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)

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

OR

ý **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2013

OR

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

OR

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

Date of event requiring this shell company report. . . . . .

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

Sanofi
(Exact name of registrant as specified in its charter)

N/A
(Translation of registrant's name into English)

France
(Jurisdiction of incorporation or organization)

54, Rue La Boétie, 75008 Paris, France
(Address of principal executive offices)

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

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

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

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ý No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes o No o

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

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

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

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

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

Item 17 o Item 18 o

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

YES o NO ý.

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.

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

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,				
(€ million, except per share data)	**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 (€)[f]	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 Merial, 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 Merial and Intervet/Schering Plough are to be maintained as two separate businesses operating independently.

(c)

Based on the weighted average number of shares outstanding in each period used to compute basic earnings per share, equal to 1,323.1 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 Seprafilm® 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 retails 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 and 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 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

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(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

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.

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 depositary of cash dividends, if any. Moreover, these fluctuations may affect the U.S. dollar price of the ADSs on the New York Stock Exchange (NYSE), whether or not we pay dividends in addition to the amounts, if any, that a holder would receive upon our liquidation or upon the sale of assets, merger, tender offer or similar transactions denominated in euros or any foreign currency other than U.S. dollars.

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

Holders of ADSs may have more difficulty exercising their rights as a shareholder than if they directly held shares. For example, if we issue new shares and existing shareholders have the right to subscribe for a portion of them, the depositary is allowed, at its own discretion, to sell for their benefit that right to subscribe for new shares instead of making it available to them. Also, holders of ADSs must instruct the depositary how to vote their shares. Because of this extra procedural step involving the depositary, the process for exercising voting rights will take longer for holders of ADSs than for holders of shares. ADSs for which the depositary does not receive timely voting instructions will not be voted at any meeting.

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

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 maligancies; 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 Aprovel®/CoAprovel®, two hypertension treatments. Our renal business includes Renagel®/Renvela®, oral phosphate binders used in patients with chronic kidney disease (CKD) on dialysis to treat high

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.

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

(2) *"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.

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

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.

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 maligancies
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&zwsp;[(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®

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.

25

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

Myozyme® has been marketed since 2006 in the United States and the 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® (agalsidase beta) is an enzyme replacement therapy used to treat Fabry disease, an inherited, progressive and potentially life-threatening LSD. Fabry disease is estimated to 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 Mucopolysaccaridosis Type I (MPS I). MPS I occurs in approximately one in 100,000 newborns worldwide, but incidence and the prevalence of phenotypic groups varies from region to region.

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

c) Multiple Sclerosis (MS)

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 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 (PIGF), preventing the bound VEGF from binding to their native receptors. VEGF-A is one of the mediators contributing to angiogenesis. VEGF-B and PlGF, related growth factors in the VEGF family, may contribute to tumor angiogenesis as well.

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® / Clexane®

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® / Tefast® have been approved in our major markets.

In the United States, the Allegra® family moved to over-the-counter (OTC) use in adults and children two years of age and older in 2011. Allegra® was also launched on the OTC market in Japan in November 2012, though it also remains available on prescription (see " 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® (dronedarone) 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.

31

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 biphosphonate 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 Intellijet, 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 Rolaids® 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, Rolaids® 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.

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:

(€ million)	**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

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.

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.

37

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.

39

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.

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 JPII). 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

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

Two compounds, **SAR260301** (PI3Kβ 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.

Fresolumimab (GZ402669 Genzyme) TGF-ß 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

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-ß 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 *clostridium difficile*	
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 of2014. 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 I/II 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

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**
	(month/year)	**U.S.**	**E.U.**	**Japan**	
Lyxumia® (lixisenatide)[3][4] (AVE0010)	May 2008[5]	2020	2020	2020	Dossier approved in Europe in February 2013 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."

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 of 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. Pharmacogivilance system.

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

B.6.3.2 Biosimilars

Products can be referred to as "biologics" when they are derived from 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.

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.

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.

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.	**E.U.**	**Japan**
Compound: August 2014, protection extended to February 2015 by Pediatric Extension[(1)]	Compound: November 2014 in most of Western Europe extended until May 2015 by Pediatric Extensions	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.	**E.U.**	**Japan**
Compound: June 2018	Compound: September 2019 in most of the EU	Compound: May 2022
Later filed patent: ranging through January 2023	Later filed patent: March 2022	Later filed patent: July 2022
	Regulatory exclusivity: September 2014	Regulatory exclusivity: April 2017

Jevtana® (cabazitaxel)

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

Lovenox® (enoxaparin sodium)

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

Table of Contents

Plavix® (clopidogrel bisulfate)

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

Aprovel® (irbesartan)

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

Multaq® (dronedarone hydrochloride)

U.S.	**E.U.**	**Japan**
Compound: July 2016 with PTE Later filed patent: formulation (June 2018) Regulatory exclusivity: July 2014	Compound: expired Later filed patent: formulation June 2018 extended with SPC up to June 2023 in most of the countries Regulatory exclusivity: November 2019	Compound: expired

Stilnox® (zolpidem tartrate)

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

Depakine® (sodium valproate)

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

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

Allegra® (fexofenadine hydrochloride)

U.S.	**E.U.**	**Japan[(1)]**
Compound: expired Generics on the market Converted to Over-the-Counter	Compound: expired Generics on the market	Compound: expired Generics on the market Converted to over-the counter Later filed patents: coverage ranging through January 2016

(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)]

U.S.	**E.U.**	**Japan**
Compound: protection extended to June 2014 by Pediatric extension	Compound: expired	Compound: expired
Later filed patents: coverage ranging through June 2018	Later filed patents: coverage ranging through June 2018	

(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)

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

Insuman® (human insulin)

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

Fabrazyme® (agalsidase beta)

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

Cerezyme® (imiglucerase)

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

Lumizyme® / Myozyme® (alglucosidase alpha)

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

Renagel® (sevelamer hydrochloride)

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

Table of Contents

Renvela® (sevelamer carbonate)

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

Synvisc® (hyaline G-F 20)

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

Synvisc-One® (hyaline G-F 20)

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

Lyxumia® (lixisenatide)

U.S.	**E.U.**	**Japan**
Compound: July 2020	Compound: July 2020 SPC coverage to July 2025 in most of Western Europe Regulatory Exclusivity: February 2023	Compound: July 2020 PTE pending for compound patent and two device patents Regulatory Exclusivity: June 2021

Zaltrap® (aflibercept)

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

Aubagio® (teriflunomide)

U.S.	**E.U.**	**Japan**
Compound: October 2014 (May 2019 if PTE is granted) Regulatory Exclusivity: September 2017	Compound: expired	Compound: expired

Aldurazyme® (laronidase)

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

Table of Contents

Mozobil® (plerixafor)

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

Lemtrada (alemtuzumab)

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

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

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

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'Etoile 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 planed 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 Garessio in Italy; Ujpest in Hungary; Prague in the Czech Republic; and on a number of sites divested to third parties and covered by contractual environmental guarantees granted by Sanofi. Sanofi may also have potential liability for investigation and cleanup at several other sites.

Provisions have been established for the sites already identified and to cover contractual guarantees for environmental liabilities for sites that have been divested. For example, the Group is currently participating in an assessment process for natural resource damage liability (NRD) and in the allocation process for future remediation costs that are related to the past operations of a former Rhone-Poulenc site in Portland 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 CO_2 Emissions Credit Trading Scheme aimed at helping to reach the targets set by the Kyoto protocol.

Our recent efforts in terms of environmental protection have mainly targeted reductions in energy consumption, greenhouse gas emissions control, improvements in the performance of water treatment installations, reduction of volatile organic compound emissions, raw material savings and recycling, and reductions in waste materials or increases in the percentage being recycled. In 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 CO_2 emissions in 2020 vs. 2010 on a constant structure basis.

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

C. Organizational Structure

Significant subsidiaries

Sanofi is the holding company of a consolidated group 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

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.

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);

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

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

France: Toulouse (Frontline® and clostridial vaccines), 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

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. ("Merial"), 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 Rolaids® 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

rejection.

In March 2013, a bioproduction platform was launched to develop synergies between Pharmaceuticals, Sanofi Pasteur, Genzyme, Merial 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 540,000m^2. 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 (Massachussetts, 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 redefiined 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 Rolaids® 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.

(€ million) **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%

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.

Table of Contents

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

(€ million)	**Pharmaceuticals**	**Vaccines**	**Animal Health**	**Other**	**Total**
Net sales	**27,250**	**3,716**	**1,985**		**32,951**
Other revenues	295	30	30		355
Cost of sales	(8,517)	(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)].

(€ million)	**Pharmaceuticals**	**Vaccines**	**Animal Health**	**Other**	**Total**
Net sales	**28,871**	**3,897**	**2,179**		**34,947**
Other revenues	933	44	33		1,010
Cost of sales	(8,745)	(1,629)	(701)		(11,075)
Research and development expenses	(4,203)	(538)	(164)		(4,905)
Selling and general expenses	(7,650)	(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)].

(€ million)	**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:

(€ million)	**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.

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

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:

(€ million)		**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
	amortization of intangible assets	*939*	*1,159*	*1,178*
	impairment of intangible assets	*527*	*42*	*37*
	fair value remeasurement of contingent consideration liabilities	*(85)*	*2*	*34*
	expenses arising from the impact of acquisitions on inventories	*2*	*7*	*143*
	restructuring costs	*97*	*370*	*399*
	other gains and losses, and litigation			*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:

(€ million)	**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

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";

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.

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.

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 Cosmétologie 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 Rolaids® brand from the McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. Rolaids® 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, Merial announced the completion of its acquisition of the animal health division of the Indian company Dosch Pharmaceuticals Private Limited, which markets 86 animal health products and 50 specialities for ruminants, poultry and companion animals.

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

The principal acquisitions during 2012 are described below:

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

In March 2012, Merial completed the acquisition of Newport Laboratories, a privately held company based in Worthington, Minnesota (United States), which 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, Massachussets (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.

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) *(€ million)*	**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	

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:

(€ million)	**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:

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

Net Sales by Product Pharmaceuticals segment

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

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

- the positive performance of growth platforms (€1,684 million), mainly our Diabetes and Genzyme businesses;
- the negative effects of generic competition (mainly on sales of Eloxatin® and Lovenox® in the United States, and of Aprovel® and Plavix® in Western Europe), totaling €1,253 million of net sales lost; and
- other impacts (negative evolution of €501 million), including the negative impact of austerity measures in the European Union and temporary difficulties in distribution channels for our Generics business in Brazil.

Our flagship products (Lantus® and Apidra®, Cerezyme®, Myozyme®/Lumizyme®, Fabrazyme®, Aubagio® and Lemtrada , 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.

Table of Contents

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

(€ million) **Product**	**Indication**	**2013 Reported**	**2012 Reported**	**Change on a reported basis**	**Change at constant exchange rates**
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%

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).

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(1)

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

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:

(€ million) **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 Healh 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.

Table of Contents

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

(€ million) **Product**	**Western Europe (1)**	**Change at constant exchange rates**	**United States**	**Change at constant exchange rates**	**Emerging Markets (2)**	**Change at constant exchange rates**	**Rest of the world (3)**	**Change at constant exchange rates**
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%

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					