Shareholders' Annual General Meeting of April 17, 2009.

Any activation of this termination benefit will be carried out in compliance with the AFEP-MEDEF Code, i.e. only if the departure is non-voluntary and linked to a change in control or strategy.

Table of Contents

This termination benefit, as well as the pension benefit, was negotiated at the time of the recruitment of Christopher Viehbacher, and hence at a time when there was no conflict of interest. Moreover, the terms and conditions for the payment of this termination benefit comply with the AFEP-MEDEF Code.

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.

In compliance with the AFEP-MEDEF Code and our Board Charter, Christopher Viehbacher has undertaken to refrain from entering into speculative or hedging transactions, and, so far as Sanofi is aware, no such instruments have been contracted.

Compensation and pension payments for Directors other than the Chairman and the Chief Executive Officer

Attendance fees

The table below shows amounts paid to each member of the Sanofi Board of Directors in respect of 2012 and 2013, including those whose term of office ended during these years.

Attendance fees in respect of 2012, the amount of which was approved by the Board meeting of March 5, 2013, were paid in 2013.

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. These fees were partially paid in July 2013. The balance will be paid in 2013.

For 2013, 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 2013, 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 receive €7,000 per Board meeting attended, and €7,500 per Committee 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 French Director who attends in person.

As an exception, some dual meetings 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 the same day, only one attendance fee is paid for both.

Edgar Filing: Sanofi - Form 20-F

Hence, in accordance with the AFEP-MEDEF Code, attendance fees are allocated predominantly on a variable basis.

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.

Name	Attendance fees in respect of 2013		Pensions paid in 2013	Total compensation	Attendance fees in respect of 2012		Pensions paid in 2012	Total compensation
	fixed	variable			fixed	variable		
<i>(in euros)</i>								
Laurent Attal (1)	15,000	50,000		65,000	10,000	40,000		50,000
Uwe Bicker	15,000	57,000		72,000	15,000	89,000		104,000
Robert Castaigne	15,000	105,000		120,000	15,000	90,000		105,000
Thierry Desmarest	15,000	65,000		80,000	15,000	75,000		90,000
Lord Douro	15,000	89,000		104,000	15,000	104,000		119,000
Jean-René Fourtou	15,000	55,000	1,704,213	1,774,213	15,000	85,000	1,676,787	1,776,787
Claudie Haigneré	15,000	55,000		70,000	15,000	65,000		80,000
Igor Landau	15,000	40,000	2,333,221	2,388,221	15,000	35,000	2,295,672	2,345,672
Fabienne Lecorvaisier(2)	10,000	30,000		40,000				
Suet-Fern Lee	15,000	64,000		79,000	15,000	64,000		79,000
Christian Mulliez	15,000	87,500		102,500	15,000	77,500		92,500
Lindsay Owen-Jones(3)					6,250	20,000		26,250
Carole Piwnica	15,000	98,750		113,750	15,000	93,750		108,750
Klaus Pohle	15,000	144,000		159,000	15,000	131,500		146,500
Gérard Van Kemmel	15,000	127,500		142,500	15,000	125,000		140,000
Total	205,000	1,067,750	4,037,434	5,310,184	196,250	1,094,750	3,972,459	5,263,459

Total attendance fees	1,272,750	1,291,000
------------------------------	------------------	------------------

Amounts reported are gross amounts before taxes.

- (1) *Assumed office May 4, 2012.*
- (2) *Assumed office May 3, 2013.*
- (3) *Left office May 4, 2012.*

Pensions

The amount recognized in 2013 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 €4.0 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, 2013 applied to 31 beneficiaries (one active executive, three early retirees and 27 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 does 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 pursuant to market practice. It rewards the individual contribution of each Executive Committee member to the Group performance as well as the performance of his/her organization.

For 2013, the variable compensation was composed of two elements:

the attainment of quantitative objectives (accounting for 75%), which are measured at Group level and at the Executive Committee member organization or function level; and

the attainment of qualitative objectives, both individually and collectively within the Executive Committee (accounting for 25%).

Table of Contents

The objectives are intended particularly to reflect growth (new product registration, 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); 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 2013, the total gross compensation paid and accrued in respect of members of the Executive Committee (including the Chief Executive Officer) amounted to €14.9 million, including €6.8 million in fixed compensation.

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 will henceforth be fully contingent upon the performance targets being achieved over several financial years, as well as a condition of still being an employee when the option is exercised or the performance share is delivered.

On March 5, 2013, 402,000 share subscription options were awarded to members of the Executive Committee (including 240,000 options awarded to Christopher Viehbacher). The entire award was contingent upon the same internal criteria based on Business Net Income and Return on Assets (ROA) as Christopher Viehbacher, but excluding the TSR-based criterion. Consequently, the weighting of the two criteria is different, with each representing 50% of the grant.

The quantitative measures of performance are the same as for the award of Christopher Viehbacher. 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.

As of December 31, 2013 a total of 3,400,000 options had been awarded to members of the Executive Committee (existing plans or plans ending in 2013). As of the same date, members of the Executive Committee held 3,015,000 unexercised options. These figures include the unexercised options awarded to Christopher Viehbacher, who is also a member of the Executive Committee.

The table below summarizes the options awarded to individuals who were members of the Executive Committee 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, 2012" below.

Origin	Date of shareholder authorization	Date of Board grant	Grant to Executive Committee Members(1)	Start date of exercise period	Expiration date	Exercise price (in €)	Number exercised as of 12/31/2013	Number canceled as of 12/31/2013	Number outstanding
sanofi-aventis	05/31/07	12/13/07	520,000	12/14/11	12/13/17	62.33	115,000	0	405,000
sanofi-aventis	05/31/07	03/02/09	650,000	03/04/13	03/01/19	45.09	170,000	50,000	430,000
sanofi-aventis	04/17/09	03/01/10	805,000	03/03/14	02/28/20	54.12	0	50,000	755,000
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	402,000	03/06/17	03/05/23	72.19	0	0	402,000

(1)

Edgar Filing: Sanofi - Form 20-F

Includes the Chief Executive Officer as of the date of grant. The number is subject to performance conditions

During 2013, 313,000 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 December 10, 2003 with an exercise price of €55.74), and two plans that post-date the creation of the Executive Committee (sanofi-aventis subscription option plan of December 13, 2007 with an exercise price of €62.33 and sanofi-aventis subscription option plan of March 9, 2009 with an exercise price of €45.09).

Table of Contents

On March 5, 2013, 120,600 performance shares (including 45,000 performance shares awarded to Christopher Viehbacher) were awarded to members of the Executive Committee. The entire award was contingent upon the same internal criteria based on Business Net Income and Return on Assets (ROA) as Christopher Viehbacher, but excluding the TSR-based criterion. Consequently, the weighting of each criterion is different, with each criterion representing 50% of the grant.

The quantitative measures of performance are the same as for the award of Christopher Viehbacher. 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 achievement for the internal criteria will be publicly disclosed at the end of the performance measurement period.

As of December 31, 2013, a total of 408,500 performance shares had been awarded to members of the Executive Committee (existing plans or plans ending in 2013). As of the same date, 258,500 performance shares were in the process of vesting. These figures include the performance shares awarded to Christopher Viehbacher, who is also a member of the Executive Committee.

The table below summarizes the performance shares awarded to individuals who were members of the Executive Committee at the time of the award. For more information on the 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 12/31/2013	Number of rights canceled as of 12/31/2013	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	85,500	0	0
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	120,600	03/05/13	03/06/16	03/06/18	0	0	120,600

(1)

Includes the Chief Executive Officer as of the date of grant. The number 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 177 Group employees benefited from PSUs in 2014.

On March 5, 2014, 622,500 share subscription options, 67,000 performance shares and 156,500 PSUs were awarded to members of the Executive Committee (including 240,000 options and 45,000 performance shares awarded to Christopher Viehbacher). The entire Executive Committee award is contingent upon the same internal criteria based on Business Net Income and Return on Assets (ROA) as Christopher Viehbacher, but excluding the TSR-based criterion. Consequently, the weighting of the two criteria is different, with each representing 50% of the grant.

The quantitative measures of performance are the same as for the award of Christopher Viehbacher. 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 achievement for the internal criteria will be publicly disclosed at the end of the performance measurement period.

As part of its commitment to transparency, Sanofi has undertaken to publish in its annual report the level of attainment determined by the Board of Directors for performance conditions applicable to future equity-based compensation plans awarded to Christopher Viehbacher and the other members of the Executive Committee. The Board considers that disclosing the level of attainment allows our shareholders to better understand the demanding nature of the performance conditions. For disclosures about the level of attainment of the various equity-based compensation plans, see " B. Compensation Compensation and pension arrangements for corporate officers

Table of Contents

Christopher Viehbacher", bearing in mind that the TSR-based criterion only applies to the Chief Executive Officer and that the criteria based on Business Net Income and the ROA each apply to 50% of the grant.

Under French law, Directors may not receive options solely as compensation for service on our Board, and consequently our Company may grant options only to those Directors who are also our officers.

Because some of our non-executive Directors were formerly officers or executive officers of our Company or its predecessor companies, some of our non-executive Directors hold Sanofi stock options.

We do not have separate profit-sharing plans for key executives. As employees, they are able to participate in our voluntary and statutory profit-sharing schemes on the same terms as our other employees. These plans are described below under " Employees Profit-sharing schemes."

The total amount accrued as of December 31, 2013 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 €125 million, including €10 million recognized in the income statement for the year ended December 31, 2013.

This total amount accrued as of December 31, 2013 included €51 million for members of the Executive Committee collectively, including €8 million recognized in the income statement for the year ended December 31, 2013.

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 Christopher Viehbacher" 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 validated by the entire Board.

The Board of Directors does not consider that 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 of a number of criteria that must be evaluated on a case by case basis, and not once for all. 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 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 competency and individual contribution to the activities of the Board and its committees is addressed not systematically each year but when a director is up for reappointment as a board or committee member. 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.

Edgar Filing: Sanofi - Form 20-F

During 2013, the Board of Directors met eight times, with an overall attendance rate among Board members of over 93%. 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 75% and 100%.

Table of Contents

The following persons attended meetings of the Board of Directors in 2013:

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 Legal Affairs and General Counsel, the Executive Vice President Chief Strategy Officer, the Executive Vice President Global Commercial Operations and the Executive Vice President Global Divisions & Strategic Commercial Development.

The agenda for each meeting of the Board is prepared by the Secretary after consultation with the Chairman, taking account of the agendas for the meetings of the specialist Committees and the suggestions of the directors.

Approximately one week prior to each meeting of the Board of Directors, the Directors each receive a file containing the agenda, the minutes for the prior meeting, and documentation relating to the agenda.

The minutes for each meeting are expressly approved at the next meeting of the Board of Directors.

In compliance with our Board Charter, certain issues are examined in advance by the various Committees according to their areas of competence in order for them to make a recommendation; these issues are then submitted for a decision by the Board of Directors.

In 2013, 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 2012 financial year, the review of the individual company and consolidated financial statements for the first half of 2013 and the consolidated financial statements for the first three quarters of 2013, 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 2012 financial year, the full-year forecasts for 2013 and the budget for 2014;

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 2012 variable compensation for the Chief Executive Officer, the determination of the 2013 fixed and variable compensation for the Chief Executive Officer, the determination of the 2013 fixed compensation of the Chairman of the Board and an update of the 2012 and 2013 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

Edgar Filing: Sanofi - Form 20-F

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 the year 2012; the principles of allocation for the year 2013 and the allocation of attendance fees for 2013 first half year, 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 2013 and the recording of the completion of the performance conditions of previous share-based plans;

the implementation of a share capital increase reserved for employees;

the composition of the Board, the proposed renewal of the mandate of Directors at the Shareholders' General Meeting in 2013, the independence of the Directors, the appointment of a new Director, the appointment of a

Table of Contents

new member of the Audit Committee and the review of the composition of the Committees in view of the new composition of the Board;

the management of the Group and succession planning;

a presentation on Compliance, on the Diabetes activity, and on the Generics activity;

the review of significant proposed acquisitions;

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 amendment of the Board Charter, the evaluation of the functioning of the Board and its Committees.

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 members of these Committees are selected from among the Directors based on their experience and are appointed by the Board of Directors.

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, 2013, this Committee was composed of:

Klaus Pohle, Chairman;

Robert Castaigne;

Fabienne Lecorvaisier (since May 3, 2013);

Christian Mulliez;

Carole Piwnica;

Gérard Van Kemmel.

On February 25, 2013 the Appointments and Governance Committee examined the independence of its members and concluded that Fabienne Lecorvaisier was an independent Director under the AFEP-MEDEF Code.

During its meeting of February 3, 2014, the Audit Committee examined the experience of Fabienne Lecorvaisier in corporate finance in various international banks and as Chief Financial Officer of Essilor and now Air Liquide. The Audit Committee concluded that Fabienne Lecorvaisier has the necessary knowledge and experience in finance and accounting, in particular with respect to IFRS standards and internal controls, to be a financial expert.

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. 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

Edgar Filing: Sanofi - Form 20-F

Table of Contents

the definition in Article L. 823-19 of the French Commercial Code. See "Item 16A. Audit Committee Financial Expert". The competencies of the Audit Committee members derive both from their academic background and their professional experience as reflected in their biographies.

The Audit Committee met eight times in 2013, 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 Audit and Evaluation of Internal Control and other members of senior management of the Group attended meetings of the Audit Committee.

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 87%. Individual attendance rates varied between 40% and 100%.

The statutory auditors attended all of the meetings of the Audit Committee; they presented their views as to the annual and half yearly financial statements at the Committee meetings of February 4, and July 29, 2013, respectively.

In 2013, the main activities of the Audit Committee related to:

the preliminary review of the individual company and consolidated financial statements for the 2012 financial year, the review of the individual company and consolidated financial statements for the first half of 2013 and of the consolidated financial statements for the first three quarters of 2013, 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;

investigation and evaluation of internal control for 2012, as certified by the statutory auditors pursuant to Section 404 of the Sarbanes-Oxley Act, and an examination of the 2012 Annual Report on Form 20-F;

reporting on guarantees;

the review of the draft resolutions to the May 3, 2013 Shareholders' General Meeting;

the principal risks facing the Company, including pharmacovigilance, the management of internal audit and computer services, update on the compliance program, impairment testing of goodwill, update on insurance, the security of computer services, update on retirement funds and actuarial assumptions, review of tax litigation, environmental litigation and other litigation (meetings of March 1, April 26, July 29, October 25, and December 16, 2013);

the conclusions of Group management as to internal control procedures, the 2012 Board of Directors' Management Report and Chairman's Report, including the description of risk factors contained in the French *Document de Référence*;

a session of the Audit Committee related specifically to the Company's business in China, held in Beijing;

reporting on computer services, on the implementation of shared services in France, update on the monitoring of acquisitions (Medley, Merial), reporting on internal audit activities and computer services;

Edgar Filing: Sanofi - Form 20-F

the budget for audit-related services and non-audit services, and the 2013 audit plan, statutory auditors' report and fees;

the expertise in financial and accounting matters of Fabienne Lecorvaisier with a view to her appointment to the Audit Committee.

The Committee did not have recourse to external consultants in 2013.

Compensation Committee

At December 31, 2013, this Committee was composed of:

Gérard Van Kemmel, Chairman;

Table of Contents

Thierry Desmarest;

Jean-René Fourtou;

Claudie Haigneré;

Christian Mulliez.

Of the five members of the Compensation Committee, three are deemed to be independent.

The Compensation Committee met three times in 2013.

The members of the Compensation Committee have a very good attendance record for meetings, with an overall attendance rate among members of over 93%. Individual attendance rates varied between over 66% 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 2013, 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, the principles of allocation of Directors attendance fees for 2013;

the review of the governance chapter of the 2012 *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 2013 requesting renewal of the delegation of authority granted to the Board to allocate options to subscribe for shares or to purchase shares, and the delegation related to the share capital increase reserved for employees who are members of the Group Savings Plan;

an update on the 2012 and 2013 fixed and variable compensation of the members of the Executive Committee, including performance share units;

the expenses of Directors and corporate officers;

analysis of the changes in the AFEP-MEDEF Code, including the introduction of the Say on Pay;

employee share ownership policy, with the share capital increase reserved for employees who are members of the Group Savings Plan during the second half of 2013.

The Committee did not have recourse to external consultants in 2013.

Appointments and Governance Committee

At December 31, 2013, this Committee was composed of:

Serge Weinberg, Chairman;

Thierry Desmarest;

Lord Douro;

Jean-René Fourtou;

Claudie Haignéré;

Gérard Van Kemmel.

Of the six members of the Appointments and Governance Committee, five are deemed to be independent.

The Appointments and Governance Committee met three times in 2013.

Table of Contents

The members of the Appointments and Governance Committee have a very good attendance record for meetings, with an overall attendance rate among members of over 93%. Individual attendance rates varied between over 66% and 100%.

In 2013, 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 2012 *Document de Référence* containing disclosures about governance;

the independence of Directors, proposals about the reappointment and appointment of Directors, the review of the independence of the proposed new Director, the appointment of a sixth member of the Audit Committee, update on the composition of the Committees after the May 3, 2013 Shareholders' General Meeting;

update on the composition of the Board of Directors and especially the impact study of the French Employment Protection Act, and succession planning;

the organization of the Group and succession planning, including for Hanspeter Spek (President Global Operations); and

the amendment of the Board Charter subsequent to the amendment of the AFEP-MEDEF Code.

The Committee did not have recourse to external consultants in 2013.

Strategy Committee

At December 31, 2013, this Committee was composed of:

Serge Weinberg, Chairman;

Christopher Viehbacher;

Laurent Attal;

Uwe Bicker;

Thierry Desmarest;

Lord Douro;

Jean-René Fourtou.

Of the seven members of the Strategy Committee, four are deemed to be independent.

Edgar Filing: Sanofi - Form 20-F

In 2013, the Strategy Committee met three times, including twice in expanded sessions to welcome other directors. A Strategy Committee in expanded session met in October in China.

The members of the Strategy Committee have a very good attendance record for meetings, with an overall attendance rate among members of over 93%. Individual attendance rates varied between over 66% and 100%.

As in previous years, the work of the Committee covered, in particular an overview of our research strategy in core disease areas, the development portfolio, the long range plan, and proposed acquisitions.

The Committee did not have recourse to external consultants in 2013.

D. Employees

Number of Employees

In 2013, Sanofi employed 112,128 people worldwide, 154 more than in 2012. The tables below give a breakdown of employees by geographic area and function for the years ended December 31, 2013, 2012 and 2011.

Table of Contents**Employees by geographic area****As of December 31,**

	2013	%	2012	%	2011	%
Europe	53,880	48.0%	56,265	50.2%	58,339	51.3%
North America	18,795	16.8%	18,994	17.0%	20,233	17.8%
Other countries	39,453	35.2%	36,715	32.8%	35,147	30.9%
Total	112,128	100%	111,974	100%	113,719	100%

Employees by function**As of December 31,**

	2013	%	2012	%	2011	%
Sales	33,509	29.9%	32,270	28.8%	32,874	28.9%
Research and Development	16,688	14.9%	17,066	15.2%	18,823	16.6%
Production	44,031	39.3%	45,035	40.2%	44,415	39.0%
Marketing and Support Functions	17,900	16.0%	17,603	15.7%	17,607	15.5%
Total	112,128	100%	111,974	100%	113,719	100%

Industrial Relations

In all countries where Sanofi operates, we strive to combine economic and social performance which we believe are inseparable.

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 social 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.

Social dialogue takes place in different ways from one country to the next, as necessitated by specific local circumstances. Depending on the case, social 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 sectorial basis, or both. Social dialogue may be informal or it may be 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.

Table of Contents

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 2013 in respect of voluntary profit-sharing for the year ended December 31, 2012 represented 4.63% 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 are 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 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 2013 in respect of the statutory scheme for the year ended December 31, 2012 represented 5.55% 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

40% on the basis of annual salary, up to a limit of three times the Social Security ceiling.

Employee Savings Schemes and Collective Retirement Savings Plan

The employee savings arrangements operated by Sanofi are based on a Group savings scheme (*Plan Epargne Groupe*) and a collective retirement savings plan (*Plan Epargne pour la Retraite Collectif*). These schemes reinvest the sums derived from the statutory and voluntary profit-sharing schemes (compulsory investments), and voluntary contributions by employees.

In June 2013, more than 85% of the employees who benefited from the profit-sharing schemes had opted to invest in the collective retirement savings plan.

In 2013, €121 million and €58.8 million were invested in the Group savings scheme and the collective retirement savings plan respectively through the voluntary and statutory schemes for 2012, and through top-up contributions.

Employee Share Ownership

At December 31, 2013, shares held by employees of Sanofi and of related companies and by former employees under Group employee savings schemes amounted to 1.30% of the share capital.

Edgar Filing: Sanofi - Form 20-F

During its meeting on October 29, 2013, the Board of Directors decided to use the delegation of powers granted by the Shareholders' General Meeting held on May 3, 2013, and to implement a share capital increase reserved for members of the Group savings plan. The subscription period took place in November 2013. The plan was open to employees of more than 80 countries. Overall, 1,672,198 shares were subscribed, including 839,892 by the Group Employee Savings Plan for employees of French subsidiaries ("FCPE Actions Sanofi") and 293,639 by the Group

Table of Contents

Employee Savings Plan for employees of non-French subsidiaries ("FCPE Sanofi Shares"). The remainder of the shares are held in local banks for local regulatory purposes. 14,770 employees participated in this share capital increase reserved for employees.

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, 2013, a total of 3,400,000 options had been granted to the members of the Executive Committee (plans existing or closed in 2012) and 3,015,000 unexercised options to subscribe for or to purchase Sanofi shares were held by the members of the Executive Committee.

In 2013, 313,000 options were exercised by members of the Executive Committee.

These exercises related to one option plan that pre-dates the creation of the Executive Committee (sanofi-aventis subscription option plan of December 10, 2003 with an exercise price of €55.74), and two others that post-date the creation of the Executive Committee (sanofi-aventis subscription option plan of December 13, 2007 with an exercise price of €62.33 and sanofi-aventis subscription option plan of March 9, 2009 with an exercise price of €45.09).

At December 31, 2013, a total of 408,500 performance shares had been awarded to the members of the Executive Committee (plans existing or closed in 2013) and 258,500 unvested performance shares were held by the members of the Executive Committee.

These figures include the options granted to Christopher Viehbacher, who is a member of the Executive Committee. The terms of these options and performance shares are summarized in the tables below.

Existing Option Plans as of December 31, 2013

As of December 31, 2013, a total of 35,708,847 options were outstanding, including 223,181 options to purchase Sanofi shares and 35,485,666 options to subscribe for Sanofi shares. Out of this total, 25,813,742 were immediately exercisable, including 223,181 options to purchase shares and 25,590,561 options to subscribe for shares.

Equity-based compensation, consisting of share subscription option plans and performance share plans, aims to align the employees' objectives on those of the shareholders and to reinforce the link between employees and the Group. Under French law, this falls within the powers of the Board of Directors. Stock options (which may be options to subscribe for shares or options to purchase shares) are granted to employees and the Chief Executive Officer by the Board of Directors on the basis of recommendations from the Compensation Committee.

Granting options is a way of recognizing the beneficiary's contribution to the Group's development, and also of securing his or her future commitment to the Group.

For each plan, the Compensation Committee and the Board of Directors assess whether it should take the form of options to subscribe for shares or options to purchase shares, based on criteria that are primarily financial.

A list of beneficiaries is proposed by the Senior Management to the Compensation Committee, which reviews the list and then submits it to the Board of Directors, which decides to grant the options. The Board of Directors also sets the terms for the exercise of the options (including the exercise price) and the lock-up period. The exercise price never incorporates a discount, and must be at least equal to the average of the quoted market prices on the 20 trading days preceding the date of grant by the Board. Stock option plans generally specify a vesting period of four years and a total duration of ten years.

In 2011, the Board of Directors made significant changes to its equity-based compensation policy. In order to limit the dilutive effect on shareholders, the Board of Directors determined to primarily award performance shares, except for a limited group of senior managers who may continue to receive options. Furthermore, whoever the beneficiary is, any award of options or performance shares will henceforth be fully contingent upon the performance targets being met over three financial years.

Edgar Filing: Sanofi - Form 20-F

Table of Contents

On March 5, 2013, 548,725 share subscription options were awarded to 57 beneficiaries (excluding 240,000 options awarded to Christopher Viehbacher). Each option entitles the grantee to subscribe for one share, in the aggregate representing 0.06% of our share capital before dilution.

The entire award was contingent upon two of the same internal criteria as the award of Christopher Viehbacher (i.e. those based on Business Net Income and Return on Assets), but not on the TSR-based criterion. Consequently, the weighting of each criterion is different, each representing 50% of the grant. The quantitative measures of performance are the same as for the award of Christopher Viehbacher.

The percentage of options awarded to Christopher Viehbacher in 2013 represents 1.81% of the total limit approved by the Shareholders' General Meeting held on May 6, 2011 (1% of our share capital) and 30.43% of the total award to all beneficiaries on March 5, 2013.

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 2011 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 €420 gross in July 2013. In total, Sanofi paid out €13.7 million in this regard (including social contributions).

On March 5, 2014, the Board of Directors awarded 769,250 share subscription options 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 0.06% of our share capital before dilution.

The entire award was contingent upon two of the same internal criteria as the award of Christopher Viehbacher (i.e. those based on Business Net Income and Return on Assets), but not on the TSR-based criterion. Consequently, the weighting of each criterion is different, each representing 50% of the grant.

As part of its commitment to transparency, Sanofi has undertaken to publish in its annual report the level of attainment determined by the Board of Directors for the performance conditions applicable to future equity-based compensation plans awarded to Christopher Viehbacher and the other members of the Executive Committee. The Board considers that disclosing the level of attainment allows our shareholders to better understand the demanding nature of the performance conditions. For disclosures about the level of attainment of the various equity-based compensation plans, see " B. Compensation Compensation and pension arrangements for corporate officers Christopher Viehbacher", bearing in mind that the TSR-based criterion only applies to the Chief Executive Officer and that the criteria based on Business Net Income and the ROA each apply to 50% of the grant.

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 granted the most options(2)		Start date of exercise period	Expiration date	Purchase price (in €)	Number exercised as of 12/31/2013	Number canceled as of 12/31/2013	ou
6/28/1990	10/18/1994	330,200	0	200,200	10/18/1999	10/18/2014	6.01	326,000	0		
6/28/1990	1/12/1996	208,000	0	52,000	1/12/2001	1/12/2016	8.56	199,130	0		
6/28/1990	4/05/1996	228,800	0	67,600	4/05/2001	4/05/2016	10.85	213,000	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	528,489	5,720		

- (1) *Comprises 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	Expiration date	Subscription price (in €)	Number exercised as of 12/31/2013	Number canceled as of 12/31/2013
5/14/2002	12/02/2003	12,012,414	352,174	715,000	12/03/2006	12/02/2013	40.48	9,791,217	2,221,197
5/18/1999	12/10/2003	4,217,700	240,000	393,000	12/11/2007	12/10/2013	55.74	3,843,545	374,155
5/31/2005	5/31/2005	15,228,505	400,000	550,000	6/01/2009	5/31/2015	70.38	4,606,672	2,163,023
5/31/2005	12/14/2006	11,772,050	450,000	585,000	12/15/2010	12/14/2016	66.91	3,821,050	1,173,030
5/31/2007	12/13/2007	11,988,975	325,000	625,000	12/14/2011	12/13/2017	62.33	4,711,596	1,064,245
5/31/2007	3/02/2009	7,736,480	250,000	655,000	03/04/2013	3/01/2019	45.09	2,985,086	610,745
4/17/2009	3/01/2010	7,316,355	0	665,000	3/03/2014	02/28/2020	54.12	15,825	574,700
4/17/2009	3/01/2010	805,000	275,000	805,000	3/03/2014	02/28/2020	54.12	0	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	18,000
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	216,000	3/06/2017	3/05/2023	72.19	0	15,000
5/06/2011	3/05/2013	240,000	240,000	0	3/06/2017	3/05/2023	72.19	0	0

(1)

Comprised 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, 2013

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 henceforth fully contingent upon the performance targets being attained over three financial years.

On March 5, 2013, the Board of Directors set up two plans in addition to the award made to the Chief Executive Officer:

a French plan awarding 1,411,910 performance shares to 2,542 beneficiaries, subject to a vesting period of three years followed by a lock-up period of two years; and

an international plan awarding 2,838,795 restricted shares to 5,119 beneficiaries, subject to a vesting period of four years.

The entire award was contingent upon two of the same internal criteria as the award of Christopher Viehbacher (i.e. those based on Business Net Income and Return on Assets), but not on the TSR-based criterion. Consequently, the weighting of each criterion is different, each representing 50% of the grant. The quantitative measures of performance are the same as for the award of Christopher Viehbacher.

The 2013 awards represent a dilution of 0.32% of our share capital before dilution as of December 31, 2013.

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 2011 to ensure that all employees have an interest in the performance of the business.

Edgar Filing: Sanofi - Form 20-F

Table of Contents

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 €420 gross in July 2013. In total, Sanofi paid out €13.7 million in this regard (including social contributions).

On March 5, 2014, the Board of Directors set up two plans:

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 with no lock-up period.

The entire award was subject to two of the same internal criteria as the award of Christopher Viehbacher (i.e. those based on Business Net Income and Return on Assets) as Christopher Viehbacher, but not on the TSR-based criterion. Consequently, the weighting of each criterion is different, each representing 50% of the grant.

As part of its commitment to transparency, Sanofi has undertaken to publish in its annual report the level of attainment determined by the Board of Directors for the performance conditions applicable to future equity-based compensation plans awarded to Christopher Viehbacher and the other members of the Executive Committee. The Board considers that disclosing the level of attainment allows our shareholders to better understand the demanding nature of the performance conditions. For disclosures about the level of attainment of the various equity-based compensation plans, see " B. Compensation Compensation and pension arrangements for corporate officers Christopher Viehbacher", bearing in mind that the TSR-based criterion only applies to the Chief Executive Officer and that the criteria based on Business Net Income and the ROA apply to 50% of the grant each.

Restricted Share Plans

	Date of shareholder authorization	Date of award	Number of shares initially awarded	- to corporate officers(1)	- to the 10 employees the most awarded shares(2)	Date of award(3)	Vesting date	Availability date	Number transferred as of 12/31/2013	Number of rights canceled as of 12/31/2013	outs
ntis	5/31/07	3/02/09	590,060	65,000	13,900	3/02/09	3/03/11	3/04/13	585,782	4,278	
ntis	5/31/07	3/02/09	604,004	0	13,200	3/02/09	3/04/13	3/04/13	541,595	62,409	
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	4,444	79,079	
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	1,600	97,480	1
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	17,300	165,240	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	1,525,100	0	126,700	3/05/2012	3/06/15	3/06/17	100	14,310	1

Edgar Filing: Sanofi - Form 20-F

4/17/09	3/05/12	3,127,160	0	96,300	3/05/2012	3/06/16	3/06/16	2,400	237,320	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	1,411,910	0	97,300	3/05/2013	3/06/16	3/06/18	0	2,900	1
5/04/12	3/05/13	2,838,795	0	85,100	3/05/2013	3/06/17	3/06/17	2,200	70,565	2
5/04/12	3/05/13	45,000	45,000	0	3/05/2013	3/06/16	3/06/18	0	0	

- (1) *Comprises the Chief Executive Officer as of the date of grant.*
- (2) *Employed as of the date of grant.*
- (3) *Subject to vesting conditions.*

As of December 31, 2013, a total of 12,473,621 restricted shares were outstanding.

Shares Owned by Members of the Board of Directors

As of December 31, 2013, members of our Board of Directors held in the aggregate 127,501 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).

Table of Contents

Transactions in Shares by Members of the Board of Directors and equivalent persons in 2013

On March 20, 2013, Karen Linehan, Senior Vice-President Legal Affairs and General Counsel, exercised 40,000 options to subscribe for shares at a price of €45.09 per share and sold the resulting 40,000 shares at a price of €73.32 per share (sanofi-aventis subscription option plan of March 2, 2009);

On March 27, 2013, Philippe Luscan, Senior Vice-President Industrial Affairs, exercised 4,000 options to subscribe for shares at a price of €55.74 per share and sold the resulting 4,000 shares at a price of €75.22 per share (sanofi-aventis subscription option plan of December 10, 2003);

On April 10, 2013, Hanspeter Spek, President Global Operations, exercised 115,000 options to subscribe for shares at a price of €62.33 per share (sanofi-aventis subscription option plan of December 13, 2007) and 120,464 options to subscribe for shares at a price of €45.09 per share (sanofi-aventis subscription option plan of March 2, 2009), and respectively sold the resulting 115,000 shares and 92,493 shares at a price of €76.42 per share;

On April 15, 2013, Hanspeter Spek, President Global Operations, exercised 9,536 options to subscribe for shares at a price of €45.09 per share (sanofi-aventis subscription option plan of March 2, 2009);

On April 15, 2013, Philippe Luscan, Senior Vice-President Industrial Affairs, sold 1,520.43 units he held in the Sanofi Group Employee Savings Plan (FCPE Actions Sanofi) at a price of €81.96 per unit;

On May 29, 2013, Fabienne Lecorvaisier, Director, bought 1,000 shares at a price of €83.65 per share;

On May 15, 2013, Christian Mulliez, Director, acquired 22.34 shares at a price of €85.22 per share by electing to receive his dividend in shares for the units he holds in the Sanofi Group Employee Savings Plan (FCPE Actions Sanofi);

On June 21, 2013, Olivier Charmeil, Senior Vice-President Vaccines, exercised 15,000 options to subscribe for shares at a price of €55.74 per share (sanofi-aventis subscription option plan of December 10, 2003) and on June 28, 2013, four related persons respectively sold the resulting 3,294 shares, 3,894 shares, 3,894 shares and 3,894 shares at a respective price per share of €79.41, €79.23, €79.27 and €79.24;

On June 25, 2013, Carole Piwnica, Director, bought 500 shares at a price of €76.50 per share.

On September 11, 2013, Laurent Attal, Director, acquired 500 shares at a price of €73.98 per share;

On November 6, 2013, Philippe Luscan, Senior Vice-President Industrial Affairs, exercised 9,000 options to subscribe for shares at a price of €55.74 per share (sanofi-aventis subscription option plan of December 10, 2003) and on November 15, 2013, three related persons each sold 3,000 of the resulting shares at a price per share of €78.87;

On November 14, 2013, Suet-Fern Lee, Director, acquired 500 shares at a price of €78.20 per share;

On December 18, 2013, Christopher Viehbacher, Chief Executive Officer, subscribed to 10,000 units of the Sanofi Group Employee Savings Plan (FCPE Actions Sanofi) at a price of €59.25 per unit;

Edgar Filing: Sanofi - Form 20-F

On December 18, 2013, Olivier Charmeil, Executive Vice President Vaccines, subscribed to 4,000 units of the Sanofi Group Employee Savings Plan (FCPE Actions Sanofi) at a price of €59.25 per unit;

On December 18, 2013, Jérôme Contamine, Executive Vice President Chief Financial Officer, subscribed to 2,500 units of the Sanofi Group Employee Savings Plan (FCPE Actions Sanofi) at a price of €59.25 per unit;

On December 18, 2013, Peter Guenter, Executive Vice President Global Commercial Operations, subscribed to 5,000 units of the Sanofi Group Employee Savings Plan (FCPE Actions Sanofi) at a price of €59.25 per unit;

On December 18, 2013, Philippe Luscan, Executive Vice President Global Industrial Affairs, subscribed to 200 units of the Sanofi Group Employee Savings Plan (FCPE Actions Sanofi) at a price of €59.25 per unit;

On December 18, 2013, Roberto Pucci, Executive Vice President Human Resources, subscribed to 3,375 units of the Sanofi Group Employee Savings Plan (FCPE Actions Sanofi) at a price of €59.25 per unit;

On December 18, 2013, Pascale Witz, Executive Vice President Global Divisions & Strategic Commercial Development, subscribed to 200 units of the Sanofi Group Employee Savings Plan (FCPE Actions Sanofi) at a price of €59.25 per unit.

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, 2014, 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 own shares)(3)		Theoretical number of voting rights (including own shares)(4)	
	Number	%	Number	%	Number	%
L'Oréal	118,227,307	8.93	236,454,614	16.17	236,454,614	16.13
Treasury shares⁽¹⁾	3,632,599	0.27			3,632,599	0.25
Employees⁽²⁾	17,366,892	1.31	33,079,522	2.26	33,079,522	2.25
Public	1,185,162,331	89.49	1,193,014,414	81.57	1,193,014,414	81.37
Total	1,324,389,129	100	1,462,548,550	100	1,466,181,149	100

(1) *Includes net position of share repurchases under the Group's liquidity contract which amounted to 31,500 as of January 31, 2014. 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, 2014.*

(4) *Based on the total number of voting rights as of January 31, 2014 as published in accordance with article 223-11 and seq. of the General Regulations of the Autorité des Marchés Financiers (i.e., calculated before 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, 2013, 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 are required to 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, 2013, we were informed that the following share ownership declaration thresholds had been passed:

Amundi Asset Management declared that, through its mutual funds, it has passed above (declaration of July 1, 2013) and then below (declaration of December 3, 2013) the threshold of 3% of our voting rights and as of its last declaration held 2.99% of our voting rights;

L'Oréal declared that, due to a change in the number of our voting rights, it had passively and successively passed below (declaration of June 25, 2013) and above (declaration of September 3, 2013) the threshold of 16% of our voting rights and as of its last declaration held 16.03% of our voting rights;

Natixis Asset Management declared that it had passed below the threshold of 2% of our voting rights and as of its last declaration held 1.99% of our voting rights (declaration of December 18, 2013);

UBS declared that it had successively passed above (declaration of May 7, 2013) and below (declaration of May 21, 2013) the threshold of 1% of our share capital and of our voting rights and as of its last declaration held 0.90% of our share capital and 0.81% of our voting rights.

Table of Contents

Since January 1, 2014 we have been informed that the following share ownership declaration thresholds mentioned in our Articles of Association had been passed:

Natixis Asset Management declared that it had passed above the threshold of 2% of our voting rights and as of its last declaration held 2.05% of our voting rights (declaration of January 9, 2014);

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).

Individual shareholders (including employees of Sanofi and its subsidiaries, as well as retired employees holding shares via the Sanofi Group Employee Savings Plan) hold approximately 7.5% of our share capital. Institutional shareholders (excluding L'Oréal) hold approximately 77.2% of our share capital. Such shareholders are primarily American (26.8%), French (15.1%) and British (13.8%). German institutions hold 3.1% of our share capital, Swiss institutions hold 2.5%, institutions from other European countries hold 8.3% and Canadian institutions hold 1.7% of our share capital. Other international institutional investors (excluding those from Europe and the United States) hold approximately 5.9% of our share capital. In France, our home country, we have 16,393 identified shareholders of record. In the United States, our host country, we have 52 identified shareholders of record and 10,683 identified ADS holders of record.

(source: a survey conducted by Euroclear France as of December 31, 2013, and internal information).

Shareholders' Agreement

We are unaware of any shareholders' agreement currently in force.

B. Related Party Transactions

In the ordinary course of business, we purchase or provide materials, supplies and services from or to numerous companies throughout the world. Members of our Board of Directors are affiliated with some of these companies. We conduct our transactions with such companies on an arm's-length basis and do not consider the amounts involved in such transactions to be material. In addition, cash management intra-group financing agreements exist between Sanofi and certain of its subsidiaries. Those and other intragroup transactions are neither unusual nor atypical but fall under the ordinary business of the companies of the Group. Such transactions are conducted on an arm's-length basis. Some examples of such transactions are listed below.

On February 21, 2012, Sanofi European Treasury Center (SETC), a 100% subsidiary of the Sanofi Group, was incorporated under the laws of Belgium, with the purpose of providing financing and payment services to other Group subsidiaries.

On June 28, 2012, the Group's parent company transferred the Genzyme Corporation shares acquired in April 2011 to Aventis, Inc.. This transfer consisted of two principal operations:

recapitalization by the Group's parent company of its subsidiary Genzyme Corporation by incorporation of two loans totaling \$16.1 billion into share capital; and

sale of Genzyme Corporation to a wholly owned subsidiary, Aventis, Inc., for a total price of \$19.2 billion.

Aventis, Inc. financed this acquisition mainly by using its available cash resources, by increasing its share capital and by long-term intragroup financing (\$15.6 billion). On March 28, 2013, Sanofi capitalized the loan to Sanofi-Aventis Amérique du Nord for an amount of €4.1 billion.

C. Interests of Experts and Counsel

N/A

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, 2013, 2012, and 2011 are included in this annual report at "Item 18. Financial Statements."

Table of Contents**Dividends on Ordinary Shares**

We paid annual dividends for the years ended December 31, 2008, 2009, 2010, 2011 and 2012 and our shareholders will be asked to approve the payment of an annual dividend of €2.80 per share for the 2013 fiscal year at our next annual shareholders' meeting. If approved, this dividend will be paid on May 15, 2014.

We expect that we will continue to pay regular dividends based on our financial condition and results of operations. The proposed 2013 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 2009, 2010, 2011 and 2012 fiscal years and the dividend that will be proposed for approval by our shareholders in respect of the 2013 fiscal year at our May 5, 2014 shareholders' meeting.

	2013(1)	2012	2011	2010	2009
Net Dividend per Share (in €)	2.80	2.77	2.65	2.50	2.40
Net Dividend per Share (in \$) ⁽²⁾	3.86	3.65	3.43	3.34	3.46

(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 2013. 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 €7 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 €2.6 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".

Edgar Filing: Sanofi - Form 20-F

Sanofi and its affiliates 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

Table of Contents

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 24 July, 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.

Apotex Settlement Claim

On November 13, 2008, Apotex filed a complaint before a state court in New Jersey against Sanofi and Bristol-Myers Squibb 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 Bristol-Myers Squibb 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. The arbitration procedure is on-going.

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.

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") by Eisai, Daiko Pharmaceutical Co. Ltd., Kyorin Rimedio Co. Ltd., Nihon Generic Co., Ltd., Nihon Pharmaceutical Industry Co. Ltd., Nippon Chemipharm 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.

Table of Contents

Synvisc-One® Patent Litigation

In April 2011, Genzyme filed suit in the U.S. District Court for the District of Massachusetts against generic manufacturers Seikagaku Corporation (Seikagaku), Zimmer Holdings, Inc., Zimmer, Inc. and Zimmer U.S., Inc. (collectively, "Zimmer") for the infringement of U.S. Patent No. 5,399,351 (the '351 patent) and U.S. Patent No. 7,931,030 (the '030 patent), upon Seikagaku's and Zimmer's launch of generic versions of Synvisc-One® in the United States.

On December 30, 2011, the U.S. District Court granted, in part, Genzyme's Motion for a preliminary injunction, enjoining Seikagaku and Zimmer from selling generic versions of Synvisc-One®, pending a decision in the infringement action, except on limited and specific pricing conditions. In August 2012, a federal jury in Massachusetts found that Seikagaku Corp's recently approved product Gel-One®, distributed in the U.S. by Zimmer, did not infringe the '030 patent. The jury also found that the '030 patent claims were invalid due to obviousness. Following the denial of the motion for judgment as a matter of law and a motion for new trial filed in September 2012, Genzyme filed an appeal before the Federal Circuit.

On January 7, 2014, Genzyme settled this litigation with Seikagaku, under the terms of the settlement:

Seikagaku agrees to drop its Motion for damages; and

Genzyme agrees to drop its appeal to the Federal Circuit from the district court order entering judgment against Genzyme in favor Seikagaku on August 7, 2012.

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.

Sanofi followed its PI actions with main infringement suits against some of the generic companies. A few of the generic companies have filed revocation actions seeking to revoke Sanofi's Co-Aprovel® SPC. Some of these revocation actions were denied (Italy), others have been suspended (United Kingdom, Belgium). In France, the *Tribunal de Grande Instance* of Paris held the SPC and the patent invalid at the end of February 2013. On December 12, 2013, further to questions raised on the SPC regulation interpretation, the Court of Justice of the European Union (CJEU) invalidated Sanofi's SPC. The decision cannot be appealed further. All countries in which litigations were ongoing will have to incorporate the CJEU's decision in their national cases. Based on the CJEU decision, the generic companies that were affected by a preliminary injunction under the now invalidated SPC may file suit for damages.

Lantus® and Lantus Solostar® Patent Litigation

In mid-December 2013, Sanofi received notifications from Eli Lilly and Company ("Lilly"), stating that it had filed a NDA (505(b)(2) New Drug Application) with the FDA for an insulin glargine drug product. Lilly also stated that its NDA included a paragraph IV certification challenging six of the seven 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, where Sanofi alleges infringement of four patents. This suit resulted in a stay during which the FDA cannot approve Eli Lilly's NDA. The stay is expected to expire the earlier of (i) a court decision favorable to Lilly or (ii) June 2016.

Multaq® Patent Litigation

In January 2014, Sanofi received notices from Watson and Glenmark, respectively, 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 of the patents listed by Sanofi in the FDA's Orange Book in connection with Multaq®. Neither Watson nor Glenmark challenge the patent

Edgar Filing: Sanofi - Form 20-F

directed to the active ingredient in Multaq®, US Patent No. 5,223,510 (the '510 patent).

In February 2014 Sanofi brought suit against Watson, Actavis (Watson's parent company) and Glenmark individually in the United States District Court for the District of Delaware for infringement of three patents: U.S. Patent Nos. 8,318,800; 8,410,167; and 8,602,215.

Table of Contents

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 Sculptra®.

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 brought by Teva Santé 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. Sanofi appealed that decision before the Paris Court of Appeals in July 2013.

In Germany, a criminal investigation was initiated against three current and two retired Sanofi employees in connection with the alleged sale in Germany of medications originally destined for humanitarian aid outside of the European Union. Two employees were convicted for commercial bribery and a fine was set against the Sanofi affiliate amounting to €28 million.

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. 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.

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

N/A

B. Significant Changes

On January 11, 2014, Regeneron, Sanofi and some of its subsidiaries (collectively "Sanofi") agreed to amend and restate the original investor agreement, dated as of December 20, 2007, as amended in its entirety and entered into the Amended and Restated Investor Agreement (the "Amended Investor Agreement"). The Amended Investor Agreement was amended to, among other things, provide Sanofi with the right to nominate a single independent director to the Regeneron's Board of Directors upon reaching 20% ownership of the Company's then outstanding shares of Class A Stock, par value \$0.001 per share and Common Stock and to extend the term of the lock-up obligations. The Amended Investor Agreement also provides Sanofi with the right to receive certain information as may be reasonably agreed upon by the parties that will facilitate Sanofi's ability to account for their investment in the Company using the equity method of accounting under International Financial Reporting Standards.

Subsequently, Sanofi has determined to purchase, directly or through its subsidiaries, additional shares of Common Stock to increase its beneficial ownership to approximately 20.5% of the Common Stock outstanding. Sanofi made no commitment in terms of the timing of such transactions, which will depend on market conditions including the price and availability of shares of Common Stock, and on such other factors considered relevant to Sanofi.

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 NYSE Euronext Paris, or 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 2014	75.79	68.29	52.21	47.06
January 2014	77.70	70.57	52.31	48.26
December 2013	78.10	71.85	53.63	49.29
November 2013	80.74	76.66	54.49	51.48
October 2013	79.12	71.68	53.94	48.43
September 2013	76.41	71.50	51.50	46.95
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

Edgar Filing: Sanofi - Form 20-F

Full Year	87.03	65.91	55.94	44.50
2012				
First quarter	59.56	54.86	39.19	34.92
Second quarter	59.74	53.20	39.33	33.03
Third quarter	69.46	59.45	44.97	36.53
Fourth quarter	72.38	65.63	47.97	42.20
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
2009				
Full Year	56.78	38.43	40.80	24.59

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

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.

Edgar Filing: Sanofi - Form 20-F

Table of Contents

Our Articles of Association specify that our corporate affairs are governed by:

applicable laws and regulations (in particular, Title II of the French Commercial Code); and

the Articles of Association themselves.

Article 3 of our Articles of Association specifies that the Company's corporate purpose, in France and abroad, is:

acquiring interests and holdings, in any form whatsoever, in any company or enterprise, in existence or to be created, connected directly or indirectly with the health and fine chemistry sectors, human and animal therapeutics, nutrition and bio-industry;

in the following areas:

purchase and sale of all raw materials and products necessary for these activities;

research, study and development of new products, techniques and processes;

manufacture and sale of all chemical, biological, dietary and hygiene products;

obtaining or acquiring all intellectual property rights related to results obtained and, in particular, filing all patents, trademarks and models, processes or inventions;

operating directly or indirectly, purchasing, and transferring for free or for consideration pledging or securing all intellectual property rights, particularly all patents, trademarks and models, processes or inventions;

obtaining, operating, holding and granting all licenses;

within the framework of a group-wide policy and subject to compliance with the relevant legislation, participating in treasury management transactions, whether as lead company or otherwise, in the form of centralized currency risk management or intra-group netting, or any other form permitted under the relevant laws and regulations;

and, more generally:

all commercial, industrial, real or personal property, financial or other transactions, connected directly or indirectly, totally or partially, with the activities described above and with all similar or related activities or having any other purposes likely to encourage or develop the Company's activities.

Directors

Transactions in Which Directors Are Materially Interested

Under French law, any agreement entered into (directly or through an intermediary) between our Company and any one of the members of the Board of Directors that is not entered into (i) in the ordinary course of our business and (ii) under normal conditions is subject to the prior authorization of the disinterested members of the Board of Directors. The same provision applies to agreements between our Company and

another company if one of the members of the Board of Directors is the owner, general partner, manager, director, general manager or member of the executive or supervisory board of the other company, as well as to agreements in which one of the members of the Board of Directors has an indirect interest.

The Board of Directors must also authorize any undertaking taken by our Company for the benefit of our Chairman, Chief Executive Officer (*directeur général*) or his delegates (*directeurs généraux délégués*) pursuant to which such persons will or may be granted compensation, benefit or any other advantage as a result of the termination of or a change in their offices or following such termination or change.

In addition, except with respect to any non-compete indemnity or certain pension benefits, any such termination package: (i) must be authorized by our shareholders through the adoption of a separate general shareholders meeting resolution for each such beneficiary, which authorization must be renewed at each renewal of such beneficiary's mandate, and (ii) cannot be paid to such beneficiary unless (a) the Board of Directors decides that such beneficiary has satisfied certain conditions, linked to such beneficiary's performance measured by our Company's performance, that must have been defined by the Board of Directors when granting such package, and (b) such decision is publicly disclosed.

Table of Contents

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, 2013, our share capital amounted to €2,648,641,762, divided into 1,324,320,881 outstanding shares with a par value of €2 per share. All of our outstanding shares are of the same class and are fully paid. Of these shares, we or entities controlled by us held 3,601,099 shares (or 0.27% of our outstanding share capital), as treasury shares as of such date. As of December 31, 2013, the carrying amount of such shares was €244 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, 2013 was 298 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.

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

Table of Contents

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.

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.

Edgar Filing: Sanofi - Form 20-F

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.

Table of Contents

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 2013

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, 2013, there were 141,851,514 shares that were entitled to double voting rights, representing 10.71% of our total share capital, approximately 9.70% of our voting rights held by holders other than us and our subsidiaries, and 9.67% 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.

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;

Table of Contents

creating a new class of equity securities;

authorizing the issuance of securities giving access to our share capital or giving the right to receive debt instruments;

establishing any other rights to equity securities;

selling or transferring substantially all of our assets; and

the voluntary liquidation of our Company.

Special meetings of shareholders of a certain category of shares or shares with certain specific rights (such as shares with double voting rights) are required for any modification of the rights derived from that category of shares. The resolutions of the shareholders' general meeting affecting these rights are effective only after approval by the relevant special meeting.

Annual Ordinary Meetings

The French Commercial Code requires the Board of Directors to convene an annual ordinary general shareholders' meeting to approve the annual financial statements. This meeting must be held within six months of the end of each fiscal year. This period may be extended by an order of the President of the Commercial Court. The Board of Directors may also convene an ordinary or extraordinary general shareholders' meeting upon proper notice at any time during the year. If the Board of Directors fails to convene a shareholders' meeting, our independent auditors may call the meeting. In case of bankruptcy, the liquidator or court-appointed agent may also call a shareholders' meeting in some instances. In addition, any of the following may request the court to appoint an agent for the purpose of calling a shareholders' meeting:

one or several shareholders holding at least 5% of our share capital;

duly qualified associations of shareholders who have held their shares in registered form for at least two years and who together hold at least 1% of our voting rights;

the works council in cases of urgency; or

any interested party in cases of urgency.

Notice of Shareholders' Meetings

All prior notice periods provided for below are minimum periods required by French law and cannot be shortened, except in case of a public 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.

Edgar Filing: Sanofi - Form 20-F

At least fifteen days prior to the date set for a first convening, and at least ten days prior to any second convening, we must send a final notice (*avis de convocation*) containing the final agenda, the date, time and place of the meeting and other information related to the meeting. Such final notice must be sent by mail to all registered shareholders who have held shares in registered form for more than one month prior to the date of the final notice and by registered mail, if shareholders have asked for it and paid the corresponding charges. The final notice must also be published in a newspaper authorized to publish legal announcements in the local administrative department (*département*) in which our Company is registered as well as in the *BALO*, with prior notice having been given to the AMF for informational purposes. Even if there are no proposals for new resolutions or items to be submitted to the shareholders at the meeting, we must publish a final notice in a newspaper authorized to publish legal announcements in the local administrative department (*département*) in with our Company is registered as well as in the *BALO*.

Table of Contents

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 Q&A section located on our website in which the question submitted by a shareholder has already been answered.

Attendance at Shareholders' Meetings; Proxies and Votes by Mail

In general, all shareholders may participate in general meetings either in person or by proxy. Shareholders may vote in person, by proxy or by mail.

The right of shareholders to participate in general meetings is subject to the recording (*enregistrement comptable*) of their shares on the third 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

Edgar Filing: Sanofi - Form 20-F

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,

Table of Contents

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 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.

For a special meeting of holders of a certain category of shares, the quorum requirement is one third of the shares entitled to vote in that category, held by shareholders present in person, voting by mail or by proxy.

If a quorum is not present at a meeting, the meeting is adjourned. However, only questions that were on the agenda of the adjourned meeting may be discussed and voted upon once the meeting resumes.

When an adjourned meeting is resumed, there is no quorum requirement for meetings cited in the first paragraph of this "*Quorum*" section. In the case of any other reconvened extraordinary general meeting or special meeting, the quorum requirement is 20% of the shares entitled to vote (or voting shares belonging to the relevant category for special meetings of holders of shares of such specific category), held by shareholders present in person or voting by mail or by proxy. If a quorum is not met, the reconvened meeting may be adjourned for a maximum of two months with the same quorum requirement. No deliberation or action by the shareholders may take place without a quorum.

Votes Required for Shareholder Action

The affirmative vote of a simple majority of the votes cast may pass a resolution at either an ordinary general meeting or an extraordinary general meeting where the only resolution(s) pertain to either (a) a proposed increase in our share capital through incorporation of reserves, profits or share premium, or (b) the potential issuance of free share warrants in the event of a public 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 offer for our shares (article L. 233-32 of the French Commercial Code).

Edgar Filing: Sanofi - Form 20-F

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

Table of Contents

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 including our annual report and a summary of the financial results of the five previous fiscal years to any shareholder who so requests.

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, 2013, our legal reserve amounted to €282,280,863, representing 10.66% of the aggregate par value of our issued and outstanding share capital as of that date. The legal reserve of any company subject to this requirement may serve to allocate losses that may not be allocated to other reserves, or may be distributed to shareholders upon liquidation of the company.

Approval of Dividends

According to the French Commercial Code, our Board of Directors may propose a dividend for approval by shareholders at the annual general shareholders' meeting. If we have earned distributable profits since the end of the preceding fiscal year, as reflected in an interim income statement certified by our independent auditors, our Board of Directors may distribute interim dividends to the extent of the 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.

Table of Contents

Timing of Payment

According to the French Commercial Code, we must pay any existing dividends within nine months of the end of our fiscal year, unless otherwise authorized by court order. Dividends on shares that are not claimed within five years of the date of declared payment revert to the French State.

Changes in Share Capital

Increases in Share Capital

As provided for by the French Commercial Code, our share capital may be increased only with shareholders' approval at an extraordinary general shareholders' meeting following the recommendation of our Board of Directors. The shareholders may delegate to our Board of Directors either the authority (*délégation de compétence*) or the power (*délégation de pouvoir*) to carry out any increase in share capital. Our Board of Directors may further delegate this power to our Chief Executive Officer or, subject to our Chief Executive Officer's approval, to his delegates (*directeurs généraux délégués*).

Increases in our share capital may be effected by:

issuing additional shares;

increasing the par value of existing shares;

creating a new class of equity securities; or

exercising the rights attached to securities giving access to the share capital.

Increases in share capital by issuing additional securities may be effected through one or a combination of the following:

in consideration for cash;

in consideration for assets contributed in kind;

through an exchange offer;

by conversion of previously issued debt instruments;

by capitalization of profits, reserves or share premium; or

subject to various conditions, in satisfaction of debt incurred by our Company.

Decisions to increase the share capital through the capitalization of reserves, profits and/or share premium or through the issuance of free share warrants in the event of a public 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,

Table of Contents

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 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.

Edgar Filing: Sanofi - Form 20-F

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.

Table of Contents

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 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.

Table of Contents

Sinking Fund Provisions

Our Articles of Association do not provide for any sinking fund provisions.

Liability to Further Capital Calls

Shareholders are liable for corporate liabilities only up to the par value of the shares they hold; they are not liable to further capital calls.

Liquidation Rights

If we are liquidated, any assets remaining after payment of our debts, liquidation expenses and all of our remaining obligations will first be distributed to repay in full the par value of our shares. Any surplus will be distributed *pro rata* among shareholders in proportion to the par value of their shareholdings.

Requirements for Holdings Exceeding Certain Percentages

The French Commercial Code provides that any individual or entity, acting alone or in concert with others, that becomes the owner, directly or indirectly, of more than 5%, 10%, 15%, 20%, 25%, 30%, 33 $\frac{1}{3}$ %, 50%, 66 $\frac{2}{3}$ %, 90% or 95% of the outstanding shares or voting rights of a listed company in France, such as our Company, or that increases or decreases its shareholding or voting rights above or below any of those percentages, must notify the company, before the end of the fourth trading day following the date it crosses the threshold, of the number of shares it holds and their voting rights. The individual or entity must also notify the AMF before the end of the fourth trading day following the date it crosses any such threshold. The AMF makes the notice public.

Pursuant to the French Commercial Code and the AMF General Regulation, the participation thresholds shall be calculated on the basis of the shares and voting rights owned, and shall take into account the shares and voting rights which are deemed to be shares and voting rights owned, even if the individual or entity does not itself hold shares or voting rights. In accordance with this deemed ownership principle, the individual or entity must take into account specific situations where shares and voting rights are deemed to be shares and voting rights owned when calculating the number of shares owned to be disclosed in the notifications to the Company and to the AMF. It includes among others situations where an individual or entity is entitled to acquire issued shares at its own initiative, immediately or at the end of a maturity period, under an agreement or a financial instrument, without set-off against the number of shares that this individual or entity is entitled to sell under another agreement or financial instrument. The individual or entity required to make such notification shall also take into account issued shares covered by an agreement or cash-settled financial instrument and having 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);

Table of Contents

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 the memorandum and articles of association of the issuer, (iv) any plans to delist a category of the issuer's financial instruments, and (v) any plans to issue the issuer's financial instruments;

any agreement for the temporary transfer of shares or voting rights of the issuer;

the way it intends to settle its agreements or instruments on the shares or voting rights of the issuer mentioned in Article L. 233-9, 4° and 4° bis of the French Commercial Code; and

whether it seeks representation on the Board of Directors.

The AMF makes the report public. Upon any change of intention within the six-month period following the filing of the report, it will have to file a new report for the following six-month period.

In order to enable shareholders to give the required notice, we must each month publish on our website and send the AMF a written notice setting forth the total number of our shares and voting rights (including treasury shares) whenever they vary from the figures previously published.

If any shareholder fails to comply with an applicable legal notification requirement, the shares in excess of the relevant threshold will be deprived of voting rights for all shareholders' meetings until the end of a two-year period following the date on which the owner complies with the notification requirements. In addition, any shareholder who fails to comply with these requirements may have all or part of its voting rights suspended for up to five years by the Commercial Court at the request of our Chairman, any shareholder or the AMF, and may be subject to criminal fines.

Under AMF regulations, and subject to limited exemptions granted by the AMF, any person or entity, acting alone or in concert, that crosses the threshold of 30% of the share capital or voting rights of a French listed company must initiate a public tender offer for the balance of the shares and securities giving access to the share capital or voting rights of such company. Cash-settled derivative instruments or agreements mentioned in Article L. 233-9, 4° bis of the French Commercial Code are not included in the calculation of the number of shares related to the mandatory public tender offer.

In addition, our Articles of Association provide that any person or entity, acting alone or in concert with others, who becomes the owner of 1%, or any multiple of 1% of our share capital or our voting rights, even beyond the minimum declaration limits permitted by the legal and regulatory provisions, must notify us by certified mail, return receipt requested, within five trading days, of the total number of shares and securities giving access to our share capital and voting rights that such person then owns. The same provisions of our Articles of Association apply whenever such owner increases or decreases its ownership of our share capital or our voting rights to such extent that it goes above or below one of the thresholds described in the preceding sentence. Any person or entity that fails to comply with such notification requirement will, upon the request of one or more shareholders holding at least 5% of our share capital or of our voting rights made at the general 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

Edgar Filing: Sanofi - Form 20-F

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.

Table of Contents

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 3, 2013, 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 €12,948,400,800. This authorization was granted for a period of 18 months from May 3, 2013 and cancelled and replaced the authorization granted to the Board of Directors by the general meeting held on May 4, 2012. A description of this share repurchase program as adopted by the Board of Directors on May 3, 2013, (*descriptif du programme de rachat d'actions*) was published on March 7, 2013.

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:

Edgar Filing: Sanofi - Form 20-F

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;

Table of Contents

subject to certain exceptions for illiquid securities, the issuer must not purchase more than 25% of the average daily volume of the shares in any one day on the regulated market on which the purchase is carried out. The average daily volume figure must be based on the average daily volume traded in the month preceding the month of public disclosure of the share repurchase program and fixed on that basis for the authorized period of that program. If the program does not make reference to this volume, the average daily volume figure must be based on the average daily volume traded in the 20 trading days preceding the date of purchase.

In addition, an issuer must not:

sell treasury shares during the period of the repurchase program (without prejudice to the right of the issuer to meet its obligations under employee share option programs or other employee share allocation plans or to use shares as acquisition currency as mentioned above); it being further specified that such prohibition is not applicable in the event of off-market block trades or if the share repurchase program is implemented by a financial services intermediary pursuant to a liquidity agreement as mentioned above; and

effect any transaction during a "blackout period" imposed by the applicable law of the Member State in which the transaction occurs (*i.e.*, under French law, during the period between the date on which the company has knowledge of insider information and the date on which such information is made public and during the 30-day period preceding the date of publication of annual and half-year financial statements and the 15-day period preceding the date of publication of quarterly financial information), without prejudice to transactions carried out pursuant to a liquidity agreement as mentioned above; or

effect any transaction in securities with respect to which the issuer has decided to defer disclosure of any material, non-public information.

Use of Share Repurchase Programs

Pursuant to the AMF rules, issuers must immediately allocate the repurchased shares to one of the purposes provided for in the Regulation and must not subsequently use the shares for a different purpose. As an exception to the foregoing, shares repurchased with a view to covering stock option plans may, if no longer needed for this purpose, be re-allocated for cancellation or sold in compliance with AMF requirements relating in particular to blackout periods. Shares repurchased in connection with one of the market practices authorized by the AMF (see above) may also be re-allocated to one of the purposes contemplated by the Regulation or sold in compliance with AMF requirements. Shares repurchased with a view to their cancellation must be cancelled within 24 months following their acquisition.

During the year ended December 31, 2013, 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 4, 2012 and on May 3, 2013, we repurchased 21,335,144 of our shares for a weighted average price of €77.46, *i.e.* a total cost of €1,653 million, €2,885,000 of which were incurred on brokerage fees and financial transaction taxes (net of income taxes).

On April, 30, 2013, the Board of Directors cancelled 8,387,236 treasury shares, as follows:

5,528,486 shares repurchased between October 1, 2012 and March 31, 2013 pursuant to the share repurchase program of the Company;

2,858,750 shares previously allocated to expired stock option programs, which had been reallocated to the purpose of cancellation.

On July 31, 2013, the Board of Directors cancelled 5,885,439 treasury shares repurchased between May 3, and June 30, 2013 pursuant to the share repurchase program of the Company.

Edgar Filing: Sanofi - Form 20-F

On December 19, 2013, the Board of Directors cancelled 6,543,301 treasury shares repurchased in August 2013 pursuant to the share repurchase program of the Company.

During 2013, pursuant to the liquidity contract, Exane BNP Paribas purchased 4,014,180 of our shares at an average weighted price of €76,56 for a total amount of €307,316,200 and sold 4,014,180 of our shares at an average weighted price of €76,63 for a total amount of €307,613,217.

In 2013, also pursuant to our repurchase program two call options were purchased and exercised in February and in May and concerned respectively 2.5 and 4 million shares. There are no outstanding options.

Table of Contents

In 2013, of the 3,150,287 shares allocated to stock purchase option plans outstanding at December 31, 2012, 68,356 shares were transferred to grantees of options.

As a result, as of December 31, 2013, out of the 3,601,099 treasury shares, representing 0.27% of our share capital, 223,181 were allocated to outstanding stock purchase option plans and 3,377,918 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, 2013, we directly owned 3,601,099 Sanofi shares with a par value of €2 representing around 0.27% of our share capital and with an estimated value of €258,379,477, 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 the acquisition of a controlling interest in our Company. Under existing administrative rulings, ownership of 33 $\frac{1}{3}$ % or more of our share capital or voting rights is regarded as a controlling interest, but a lower percentage might be held to be a controlling interest in certain circumstances depending upon factors such as:

the acquiring party's intentions;

the acquiring party's ability to elect directors; or

financial reliance by the company on the acquiring party.

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, it may be difficult for investors 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. Actions for enforcement of foreign judgments against such persons would require such persons who are of French nationality to waive their right under Article 15 of the French Civil Code to be sued only in France. We believe that no such French persons have waived such right with respect to actions predicated solely upon 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.

Table of Contents

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 first milestone (related to manufacturing of Cerezyme® and Fabrazyme®) had to be met by December 31, 2011 in order for the payment to be triggered. This milestone was not met and therefore lapsed.

Further to the Complete Response Letter received from the FDA in December 2013, Sanofi announced that the second milestone, triggered by U.S. regulatory approval of Lemtrada for treatment of MS on or before March 31, 2014 ("Approval Milestone") would not be met and therefore no payment would be made. 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 exceeds 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. If Product Sales Milestone #2 is achieved but the Approval Milestone was not achieved prior to March 31, 2014, the milestone payment amount will be \$4 per CVR (however, in such event the Approval Milestone shall not also be payable).

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 (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 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 (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).

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 the third anniversary of the launch of Lemtrada, 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

Edgar Filing: Sanofi - Form 20-F

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 one billion U.S. dollars 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

Table of Contents

such exhibit for a more complete description of the terms and conditions of the CVR Agreement, and the foregoing summary of such terms and conditions is qualified in its entirety by such exhibit.

D. Exchange Controls

French exchange control regulations currently do not limit the amount of payments that we may remit to non-residents of France. Laws and regulations concerning foreign exchange controls do require, however, that all payments or transfers of funds made by a French resident to a non-resident be handled by an accredited intermediary.

E. Taxation

General

The following generally summarizes the material French and U.S. federal income tax consequences to U.S. holders (as defined below) of purchasing, owning and disposing of our ADSs and ordinary shares (collectively the "Securities"). This discussion is intended only as a descriptive summary and does not purport to be a complete analysis or listing of all potential tax effects of the purchase, ownership or disposition of our Securities. All of the following is subject to change. Such changes could apply retroactively and could affect the consequences described below.

This summary does not constitute a legal opinion or tax advice. Holders are urged to consult their own tax advisers regarding the tax consequences of the purchase, ownership and disposition of Securities in light of their particular circumstances, including the effect of any U.S. federal, state, local or other national tax laws.

A set of tax rules is applicable to French assets that are held by or in foreign trusts. These rules provide *inter alia* for the inclusion of trust assets in the settlor's net assets for purpose of applying the French wealth tax, for the application of French gift and death duties to French assets held in trust, for a specific tax on capital on the French assets of foreign trusts not already subject to the French wealth tax and for a number of French tax reporting and disclosure obligations. The following discussion does not address the French tax consequences applicable to Securities held in trusts. *If Securities are held in trust, the grantor, trustee and beneficiary are urged to consult their own tax adviser regarding the specific tax consequences of acquiring, owning and disposing of Securities.*

The description of the French and U.S. federal income tax consequences set forth below is based on the laws (including, for U.S. federal income tax purposes, the Internal Revenue Code of 1986, as amended (the "Code"), final, temporary and proposed U.S. Treasury Regulations promulgated thereunder and administrative and judicial interpretations thereof) in force as of the date of this annual report, the Convention Between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income and Capital of August 31, 1994 (the "Treaty"), which entered into force on December 30, 1995 (as amended by any subsequent protocols, including the protocol of January 13, 2009), and the tax regulations issued by the French tax authorities (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

Table of Contents

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. *Holder 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 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 is published annually by the French state. Pursuant to a ministerial regulation (*arrêté*) dated January 11, 2013, Sanofi is included in such list as a company whose market capitalization exceeds 1 billion euros as of December 1, 2012 and therefore, purchases of Sanofi's Securities are subject to such tax.

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

Table of Contents

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, 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.

Table of Contents

Form 5000 and Form 5001, together with instructions, will be provided by the depositary to all U.S. holders registered with the depositary and are also available from the U.S. Internal Revenue Service. The depositary will arrange for the filing with the French Tax authorities of all such forms properly completed and executed by U.S. holders of ordinary shares or ADSs and returned to the depositary in sufficient time that they may be filed with the French tax authorities before the distribution so as to obtain immediately a reduced withholding tax rate.

The withholding tax refund, if any, ordinarily is paid within 12 months of filing the applicable French Treasury Form, but not before January 15 of the year following the calendar year in which the related dividend is paid.

Tax on Sale or Other Disposition

In general, under the Treaty, a U.S. holder who is a U.S. resident for purposes of the Treaty will not be subject to French tax on any capital gain from the redemption (other than redemption proceeds characterized as dividends under French domestic law), sale or exchange of ordinary shares or ADSs unless the ordinary shares or the ADSs form part of the business property of a permanent establishment or fixed base that the U.S. holder has in France. Special rules apply to holders who are residents of more than one country.

U.S. Taxes

Taxation of Dividends

For U.S. federal income tax purposes, the gross amount of any distribution paid to U.S. holders (that is, the net distribution received plus any tax withheld therefrom) will be treated as ordinary dividend income to the extent paid or deemed paid out of the current or accumulated earnings and profits of Sanofi (as determined under U.S. federal income tax principles). Dividends paid by Sanofi will not be eligible for the dividends-received deduction generally allowed to corporate U.S. holders.

Subject to certain exceptions for short-term and hedged positions, the U.S. dollar amount of dividends received by an individual U.S. holder with respect to the ADSs or our ordinary shares is currently subject to taxation at a maximum rate of 20% if the dividends are "qualified dividends". Dividends paid on the ordinary shares or ADSs will be treated as qualified dividends if (i) the issuer is eligible for the benefits of a comprehensive income tax treaty with the United States that the Internal Revenue Service has approved for the purposes of the qualified dividend rules and (ii) the issuer was not, in the year prior to the year in which the dividend was paid, and is not, in the year in which the dividend is paid, a passive foreign investment company ("PFIC"). The Treaty has been approved for the purposes of the qualified dividend rules. Based on our audited financial statements and relevant market and shareholder data, we believe Sanofi was not a PFIC for U.S. federal income tax purposes with respect to its 2013 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 2014 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).

Table of Contents

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.

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

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 these 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.

(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

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, 2013, cash and cash equivalents amounted to €8,257 million, and 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*, and in 'money market' U.S. dollar-denominated funds subject to U.S. Securities and Exchange Commission regulation 2a-7. 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 deposits 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, 2013, the Group had €10 billion of undrawn general corporate purpose confirmed credit facilities, of which €3 billion expire in December 2014 and €7 billion in December 2018. These 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 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 4.1 years as of December 31, 2013, compared with 3.2 years as of December 31, 2012. In 2013, the French commercial paper program was not drawn down. Average drawdowns under the U.S. commercial paper program were €2.2 billion (maximum €3.1 billion); the average maturity of these drawdowns was two months. As of December 31, 2013, these programs were not 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. These derivative instruments are predominantly denominated in euros, and in U.S. dollars.

The projected full-year sensitivity to interest rate fluctuations of our debt, net of cash and cash equivalents for 2014 is as follows:

Change in EUR and USD short-term interest rates	Impact on pre-tax net income (€ million)	Impact on pre-tax income/(expense) recognized directly in equity (€ million)
--	---	---

Edgar Filing: Sanofi - Form 20-F

+100 bp	23	13
+25 bp	6	3
-25 bp	(6)	(3)
-100 bp	(23)	(12)

215

Table of Contents**Foreign Exchange Risk****a. Operational 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 2013, for example, 32% of our consolidated net sales were generated in the United States, 33% in emerging countries and 8% in Japan. Although we also incur expenses in those countries, the impact of such expenses is not enough wholly to offset the impact of exchange rates on 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. These transactions mainly comprise sales, purchases, research costs, co-marketing and co-promotion expenses, and royalties. To reduce the exposure of these 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 operational currency hedging instruments in place as of December 31, 2013, 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, 2013.

Operational foreign exchange derivatives as of December 31, 2013⁽¹⁾:

<i>(€ million)</i>		Notional amount	Fair value
Forward currency sales		2,943	32
Of which	U.S. dollar	1,379	14
	Singapore dollar	345	1
	Russian rouble	184	1
	Japanese yen	118	9
	Chinese yuan renminbi	118	
Forward currency purchases		537	(1)
Of which	Hungarian forint	119	1
	Russian rouble	64	(1)
	Japanese yen	54	(1)
	U.S. dollar	51	
	Mexican peso	32	
Total		3,480	31

(1)

As of December 31, 2012, the notional amount of forward currency sales was €2,972 million with a fair value of €21 million (including forward sales of U.S. dollars of a notional amount of €972 million with a fair value of €6 million). As of December 31, 2012, the notional amount of forward currency purchases was €944 million with a fair value of -€4 million (including forward purchases of U.S. dollars of a notional amount of €69 million with an immaterial fair value).

These 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, 2013 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 foreign exchange profit and loss on these items (hedging instruments and hedged transactions as of December 31, 2013) will be immaterial in 2014.

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). This foreign exchange exposure is hedged by the Sanofi holding company using firm financial instruments (usually currency swaps and forward contracts) contracted with banking counterparties.

Table of Contents

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, 2013, 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, 2013.

Financial foreign exchange derivatives as of December 31, 2013⁽¹⁾:

<i>(€ million)</i>		Notional amount	Fair value	Expiry
Forward currency sales		1,860	63	
Of which	U.S. dollar	833	8	2014
	Japanese yen	698	50	2014
	Australian dollar	123	4	2014
Forward currency purchases		2,197	(9)	
Of which	Pound sterling	525	2	2014
	Singapore dollar	485	(6)	2014
	U.S. dollar	389	(1)	2014
Total		4,057	54	

(1)

As of December 31, 2012, the notional amount of forward currency sales was €3,970 million with a fair value of €38 million (including forward sales of U.S. dollars of a notional amount of €1,897 million with a fair value of €1 million). As of December 31, 2012, the notional amount of forward currency purchases was €2,638 million with a fair value of -€12 million (including forward purchases of U.S. dollars of a notional amount of €521 million with a fair value of €1 million).

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, 2013, we had no derivative instruments in place to limit the effect of such fluctuations.

Counterparty Risk

Edgar Filing: Sanofi - Form 20-F

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.

Table of Contents

The table below shows our total exposure as of December 31, 2013 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+	200			
AA-	727	1,226	1,025	660
A+	965	1,652	1,168	1,980
A	2,017	2,843	2,001	5,700
A-	723	1,663	467	1,000
BBB+	150			
BBB	405	129	600	660
Not split	141			
Total	5,328	7,513	5,261	10,000
% / rating of dominant counterparty	14% / AA-	17% / A-	19% / AA-	7% / BBB

(1) *Cash equivalents include mutual fund investments of €2,929 million.*

(2) *Notional amounts are computed on the basis of the forward rates negotiated at the inception date of the derivative instruments.*

As of December 31, 2013, 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*, and in 'money market' U.S. dollar-denominated funds subject to U.S. Securities and Exchange Commission regulation 2a-7. These instruments have low volatility, low sensitivity to interest rate risk, and a very low probability of loss of principal. The depository 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.

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.

Table of Contents

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 1 Chase Manhattan Plaza, Floor 58, New York, New York 10005-1401.

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. The form of our deposit agreement has been filed as an exhibit to our Form F-6 filed on August 7, 2007, and the amendment to our deposit agreement has been filed as an exhibit to Post-Effective Amendment No. 1 to our Form F-6 filed on April 30, 2011. For more complete information, holders should read the entire deposit agreement (including the amendment) and the ADR itself. Holders may also inspect a copy of the deposit agreement at the depositary's office.

Share Dividends and Other Distributions

Receipt of dividends and other distributions

The depositary has agreed to pay to holders of Sanofi ADSs the cash dividends or other distributions that it or the custodian receives on the deposited Sanofi ordinary shares and other deposited securities after deducting its fees and expenses. Holders of Sanofi ADSs will receive these distributions in proportion to the number of Sanofi ADSs that they hold.

Cash. The depositary will convert any cash dividend or other cash distribution paid on the shares into U.S. dollars if, in its judgment, it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If the depositary determines that such a conversion and transfer is not possible, or if any approval from the French government is needed and cannot be obtained within a reasonable period, then the depositary may (1) distribute the foreign currency received by it to the holders of Sanofi ADSs or (2) hold the foreign currency distribution (uninvested and without liability for any interest) for the account of holders of Sanofi ADSs.

In addition, if any conversion of foreign currency, in whole or in part, cannot be effected to some holders of Sanofi ADSs, the deposit agreement allows the depositary to distribute the dividends only to those ADR holders to whom it is possible to do so. It will hold the foreign currency it cannot convert into U.S. dollars for the account of the ADR holders who have not been paid. It will not invest the funds it holds and it will not be liable for any interest.

Before making a distribution, any withholding taxes that must be paid under French law will be deducted. The depositary will distribute only whole U.S. dollars and cents and will round fractional cents down to the nearest whole cent. ***Exchange rate fluctuations during a period when the depositary cannot convert euros into U.S. dollars may result in holders losing some or all of the value of a distribution.***

Shares. The depositary may, and at our request will, distribute new ADRs representing any shares we distribute as a dividend or free distribution, if we furnish it promptly with satisfactory evidence that it is legal to do so. At its option, the depositary may distribute fractional Sanofi ADSs. If the depositary does not distribute additional Sanofi ADSs, the outstanding ADRs will also represent the new shares. The depositary may withhold any tax or other governmental charges, or require the payment of any required fees and expenses, prior to making any distribution of additional Sanofi ADSs.

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

Table of Contents

these rights available to holders or (2) dispose of such rights on behalf of holders and make the net proceeds available to holders. The depositary may make rights available to certain holders but not others if it determines it is lawful and feasible to do so. However, if, under the terms of the offering or for any other reason, the depositary may not make such rights available or dispose of such rights and make the net proceeds available, it will allow the rights to lapse. In that case, holders of Sanofi ADSs will receive no value for them.

In circumstances where rights would not otherwise be distributed by the depositary to holders of Sanofi ADSs, a holder of Sanofi ADSs may nonetheless request, and will receive from the depositary, any instruments or other documents necessary to exercise the rights allocable to that holder if the depositary first receives written notice from Sanofi that (1) Sanofi has elected, in its sole discretion, to permit the rights to be exercised and (2) such holder has executed the documents Sanofi has determined, in its sole discretion, are reasonably required under applicable law.

If the depositary makes rights available to holders of Sanofi ADSs, upon instruction from such holders, it will exercise the rights and purchase the shares on such holder's behalf. The depositary will then deposit the shares and deliver ADRs to such holders. It will only exercise rights if holders of Sanofi ADSs pay it the exercise price and any other charges the rights require such holders to pay.

U.S. securities laws may restrict the sale, deposit, cancellation or transfer of ADRs issued upon exercise of rights. For example, holders of Sanofi ADSs may not be able to trade Sanofi ADSs freely in the United States. In this case, the depositary may deliver Sanofi ADSs under a separate restricted deposit agreement that will contain the same provisions as the deposit agreement, except for changes needed to implement the required restrictions.

Other Distributions. The depositary will distribute to holders of Sanofi ADSs anything else we may distribute on deposited securities (after deduction or upon payment of fees and expenses or any taxes or other governmental charges) by any means it thinks is legal, equitable and practical. If, for any reason, it cannot make the distribution in that way, the depositary may sell what we distributed and distribute the net proceeds of the sale in the same way it distributes cash dividends, or it may choose any other method to distribute the property it deems equitable and practicable.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of Sanofi ADSs. We have no obligation to register Sanofi ADSs, shares, rights or other securities under the U.S. Securities Act of 1933, as amended. We also have no obligation to take any other action to permit the distribution of ADRs, shares, rights or anything else to holders of Sanofi ADSs. This means that holders may not receive the distribution we make on our shares or any value for them if it is illegal or impractical for the depositary to make them available to such holders.

Elective Distributions. Whenever we intend to distribute a dividend payable at the election of shareholders either in cash or in additional shares, we will give prior notice thereof to the depositary and will indicate whether we wish the elective distribution to be made available to holders of Sanofi ADSs. In that case, we will assist the depositary in determining whether that distribution is lawful and reasonably practicable. The depositary will make the election available to holders of Sanofi ADSs only if it is reasonably practicable and if we have provided all the documentation contemplated in the deposit agreement. In that case, the depositary will establish procedures to enable holders of Sanofi ADSs to elect to receive either cash or additional ADSs, in each case as described in the deposit agreement. If the election is not made available to holders of Sanofi ADSs, such holders will receive either cash or additional Sanofi ADSs, depending on what a shareholder in France would receive for failing to make an election, as more fully described in the deposit agreement.

Deposit, Withdrawal and Cancellation

Delivery of ADRs

The depositary will deliver ADRs if the holder or his or her broker deposit shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of Sanofi ADSs in the names the holder requests and will deliver the ADRs to the persons the holder requests at its office.

Obtaining Sanofi ordinary shares

A holder may turn in his or her ADRs at the depositary's office. Upon payment of its fees and expenses and any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver (1) the underlying shares to an account designated by the holder and (2) any other deposited securities underlying the ADR at the office

Table of Contents

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 mail 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 assure holders that they will receive the voting materials in time to ensure that holders can instruct the depositary 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 to comply with French or United States law or our *statuts*. ***For example, holders might be required to arrange to have their Sanofi ADSs deposited in a blocked account for a specified period of time prior to a shareholders' meeting in order to be allowed to give voting instructions.***

Notices and Reports; Rights of Holders to Inspect Books

On or before the first date on which we give notice, by publication or otherwise, of any meeting of holders of shares or other deposited securities, or of any adjourned meeting of such holders, or of the taking of any action in respect of any cash or other distributions or the offering of any rights, we will transmit to the depositary a copy of the notice.

Upon notice of any meeting of holders of shares or other deposited securities, if requested in writing by Sanofi, the depositary will, as soon as practicable, mail to the holders of Sanofi ADSs a notice, the form of which is in the discretion of the depositary, containing (1) a summary in English of the information contained in the notice of meeting provided by Sanofi to the depositary, (2) a statement that the holders as of the close of business on a specified record date will be entitled, subject to any applicable provision of French law and of our *statuts*, to instruct the depositary as to the exercise of the voting rights, if any, pertaining to the amount of shares or other deposited securities represented by their respective ADSs and (3) a statement as to the manner in which such instructions may be given.

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

Table of Contents

holders in the interest of a business or object other than our business or a matter related to the deposit agreement or the ADRs.

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)

\$0.02 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
 Any other charges payable 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

Servicing of shares or other deposited securities

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

Table of Contents

additional amounts to us based on certain performance indicators relating to the ADR facility and fees collected by it. From January 1, 2013 to December 31, 2013, we received from JPMorgan reimbursements of \$5,000,000 for expenses and no additional amounts were paid. In addition 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.

Edgar Filing: Sanofi - Form 20-F

After termination, the depositary and its agents will be required to do only the following under the deposit agreement: (1) collect distributions on the deposited securities, (2) sell rights and other property as provided in the deposit agreement and (3) deliver shares and other deposited securities upon cancellation of ADRs. Six months or more after termination, the depositary may sell any remaining deposited securities by public or private sale. After that, the depositary will hold the money it receives on the sale, as well as any other cash it is holding under the deposit agreement, for the pro rata benefit of the holders of Sanofi ADSs that have not surrendered their Sanofi ADSs. It will have no liability for interest. Upon termination of the deposit agreement, the depositary's only obligations will be to account for the proceeds of the sale and other cash and with respect to indemnification. After termination, our only obligation will be with respect to indemnification and to pay certain amounts to the depositary.

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. We and the depository:

are obligated only to take the actions specifically set forth in the deposit agreement without gross negligence or bad faith;

are not liable if either is prevented or delayed by law or circumstances beyond its control from performing its obligations under the deposit agreement;

are not liable if either exercises, or fails to exercise, any discretion permitted under the deposit agreement;

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;

are not liable for the acts or omissions made by any securities depository, clearing agency or settlement system or the insolvency of the custodian to the extent the custodian is not a branch or affiliate of JPMorgan;

may rely without any liability upon any written notice, request or other document believed by either of us to be genuine and to have been signed or presented by the proper parties; and

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;

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.

Edgar Filing: Sanofi - Form 20-F

The depositary may refuse to deliver Sanofi ADSs, register transfers of Sanofi ADSs or permit withdrawals of shares when the transfer books of the depositary or our transfer books are closed, or at any time if the depositary or we think it advisable to do so.

Right to Receive the Shares Underlying the Sanofi ADSs

Holders have the right to cancel their Sanofi ADSs and withdraw the underlying Sanofi ordinary shares at any time except:

when temporary delays arise when we or the depositary have closed our transfer books or the deposit of shares in connection with voting at a shareholders' meeting, or the payment of dividends;

when the holder or other holders of Sanofi ADSs seeking to withdraw shares owe money to pay fees, taxes and similar charges; or

when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to Sanofi ADSs or to the withdrawal of shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Table of Contents

Pre-Release of Sanofi ADSs

Unless we instruct the depositary not to, the deposit agreement permits the depositary to deliver Sanofi ADSs before deposit of the underlying shares. This is called a pre-release of the Sanofi ADSs. The depositary may also deliver shares upon cancellation of pre-released Sanofi ADSs (even if the Sanofi ADSs are cancelled before the pre-release transaction has been closed out). A pre-release is closed out as soon as the underlying shares are delivered to the depositary. The depositary may receive Sanofi ADSs instead of shares to close out a pre-release. Unless otherwise agreed in writing, the depositary may pre-release Sanofi ADSs only under the following conditions: (1) before or at the time of the pre-release, the person to whom the pre-release is being made must represent to the depositary in writing that it or its customer (i) owns the shares or Sanofi ADSs to be deposited, (ii) assigns all beneficial rights, title and interest in such shares or ADRs to the depositary in its capacity as depositary and (iii) will not take any action with respect to such shares or ADRs that is inconsistent with the transfer of beneficial ownership, other than in satisfaction of such pre-release; (2) the pre-release must be fully collateralized with cash, U.S. government securities or other collateral that the depositary considers appropriate; (3) the depositary must be able to close out the pre-release on not more than five business days' notice; and (4) the depositary may require such further indemnities and credit regulations as it deems appropriate. In addition, the depositary will limit the number of Sanofi ADSs that may be outstanding at any time as a result of pre-release, although the depositary may disregard the limit from time to time, if it thinks it is appropriate to do so. The depositary may retain for its own account any compensation received by it in connection with the foregoing. Any holder of pre-release ADRs should consult its tax and other advisors about the implications of pre-release for its particular situation.

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, 2013 based on the framework in "Internal Control – Integrated Framework" (1992 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, 2013 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, 2013, 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 Mrs. Piwnica, Mr. Castaigne, Mrs. Lecorvaisier, Mr. Pohle and Mr. 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 2013, 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
February 2013	4,190,881	€71.70	4,190,881	€12,647,902,992
March 2013	5,528,486	€72.36	5,528,486	€12,247,846,933
May 2013	4,283,000	€84.39	4,283,000	€11,886,390,736
June 2013	1,602,439	€79.31	1,602,439	€11,759,296,516
August 2013	6,543,301	€76.41	6,543,301	€11,259,296,540

Edgar Filing: Sanofi - Form 20-F

December 2013	3,377,918	€74.01	3,377,918	€11,009,296,572
---------------	-----------	--------	-----------	-----------------

(1)

The Company was authorized to repurchase up to €12,948,400,800 of shares for a period of eighteen months (i.e., through November 3, 2014) by the Annual Shareholders' Meeting held on May 3, 2013.

This schedule does not include purchases and sales conducted by Exane under a liquidity contract entered into in 2010 and that is still in effect. For more information see Item 10.B *Memorandum and Articles of Association Use of Share Repurchase Programs*.

Item 16F. Change in Registrant's Certifying Accountant

N/A

Item 16G. Corporate Governance

Sanofi is incorporated under the laws of France, with securities listed on regulated public markets in the United States (New York Stock Exchange) and France (Euronext Paris). Consequently, as described further in our

Table of Contents

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 at least half of the members of which 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 non-independent members, 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-122 incorporated herein by reference.

Item 19. Exhibits

1.1 Articles of association (