Sanofi
Form 20-F
March 07, 2013

Use these links to rapidly review the document

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, 2012

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, Senior 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, 2012 was:
Ordinary shares: 1,340,918,811

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 ý

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, 2012.

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.; BiTE® a trademark of Micromet 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); Dynamic Electrochemistry® a trademark of AgaMatrix Inc.; Fludara® and Leukine® trademarks of Alcafleu; Flutiform a trademark of Jagotec AG; Gardasil®, RotaTeq® and Zostavax® trademarks of Merck & Co.; Hyalgan® a trademark of Fidia Farmeceutici S.p.A, under license agreement in the United States; Mutagrip® a trademark of Institut Pasteur; Optinate® a trademark of Warner Chilcott on certain geographical areas and of Shionogi Pharma Inc. in the United States; 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 Acrel® a trademark of Warner Chilcott; Aspirine®, Cipro®, Advantage® and Advantix® trademarks of Bayer; 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; IC31® a trademark of Intercell AG; iPhone® and iPod Touch® trademarks of Apple Inc.; JAKAFI® a trademark of Incyte Corporation; JAKAVI® a trademark of Novartis; Lactacyd® a trademark of Omega Pharma NV in the EU; LentiVector®, Stargen and UshStat® trademarks of Oxford BioMedica; Libertas a trademark of International Contraceptive & SRH Marketing Limited in the EU; PetArmor® a trademark of Velcera, Inc.; Rebif® a trademark of Ares Trading SA; Rotarix® a trademark of GSK; Trajenta® a trademark of Boehringer Ingelheim; 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 2012, in constant euros (unless otherwise indicated).

Table of Contents

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

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

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

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

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

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

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

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

- projections of operating revenues, net income, business net income, earnings per share, business earnings per share, capital expenditures, cost savings, restructuring costs, positive or negative synergies, dividends, capital structure or other financial items or ratios;
- statements of our profit forecasts, trends, plans, objectives or goals, including those relating to products, clinical trials, regulatory approvals and competition; and
- statements about our future events and economic performance or that of France, the United States or any other countries in which we operate.

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

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

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

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

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

TABLE OF CONTENTS

Table of Contents

PART I

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, 2012, 2011 and 2010 are included in Item 18 of this annual report.

The consolidated financial statements of Sanofi for the years ended December 31, 2012, 2011 and 2010 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, 2012. 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, 2012.

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)	**2012**	**2011**	**2010**	**2009**	**2008**
IFRS Income statement data [a]					
Net sales	34,947	33,389	32,367	29,785	27,568
Gross profit	24,839	24,156	24,638	23,125	21,480
Operating income	6,337	5,731	6,535	6,435	4,394
Net income attributable to equity holders of Sanofi	4,967	5,693	5,467	5,265	3,851
Basic earnings per share (€)[a]/[b] :					
Net income attributable to equity holders of Sanofi	3.76	4.31	4.19	4.03	2.94
Diluted earnings per share (€)[a]/[c] :					
Net income attributable to equity holders of Sanofi	3.74	4.29	4.18	4.03	2.94
IFRS Balance sheet data					
Goodwill and other intangible assets	58,265	62,221[g]	44,411	43,480	43,423
Total assets	100,407	100,668[g]	85,264	80,251	71,987
Outstanding share capital	2,646	2,647	2,610	2,618	2,611
Equity attributable to equity holders of Sanofi	57,338	56,203[g]	53,097	48,322	44,866
Long term debt	10,719	12,499	6,695	5,961	4,173
Cash dividend paid per share (€)[d]	2.77 [e]	2.65	2.50	2.40	2.20
Cash dividend paid per share ($) [d][f]	3.65 [e]	3.43	3.34	3.46	3.06

(a) *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.*

(b) *Based on the weighted average number of shares outstanding in each period used to compute basic earnings per share, equal to 1,319.5 million shares in 2012, 1,321.7 million shares in 2011, 1,305.3 million shares in 2010, 1,305.9 million shares in 2009, and 1,309.3 million shares in 2008.*

(c) *Based on the weighted average in each period of the number of shares outstanding plus stock options and restricted shares with a potentially dilutive effect; i.e., 1,329.6 million shares in 2012, 1,326.7 million shares in 2011, 1,308.2 million shares in 2010, 1,307.4 million shares in 2009, and 1,310.9 million shares in 2008.*

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

(e) *Dividends for 2012 will be proposed for approval at the annual general meeting scheduled for May 3, 2013.*

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

(g) *In accordance with IFRS 3 (Business Combinations), Sanofi made adjustments during the Genzyme purchase price allocation period to some of the provisional amounts recognized in 2011 (see Note D.1.2. to our consolidated financial statements included at Item 18 of this annual report).*

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 2008 through March 2013 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)			
2008	1.39	1.47	1.60	1.24
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
Last 6 months				
2012				
September	1.29	1.29	1.31	1.26
October	1.30	1.30	1.31	1.29
November	1.30	1.28	1.30	1.27
December	1.32	1.31	1.33	1.29
2013				
January	1.36	1.33	1.36	1.30
February	1.31	1.33	1.37	1.31
March [2]	1.30	1.30	1.30	1.30

(1) *The average of the Noon Buying Rates on the last business day of each month during the relevant period for the full year average, and on each business day of the month for the monthly average. The latest available Noon Buying Rate being March 1, 2013, we have used European Central Bank Rates for the period from March 4, 2013 through March 6, 2013.*

(2) *In each case, measured through March 6, 2013.*

On March 6, 2013 the European Central Bank Rate was 1.3035 per euro.

B. Capitalization and Indebtedness

N/A

C. Reasons for Offer and Use of Proceeds

N/A

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 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 supplementary protection certificates in Europe for instance, 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 variations in the patents, differences in national law or legal systems, development in law or jurisprudence, or inconsistent judgments. Moreover, some countries are becoming more likely to consider granting a compulsory license to patents protecting an innovator's product; India's decision of March 2012 granting a compulsory license to a generic company to a Bayer patent is illustrative of this risk. We are involved in litigation worldwide to enforce certain of these 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). Moreover, patent rights are limited in time and do not always provide effective protection for our products: competitors may successfully avoid patents through design innovation, 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 claim may not result in a decision that our rights are valid, enforceable or infringed.

Even in cases where we ultimately prevail in our 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.

Further, our successful assertion of a given patent against one competing product is not necessarily predictive of our future success or failure in asserting the same patent against a second competing product because of such factors as possible differences in the formulations. Also a successful result in one country may not predict success in another country because of local variations in the patents and patent laws.

To the extent valid third-party patent rights cover our products, we or our partners may be required to obtain licenses from the holders of these patents in order to manufacture, use or sell these products, and payments under these licenses may reduce our profits from these products. 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 a third-party patent, 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 (see notably " The diversification of the Group's business exposes us to increased risks." below). 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. Several pharmaceutical companies have withdrawn products from the market because of newly detected or suspected adverse reactions to their products, and as a result of such withdrawal 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 our liability (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, particularly in the United States, and 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"). 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 attention, may harm our reputation and can impact the demand for our products. Substantial product liability claims, if successful, could adversely affect our business, results of operations and financial condition.

Claims and investigations relating to competition law, marketing practices, pricing, compliance issues, 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. Despite our efforts any failure to comply directly or indirectly (including as a result of a business partners' breach) with law could lead to substantial liabilities. 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. 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 and could have a material adverse effect on our business, results of operations or financial conditions. These risks may encourage the company to enter into settlement agreement with governmental authorities including with no admission of wrongdoing. Those settlements may involve large cash payments and penalties. Settlement of healthcare fraud cases may require companies to enter into a corporate integrity agreement, which is intended to regulate company behavior for a period of years. For instance in December 2012, Sanofi U.S. entered into a settlement agreement with the U.S. Attorney's Office, District of Massachusetts, the United States Department of Justice and multiple states to resolve all claims arising out of an

investigation into sampling of Sanofi's former viscosupplement product, Hyalgan®. As part of the settlement, Sanofi U.S. paid U.S.$109 Million to the settling parties and will 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.

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, if enacted, could make prosecution of patents for new products more difficult and time consuming or could adversely affect the exclusivity period for our products, thereby materially and adversely affecting our financial results.

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.

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 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 over 2012-2015. 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 which we expect, together with the expected synergies from our acquisition of Genzyme, to generate additional incremental cost savings by 2015. This also includes an adaptation plan regarding the activities of the Group in France. There is no assurance that the Group will successfully realize this plan. Moreover, the publicity given to this adaptation plan, may prejudice the Group's image and its reputation (see " The expansion of social media platforms and mobile technologies present new risks and challenges." below). We may fail to realize all the expected cost savings resulting from these initiatives, which could materially and adversely affect our financial results.

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

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 2012, we spent €4,922 million on research and development, amounting to approximately 14.1% of our net sales.

We may not be investing in the right technology platforms, therapeutic area, 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.

Developing a product is a costly, lengthy and uncertain process. 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" and "Item 4. Information on the Company B. Business Overview Vaccines Research and Development". Accordingly, there is a substantial risk at each stage of development that we will not achieve our goals of safety and/or effectiveness including during the course of a development trial and that we will have to abandon a product in which we have invested substantial amounts and human resources, including in late stage development (Phase III). 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.

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 may negatively affect our operating results.

Obtaining regulatory marketing approval is not a guarantee that the product will achieve commercial success. Following each product marketing approval, the medical need served by the product and the corresponding reimbursement rate are evaluated by other governmental agencies which may in some cases require additional studies, including comparative studies, which may both effectively delay marketing of the new product and add to its development costs.

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, then 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.

On the same topic, for the research and development of drugs in 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 and we may not receive additional manufacturing approvals in sufficient time to meet product demand, which could lead to a significant loss of sales of that drug and could affect our business, results of operations or financial condition.

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. 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 affect our results of operations.

In 2012, our patented pharmaceutical business faced important patent expirations and generic competition. For example Avapro®, Plavix®, and Eloxatin® lost their market exclusivity in the U.S in March, May and August 2012, and Aprovel® lost its market exclusivity in the E.U in August 2012.

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. Approval and market entry of a generic product often reduces the price that we receive for these products and/or the volume of the product that we would be able to sell and could materially and adversely affect our business, results of operations and financial condition. The extent of sales erosion also depends on the number of generic versions of our products that are actually marketed.

Additionally, in many countries such as the United States or France, applicable legislation encourages the use of generic products to reduce spending on prescription drugs. 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.

Additional products of the Group could become subject to generic competition in the future as we expect this generic competition to continue and to implicate drug products even those with relatively modest revenues.

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, 2012 compared with year ended December 31, 2011 Net Sales by Product Pharmaceuticals segment"), which represented 42.2% of the Group's consolidated revenues in 2012. Among these products is Lantus®, which was the Group's leading product with revenues of €4,960 million in 2012, representing 14.2% 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 impact on our business, results of operations and financial condition could be significant.

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 partnerships 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).

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.

Once identified, the inability to quickly or efficiently integrate newly acquired activities or businesses; a longer integration than expected; the loss of key employees; or higher than anticipated integration costs, could delay our growth objectives and prevent us from achieving expected synergies.

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.

While pursuing our objective to become a global and diversified leader within the health industry, we are exposed to a number of new risks inherent in sectors in which, in the past, we have been either less active or not present at all. As an example:

- 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, and the effect of reduced veterinary expenditures during an economic crisis (see " The ongoing slowdown of global economic growth and the financial crisis could have negative consequences for our business" below).

- the margins of consumer health and generic products are generally lower than those of the traditional branded prescription pharmaceutical business. Moreover, the periodic review of the effectiveness, safety and use of certain over-the-counter drug products by health authorities or lawmakers may result in modifications to the regulations that apply to certain components of such products, which may require them be withdrawn from the market and/or that their formulation be modified.

- 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.

Moreover, losses that may be sustained or caused by these 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 (see " Product liability claims could adversely affect our business, results of operations and financial condition" above), and thus our current risk management and insurance coverage may not be adapted to such losses. 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 and/or a significant decline in the anticipated growth rate in these regions could impair our ability to take advantage of these growth opportunities and could affect our business, results of operations or financial condition.

There is no guarantee that our efforts to expand sales in emerging markets will continue to succeed. 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, 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," below)), and compliance issues including corruption and fraud, as we operate in many parts of the world where these problems exist. Our existing policies and procedures, which are designed to help ensure that we, our employees, agents, intermediaries, and other third parties comply with the U.S. Foreign Corrupt Practices Act (FCPA), the UK Bribery Act, and other anti-bribery laws, may not adequately protect us against liability under these laws for actions we or they may take with respect to our business.

Failure to comply with domestic or international laws could result in various adverse consequences, including possible delay in the approval or refusal to approve a product, recalls, seizures, withdrawal of an approved product from the market, or the imposition of criminal or civil sanctions, including substantial monetary penalties.

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.

The industry in which we operate faces a changing regulatory environment and heightened public scrutiny worldwide, which simultaneously require greater assurances than ever as to the safety and efficacy of medications and health products on the one hand, and effectively provide reduced incentives for innovative pharmaceutical research on the other hand.

Each regulatory authority may also 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 August 2012, Genzyme received a Refuse to File letter from the FDA in response to the supplemental Biologics License Application to the FDA seeking approval of Lemtrada . The FDA did not request additional data or further studies but requested a modified presentation of the data sets to enable agency to better navigate the application. Finally, Genzyme resubmitted at the end of November 2012 the Lemtrada file and the FDA accepted on January 28, 2013 the application for review. In December 2012, the CHMP of the European Medicines Agency (EMA) has adopted a negative opinion for the marketing authorization application for Kynamro , but this product was approved by the FDA in January 2013.

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 imposed increasingly burdensome requirements on pharmaceutical companies, particularly in terms of the volume of data needed to demonstrate a product's efficacy and safety. For the same reasons, the marketed products are subject to continual review, risk evaluations or comparative effectiveness studies even after regulatory approval. These requirements have resulted in increasing the costs associated with maintaining regulatory approvals and achieving reimbursement for our products.

Later discovery of previously undetected problems may result in marketing restrictions or the suspension or withdrawal of the product, as well as an increased risk of litigation for both pharmaceutical and animal health products. These post-regulatory approval reviews and data analyses can lead to the issuance of recommendations by government agencies, health professional and patient organizations or other specialized organizations regarding the use of products, which may result in a reduction in sales volume, such as, for example, a recommendation to limit the patient scope of a drug's indication. For instance in September 2011, the EMA defined a more restrictive indication for Multaq®, one of our cardiovascular products. Such reviews may result in the discovery of significant problems with respect to a competing product that is similar to one sold by the Group, which may in turn cast suspicion on the entire class to which these products belong and ultimately diminish the sales of the relevant product of the Group. When such issues arise, the contemplative 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.

Government authorities and regulators in the U.S. and in E.U. are considering measures to reduce the risk of supply shortages of live-saving medicine in particular if there are no viable therapeutic alternatives. It cannot be ruled out that these ongoing initiatives may generate additional costs for the Group if they result in a requirement to set-up back up supply channels or to increase the level of the inventories to avoid shortages.

In addition, to the extent that new regulations raise the costs of obtaining and maintaining product authorization, or limit the economic value of a new product to its inventor, the growth prospects of our industry and of the Group are diminished. Also about 50% of our current research and development portfolio is constituted by biological products, that may bring in the future new therapeutic responses to current unmet medical needs but which may also lead to more technical constraints and costly investments from an industrial standpoint.

Moreover, we and certain of our third-party suppliers are also required to comply with applicable regulations, known as good manufacturing practices, which govern the manufacture of pharmaceutical products. To monitor our

compliance with those applicable regulations, the FDA, the EMA and comparable agencies in other jurisdictions routinely conduct inspections of our facilities and may identify potential deficiencies which might be expensive and time consuming to address. For example, in July 2012, Sanofi Pasteur received a Warning Letter from the FDA following regular inspections conducted at manufacturing facilities in Canada and France. If we fail to adequately respond to a 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 2010, Genzyme entered into a consent decree with the FDA relating to its Allston facility and paid U.S.$175.0 million to the U.S. Federal Government as disgorgement of past profits. The consent decree required Genzyme to implement a plan to bring the Allston facility into compliance with applicable laws and regulations. Genzyme submitted a comprehensive remediation plan to FDA in April 2011 and the plan was accepted by FDA. Remediation of the Allston facility in accordance with that plan is underway and is currently expected to continue for three more years.

Our indebtedness may limit our business flexibility compared to some of our peers.

Our consolidated debt increased substantially in connection with our acquisition of Genzyme in 2011. Although we continued to reduce our debt in 2012 (as of December 31, 2012, our debt, net of cash and cash equivalents amounted to €7.7 billion), we still make significant debt service payments to our lenders and this could limit our ability to engage in new transactions which could have been part of our strategy.

We face increasing pricing and reimbursement pressure on our pharmaceutical products that could negatively affect our revenues and/or margins.

The commercial success of our existing products and our products 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; 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. In the United States, the new 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 health care sector. This law also imposed cost containment measures and rebates and fees on pharmaceutical companies. Implementation of health care reform has affected and could still 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 of 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 EU and Canada, the coverage of prescription drugs, pricing and levels of reimbursement are subject to governmental control. For instance early 2013, in China the National Development and Reform Commission set new national retail ceiling prices for 700 formulations of 400 drugs; among them was Lantus® whose price was cut by 12.9% (effective February 1, 2013).

Due to the ongoing cost containment policies being pursued in many jurisdictions in which we operate, we are unable to predict the availability or amount of reimbursement for our product candidates.

In addition, 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 product on low cost markets for resale on higher cost markets.

The ongoing slowdown of global economic growth and the financial crisis could have negative consequences for our business[1].

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 or major national economies 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, levels and increases in co-pays, lack of developed third party payer system, 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.

The growth of our OTC and CHC business may also be negatively affected by the current slowdown in global economic growth as consumer spending is closely tied to the global economy. Also our animal health business could be impacted. For example, tight credit conditions may limit the borrowing power of livestock producers, causing some to switch to lower-priced products.

Although macroeconomic and financial measures have been taken in 2012 by governments and monetary authorities, notably in Europe reducing thus 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 below at "We are subject to the risk of non-payment by our customers". Moreover, to the extent that the economic and financial crisis is directly affecting business, it may also lead to a disruption or delay in the performance of third parties on which we rely for parts of our business, including collaboration partners and suppliers (for more information see "Item 5. Operating and Financial Review and Prospects Liquidity."). Such disruptions or delays could have a material and adverse effect on our business and results of operations. See " We rely on third parties for the discovery, manufacture and marketing of some of our products" below.

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 and delay the launch of new products.

Many of our products are manufactured using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. 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 to the processing of biological materials and the potential unavailability of adequate amounts of raw materials meeting our standards. We may not have redundant manufacturing capacity for certain products particularly 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 may require significant time.

---

(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.

Additionally, specific conditions must be respected both by the Group and our customers for the storage and distribution of many of our products, *e.g.*, 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. The occurrence or suspected occurrence of out-of-specification production or storage can lead to lost inventories, and in some cases product recalls, with consequential reputational damage and the risk of product liability (see " Product liability claims could adversely affect our business, results of operations and financial condition," above). Group products are increasingly reliant on the use of product-specific devices for administration; a technical problem in these devices could jeopardize the approval or the commercialization of the products or require a recall.

Supply shortages are subject to public scrutiny and are subject to even greater public criticism when they occur with respect to life saving medicines with limited 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. The investigation and remediation of any identified manufacturing problems can cause production delays, substantial expense, lost sales and delay the launch of new products, which could adversely affect our operating results and financial condition.

Like many of our competitors, we have faced and may face in the future manufacturing issues. For example, Genzyme experienced in the past significant difficulties in manufacturing Cerezyme® and Fabrazyme® for several years. In summer 2011 a technical incident occurred in the filling line used for Apidra 3mL cartridges at our manufacturing site in Frankfurt which caused temporary shortages for Apidra 3mL cartridges. In April 2012 Sanofi Pasteur temporarily 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 U.S. In June 2012 Sanofi Pasteur voluntarily recalled the Bacille Calmette-Guérin (BCG) vaccine produced in its Canadian facility due to manufacturing issues. This withdrawal is expected to last several months while the renovation of the building is completed. 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.

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.

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 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®. Heparin purchase prices can also fluctuate. 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.

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 and delay the launch of new products" 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, Warner Chilcott for the osteoporosis treatment Actonel®, 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 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.

Counterfeit versions of our products harm our business.

The drug supply has been increasingly challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the Internet. Counterfeit products are frequently unsafe or ineffective, and can be potentially life-threatening. To distributors and users, counterfeit products may be visually indistinguishable from the authentic version. Reports of adverse reactions to counterfeit drugs or increased levels of counterfeiting could materially affect patient confidence in the authentic product, and harm the business of companies such as Sanofi. Additionally, it is possible that adverse events caused by unsafe counterfeit products will mistakenly be attributed to the authentic product. If a Group product was the subject of counterfeits, the Group could incur substantial reputational and financial harm. See "Item 4. Information on the Company B. Business Overview Competition."

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 crisis. 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. In addition, the Group's three main customers represent 17.0% of our gross total revenues. We are also exposed to large wholesalers in other markets, particularly in Europe. 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).

Since 2010, some countries of southern Europe have faced important financial difficulties. Some customers in these countries are public or subsidized health systems. The deteriorating economic and credit conditions in these countries may lead to longer payment terms. Because of this trend 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.").

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).

---

(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.

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.

New or revised accounting standards, rules and interpretations issued from time to time by the IASB (International Accounting Standards Board) could result in changes to the recognition of income and expense that may materially and adversely affect the Group's financial results.

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

Also 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.

In addition the global financial crisis and in particular the ongoing sovereign debt crisis affecting certain European countries could also negatively affect the value of our assets (see " The ongoing slowdown of global economic growth and the financial crisis 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).

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" above) or the unavailability of our products. While we have invested heavily in the protection of data and information technology, there can be no assurance that our efforts or those of our third-party service providers (for instance the accounting of some of our subsidiaries has been externalized) to implement adequate security and quality measures for data processing would be sufficient to protect against 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 business, operating results and financial condition.

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

New technologies are increasingly used to communicate about our products or the diseases they are intended to treat. 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. Negative posts or comments about the Company, its business, its directors or officers on any social networking web site could seriously damage our reputation. In addition, our associates may use the social media tools and mobile technologies inappropriately which may give rise to liability, 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.

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

Some of our production sites are located in areas exposed to natural disasters, such as earthquakes (in North Africa, Middle East, Asia, Pacific, Europe, Central and Latin Americas), floods (in Africa, Asia Pacific and Europe) and hurricanes. In the event of a major disaster we could experience severe destruction or interruption of our operations and production capacity. As a result, our operations could suffer serious harm which could have a material adverse effect on our business, financial condition and results of operations.

Environmental Risks of Our Industrial Activities

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

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

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

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

- the shutdown of affected facilities; and
- the imposition of civil or criminal penalties.

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.

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)."

Risks Related to Financial Markets[1]

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 British pound, the Japanese yen, and to currencies in emerging countries. In 2012, 31% of our net sales were realized in the United States. 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. In addition, in the specific context of the sovereign debt crisis affecting certain European countries, the threatened or actual withdrawal of the euro as currency in one or more European Monetary Union countries and the associated fluctuations in currency exchange rates could have a material effect on our financial condition and earnings, the magnitude and consequences of which are unpredictable. For more information concerning our exchange rate exposure, see "Item 11. Quantitative and Qualitative Disclosures about Market Risk."

In the context of the worldwide financial crisis, our liquidity may be constrained.

As of December 31, 2012, the Group's net debt amounted approximately to €7.7 billion. In addition to debt outstanding, the Group has contracted a number of credit lines and put into place commercial paper and medium term note programs with the aim of providing liquidity. See "Item 11. Quantitative and Qualitative Disclosures about Market Risk." In the event of a market-wide liquidity crisis, the Group might be faced with reduced access to sources of financing, including under programs currently in place, or less favorable conditions.

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.

---

(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.

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.

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

The implementation of new 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 would be assessed and collected from beneficial owners or financial intermediaries outside of France could discourage holding of 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, 2012, L'Oréal held approximately 8.91% of our issued share capital, accounting for approximately 16.13% of the voting rights (excluding treasury shares) of Sanofi. See "Item 7. Major Shareholders and Related Party Transactions A. Major Shareholders." Affiliates of L'Oréal currently serve on our Board of Directors. To the extent L'Oréal continues to hold a large percentage of our share capital and voting rights, it will remain in a position to exert 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 attached as exhibit 4.1 to our Registration Statement on Form F-4 (Registration No. 333-172638), as amended. Pursuant to the CVR agreement, each holder of a CVR is entitled to receive cash payments upon the achievement of certain milestones, 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:

- an active public market for the CVRs may not develop 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 on September 4, 2012 Sanofi launched a tender offer to purchase up to 30% of its outstanding CVRs (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, until the CVR agreement is terminated, to achieve each of the Lemtrada related CVR milestones set forth in the CVR agreement, we are not required to take all possible actions to achieve these goals, and the failure to achieve such goals would have an adverse effect on the value, if any, of the CVRs.

Item 4. Information on the Company

Introduction

We are an integrated, global healthcare company focused on patient needs and engaged in the research, development, manufacture and marketing of healthcare products. In 2012, our net sales amounted to €34,947 million. We are the fourth largest pharmaceutical group in the world and the third largest pharmaceutical group in Europe (source: IMS sales 2012). 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 Limited (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, Vaccines, Consumer Health Care, Animal Health, New Genzyme[2], and Other Innovative Products[3]. 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, Consumer Health Care, New 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 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 2012 and 2011, refer to "Item 5. Results of Operations Year Ended December 31, 2012 Compared with year Ended December 31, 2011".

---

(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) "New Genzyme" covers rare diseases and treatment for multiple sclerosis.

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

In our Pharmaceuticals activity, which generated net sales of €28,871 million in 2012, 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; Apidra®, a rapid-acting analog of human insulin; Insuman®, a range of human insulin solutions and suspensions; Amaryl®, an oral once-daily sulfonylurea; and BGStar® and iBGStar blood glucose meters.

Rare Diseases: our principal products are enzyme replacement therapies: Cerezyme®, to treat Gaucher disease; Fabrazyme® to treat Fabry disease; and Myozyme®/Lumizyme® to treat Pompe disease.

Multiple sclerosis (MS): with Aubagio® a once daily, oral immunomodulator launched in October 2012 in the United States.

Rare Diseases and multiple sclerosis are the therapeutic areas of the "New Genzyme" growth platform.

Oncology: with Taxotere®, a taxane derivative representing a cornerstone therapy in several cancer types; Eloxatine®, a platinum agent, which is a key treatment for colorectal cancer; Jevtana®, a taxane derivative, indicated for patients with prostate cancer; 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, launched in August 2012 in the United States.

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 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 other products in Consumer Health Care (CHC), a category in which we have become the third largest player in terms of global sales, and other prescription drugs including generics.

We are a world leader in the vaccines industry. Our net sales amounted to €3,897 million in 2012, with leading vaccines in five areas: pediatric vaccines, influenza vaccines, adult and adolescent booster vaccines, meningitis vaccines, and travel and endemics 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 €2,179 million in 2012.

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 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®), and Ambien® CR (an extended-release formulation of zolpidem tartrate, not sold in France).

For our pharmaceutical activity, except where otherwise stated, all market share percentages and rankings are based on full-year 2012 sales figures from IMS Health MIDAS (retail and hospital).

For our vaccines activity, market shares and rankings are based on our own estimates. These estimates have been made from public domain information collated from various sources, including statistical data collected by industry associations and information published by competitors.

We present our consolidated net sales for our leading products sold directly and through alliances. As regards the products sold through our alliance with Bristol-Myers Squibb (BMS), we also present the aggregate worldwide sales of Plavix® and Aprovel®, whether consolidated by Sanofi or by BMS. A definition of worldwide sales can be found in "Item 5. Operating and Financial Review and Prospects Results of Operations".

A. History and Development of the Company

The current Sanofi corporation was incorporated under the laws of France in 1994 as a *société anonyme*, a form of limited liability company, for a term of 99 years. Since May 2011, we have operated under the commercial name "Sanofi" (formerly known as sanofi-aventis). Our registered office is located at 54, rue La Boétie, 75008 Paris, France, and our main telephone number is +33 1 53 77 40 00. Our principal U.S. subsidiary's office is located at 55 Corporate Drive, Bridgewater, NJ 08807; telephone: +1 (908) 981-5000.

We are present in approximately 100 countries on five continents with 111,974 employees at year end 2012. As a global diversified healthcare company our business includes a diversified offering of medicines, consumer healthcare products, generics, animal health and human vaccines.

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 the second half of the 19th century) were combined in 2004 and are the principal legacy companies of our continuously expanding Group.

Important Corporate Developments 2009-2012

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;

On February 24, 2011, Sanofi acquired BMP Sunstone Corporation (a specialty pharmaceutical company with a proprietary portfolio of branded pharmaceutical and healthcare products in China) through a merger between BMP Sunstone and a wholly-owned subsidiary;

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 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

On April 4, 2011, following a tender offer, Sanofi acquired Genzyme Corporation, a leading biotechnology group headquartered in Cambridge, Massachusetts and specialized 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

Strategy

Sanofi is an integrated, 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 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 & Development (R&D), increasing our diversification, and investing in seven growth platforms (Emerging Markets, Diabetes Solutions, Vaccines, Consumer Health Care, Animal Health, New Genzyme, and Innovative Products).

We regularly review our strategy and its implementation, and are continuing to execute this 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 and 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. Also, 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, MA area (United States) with its concentration of universities and innovative biotechnology companies. Our R&D is now 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 2012 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 five innovative products (NMEs) submitted to regulatory agencies in 2012 and 18 potential new product launches possible between now and the end of 2015.

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 2012, we actively pursued this targeted policy, announcing 26 new transactions, including 8 acquisitions and 18 major R&D alliances.

In 2012, we strengthened our Emerging Markets growth platform with the agreement to acquire Genfar S.A. (announced in October 2012), a leading pharmaceuticals manufacturer headquartered in Bogota, Colombia. Also, we acquired the rights to lines of generic products for Sub Saharan Africa and for Vietnam. With these acquisitions, Sanofi intends to become a market leader in both Colombia and Nigeria, and has expanded its portfolio of affordable pharmaceuticals in Latin America, Africa and Southeast Asia.

Our animal health business was also reinforced in 2012 by the acquisition of Newport Laboratories, a privately held company based in Worthington, Minnesota (United States), a leader in autogenous vaccines with a focus on swine and bovine production markets, and with the agreement to acquire the Animal Health Division of Dosch

Pharmaceuticals in India (announced end of December 2012). When completed, this last acquisition will create a market entry for Merial in that country's strategically important and growing Indian animal health sector.

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 geographical reach. In particular, we have tailored our strategy, structure and 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 2012, 67.4% of our sales were generated by our growth platforms. In addition, 31.9% of our 2012 sales were in emerging markets, where we have enhanced our offerings in high growth segments such as Generics and Consumer Health Care by completing 25 transactions and investing a total of approximately €3.9 billion in acquisitions over the last four years.

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.

Pharmaceutical Products

Main Pharmaceutical Products

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

The following table sets forth the net sales of our main pharmaceutical products for the year ended December 31, 2012.

Therapeutic Area / Product Name	2012 Net Sales (€ million)	Drug Category / Main Areas of Use
Diabetes Solutions		
Lantus® (insulin glargine)	4,960	Long-acting analog of human insulin Type 1 and 2 diabetes mellitus
Apidra® (insulin glulisine)	230	Rapid-acting analog of human insulin Type 1 and 2 diabetes mellitus
Insuman® (insulin)	135	Human insulin (rapid and intermediate acting) Type 1 and 2 diabetes mellitus
Amaryl® (glimepiride)	421	Sulfonylurea Type 2 diabetes mellitus
Rare Diseases		
Cerezyme® (imiglucerase for injection)	633	Enzyme replacement therapy Gaucher disease
Fabrazyme® (agalsidase beta)	292	Enzyme replacement therapy Fabry disease
Myozyme®/Lumizyme® (alglucosidase alpha)	462	Enzyme replacement therapy Pompe disease
Multiple Sclerosis		
Aubagio® (teriflunomide)	7	Oral immunomodulating agent Multiple Sclerosis
Oncology		
Taxotere® (docetaxel)	563	Cytotoxic agent Breast cancer Non small cell lung cancer Prostate cancer Gastric cancer Head and neck cancer
Eloxatine® (oxaliplatin)	956	Cytotoxic agent Colorectal cancer
Jevtana® (cabazitaxel)	235	Cytotoxic agent Prostate cancer
Mozobil® (plerixafor)	96	Hematopoietic stem cell mobilizer Hematologic maligancies
Zaltrap® (aflibercept)	25	Recombinant fusion protein Oxaliplatin resistant metastatic colorectal cancer

Therapeutic Area / Product Name	2012 Net Sales (€ million)	Drug Category / Main Areas of Use
Other Prescription Drugs		
Lovenox® (enoxaparin sodium)	1,893	Low molecular weight heparin
		Treatment and prevention of deep vein thrombosis
		Treatment of acute coronary syndromes
Plavix® (clopidogrel bisulfate)	2,066	Platelet adenosine disphosphate receptor antagonist
		Atherothrombosis
		Acute coronary syndrome with and without ST segment elevation
Aprovel® (irbesartan) / CoAprovel® (irbesartan & hydrochlorothiazide)	1,151	Angiotensin II receptor antagonist Hypertension
Multaq® (dronedarone)	255	Anti-arrhythmic drug Atrial Fibrillation
Renagel® (sevelamer hydrochloride) / Renvala® (sevelamer carbonate)	653	Oral phosphate binders High phosphorus levels in patients with chronic kidney disease (CKD) on dialysis
Synvisc® / Synvisc-One® (hylan G-F 20)	363	Viscosupplements Pain associated with osteoarthritis of the knee
Stilnox® /Ambien®/Myslee® (zolpidem tartrate)	497	Hypnotic Sleep disorders
Allegra® (fexofenadine hydrochloride)	553[(1)]	Anti-histamine
		Allergic rhinitis
		Urticaria
Depakine® (sodium valproate)	410	Anti-epileptic Epilepsy
Consumer Health Care		
Total	3,008	
Generics		
Total	1,844	

(1) *Excluding Allegra® OTC sales.*

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; Apidra®, a rapid-acting analog of human insulin; Insuman®, a human insulin; and Amaryl®, a sulfonylurea. In 2011, in some European markets, we launched the BGStar® range of blood glucose meter solutions for patients with diabetes, whether they are treated with insulin or not. 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 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 aged two years (label extension for pediatric use was granted in the EU in 2012) and above with type 1 diabetes mellitus.

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 (ADA) and European Association for the Study of Diabetes (EASD) have 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 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, 2012 sales) and is available in over 120 countries worldwide. The three leading countries for sales of Lantus® in 2012 were the United States, France and Japan.

International epidemiology program

The epidemiological program sponsored by Sanofi was aimed at evaluating cancer risk in diabetes and generating comprehensive insulin glargine exposure data from large databases. It is the largest observational program designed for this purpose to date. The program results reinforce the robust safety profile of Lantus®, complementing the existing wealth of data already available from more than 80,000 patients enrolled in clinical trials.

The now completed epidemiological program comprised three major studies. These were designed independently of the company by the lead investigators and endorsed by the European Medicines Agency (EMA) and shared with the Food and Drug Administration (FDA). They used state-of-the-art biostatistical methodology with protocols that were discussed with a senior-level Biostatistics Advisory Group:

- The Northern European Study analyzed over 1.5 million person-years of insulin exposure using databases from five countries Denmark, Finland, Sweden, Norway and Scotland. The study reported no increased risk of breast cancer in women, prostate cancer in men and colorectal cancer in men and women in users of insulin glargine versus other insulins, among all users of insulin, and similarly among users of human insulin.

- The U.S. Study analyzed over 0.4 million patient-years of insulin exposure from the Kaiser Permanente database (Northern and Southern California regions). Among all insulin users (insulin glargine and NPH insulin), and similarly among those switching to Lantus® and new insulin users, there was no association between use of insulin glargine and risk of breast cancer, prostate cancer, colorectal cancer or all cancers combined.

The International Study of Insulin and Cancer (ISICA) was a case-control study of female patients with diabetes in the UK, Canada and France. The study found no increase in the risk of breast cancer with insulin glargine use in diabetes patients and, furthermore, high doses or longer treatment duration with Lantus® were not associated with an increased risk of breast cancer.

ORIGIN

ORIGIN was a seven-year randomized clinical trial designed to assess the effects of treatment with insulin glargine versus standard care on cardiovascular outcomes. This landmark study involved over 12,500 participants worldwide with pre-diabetes or early type 2 diabetes mellitus and high cardiovascular (CV) risk, with 6,264 participants randomized to receive insulin glargine titrated to achieve fasting normoglycemia. The co-primary endpoints were the composite of CV death, or non-fatal myocardial infarction, or nonfatal stroke; and the composite of CV death, or non-fatal myocardial infarction, or non-fatal stroke, or revascularization procedure, or hospitalization for heart failure.

Results showed that Lantus® had no statistically significant positive or negative impact on CV outcomes versus standard care during the study period. Results also showed that insulin glargine delayed progression from pre-diabetes to type 2 diabetes and there was no association between insulin glargine use and increased risk of any cancer. (New England Journal of Medicine, July 2012)

Sanofi is sponsoring a 2-year extension to ORIGIN, called ORIGINALE (Outcome Reduction with an Initial Glargine Intervention and Legacy Effect).

The results of the ORIGIN trial have been filed with the FDA and the EMA to update the Lantus® dossier at the end of 2012.

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 in combination with long-acting insulins such as Lantus® for supplementary glycemic control at mealtime.

In addition, Apidra® is equally effective in adult diabetics ranging from lean to obese and offers patients greater flexibility of administration, either before or just after mealtime.

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.

After a temporary shortage of Apidra® 3mL cartridges (including Apidra® SoloSTAR®) in 2011 which impacted supplies in some markets, production of Apidra® 3mL cartridges returned to full capacity in the first half of 2012.

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®) containing the active substance human insulin. 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- and intermediate-acting insulins in various proportions (Insuman® Comb). Insuman® is principally sold in Germany.

Amaryl®/Amarel®/Solosa®

Amaryl® (glimepiride) is a latest-generation, orally administered once-daily sulfonylurea (a glucose-lowering agent) 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 mealtime and between meals, and by decreasing insulin resistance.

The combination of metformin (which reduces hepatic glucose production and decreases insulin resistance) with a sulfonylurea such as Amaryl® is effective in combating the two causes of type 2 diabetes. It is one of the most prescribed combinations of diabetes drugs worldwide. Amaryl M®, a fixed-dose combination of Amaryl® plus metformin in a single presentation, was launched in 2007.

A number of generics have received marketing authorization and have been launched in Europe, the United States and Japan.

BGStar® / iBGStar®

Sanofi and its partner AgaMatrix are co-developing intelligent solutions in diabetes care that demonstrate their commitment to simplifying and innovating the diabetes management experience for people with diabetes and healthcare providers. The blood glucose monitoring solutions are exclusive to Sanofi and are designed to be synergistic with the rest of the diabetes portfolio. BGStar® and iBGStar® 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.

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

BGStar® and iBGStar® are available in France, Germany, Spain, Italy, the Netherlands, Switzerland, Belgium, Luxembourg, Canada, Estonia, Australia, the UK and the Philippines. iBGStar® is also available in the United States and Saudi Arabia.

Lyxumia®

Lyxumia® (lixisenatide) is a once-daily prandial GLP-1 receptor agonist. In February 2013, the European Commission granted marketing authorization in Europe for Lyxumia® 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. On completion of pricing and reimbursement discussions, Sanofi will initiate a phased launch of Lyxumia® throughout the European Union. Applications for regulatory approval were also submitted in several other countries around the world and are being reviewed. The FDA accepted the file for review in February 2013.

Additional Phase IIIb studies have been initiated and the ELIXA cardiovascular outcomes trial is ongoing.

A proof-of-concept study to compare insulin glargine/lixisenatide fixed ratio combination versus insulin glargine on glycemic control over 24 weeks has been fully recruited.

GLP-1 is a naturally-occurring peptide hormone that is released within minutes after eating a meal. It is known to suppress glucagon secretion from pancreatic alpha cells and stimulate glucose-dependent insulin secretion by pancreatic beta cells.

The active ingredient of Lyxumia® is in-licensed from Zealand Pharma.

The main compound currently in Phase III clinical development in the Diabetes field is New Glargine Formulation: A new formulation of insulin glargine with an improved pharmacodynamic profile is now in Phase III clinical testing. In addition to the two Phase III studies started during 2011, in the second half of 2012 the EDITION III and IV Phase III trials were initiated together with two dedicated clinical studies in Japan.

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 Disease 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. Our principal rare disease products are enzyme replacement therapies: Cerezyme® (imiglucerase for injection) to treat Gaucher disease, Fabrazyme® (agalsidase beta) to treat Fabry disease and Myozyme® / Lumizyme® (alglucosidase alpha) to treat Pompe disease. In January 2013, Kynamro (mipomersen), an antisense oligonucleotide that inhibits the synthesis of apolipoprotein B-100, was approved by the FDA for homozygous familial hypercholesterolemia.

Cerezyme®

Cerezyme® (imiglucerase for injection) is an enzyme replacement therapy used to treat Gaucher disease, an inherited, potentially life-threatening LSD. It is estimated that there are approximately 10,000 Gaucher patients worldwide.

Cerezyme® is the only therapy with 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 1-2 hours.

In 2012, significant progress was made in resolving supply challenges encountered starting in 2009, and successfully restoring existing patients in major markets to normal dosing. For more information regarding manufacturing issues related to Cerezyme®, see "Item 4 Information on the Company Production and Raw Materials".

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

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.

The strong recovery of Fabrazyme®, following manufacturing issues which began in 2009, continued in 2012 with the approval of the new Framingham plant in January 2012, stable production runs, the return of all existing patients in all markets to full dose and the addition of new patients. In the U.S., Fabrazyme® also benefited from Shire's withdrawal of the Replagal® BLA. For more information regarding manufacturing issues related to Fabrazyme®, see "Item 4 Information on the Company Production and Raw Materials".

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 EU and is currently available in 48 markets worldwide. Lumizyme® is the first treatment approved in the United States specifically to treat patients

with late-onset Pompe disease: Lumizyme® has been marketed since June 2010. Myozyme® and Lumizyme® are administered by intravenous infusion. Lumizyme® is used to treat Pompe disease in patients over eight years of age without evidence of cardiac hypertrophy.

Both products are a recombinant form of the same human enzyme but are manufactured using different sized bioreactors.

Kynamro

Kynamro (mipomersen) is an antisense oligonucleotide (ASO) that inhibits the synthesis of apoB, a primary protein constituent of atherogenic lipoproteins. Mipomersen is being developed, in collaboration with Isis Pharmaceuticals Inc., for the treatment of patients with homozygous familial hypercholesterolemia (HoFH) and severe heterozygous FH (HeFH). FH is a genetic disorder that causes chronic and lifelong exposure to markedly elevated concentrations and numbers of atherogenic, apoB-containing lipoproteins (LDL, Lp(a)) leading to premature and severe cardiovascular disease. On January 29, 2013, Genzyme and Isis announced the FDA approval of Kynamro (Mipomersen sodium) for homozygous familial hypercholesterolemia. On December 14, 2012 Genzyme and Isis announced that the Committee for Medicinal Products for Human Use (CHMP) had adopted a negative opinion for its marketing authorization application submitted in 2011. In January 2013, Genzyme requested a re-examination of the CHMP opinion.

The main compounds currently in Phase II or III clinical development in the Rare Diseases field are:

Eliglustat tartrate 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. The fourth year of data from the Phase II trial of eliglustat tartrate suggests continued improvement across all endpoints including markers of bone disease. On February 15, 2013 Sanofi and Genzyme announced positive new data from the Phase III ENGAGE and ENCORE Studies.
In ENGAGE, a Phase III trial aimed at evaluating the safety and efficacy of eliglustat in 40 treatment-naive patients with Gaucher disease type 1, improvements were observed across all primary and secondary efficacy endpoints over the nine-month study period.

In ENCORE, a Phase III study assessing eliglustat vs. Cerezyme® in 160 patients with Gaucher disease type 1, the primary composite endpoint of clinical stability was met as well as for the individual components of the composite endpoint which was secondary endpoints.

Multiple Sclerosis (MS)

Our Multiple Sclerosis franchise is focused on the development and commercialization of therapies that treat this chronic autoimmune disease of the central nervous system. More than 2 million people suffer from MS worldwide. Our MS franchise consists of Aubagio® (teriflunomide), a once daily, oral immunomodulator that is approved in the United States and Australia, and Lemtrada (alemtuzumab), a monoclonal antibody that has completed two Phase III pivotal studies and has marketing applications under review by regulatory authorities in the U.S. and Europe.

Aubagio®

Aubagio® (teriflunomide), an immunomodulatory agent with anti-inflammatory properties, 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 CNS. Aubagio® has shown significant efficacy across key measures of MS disease activity, including reducing relapses, slowing the progression of physical disability, and reducing the number of brain lesions as detected by MRI. Results of the first pivotal study (TEMSO), indicating that the product had an effect on disease activity in terms of relapse rate, disability progression and brain lesions with a favorable safety profile, were published in the New England Journal of Medicine in October 2011. Results from the second pivotal study (TOWER) were presented at 28th Congress of the European Committee for Treatment and Research

in Multiple Sclerosis (ECTRIMS) in October 2012. These results showed that Aubagio® significantly reduced the annualized relapse rate and slowed progression of disability in patients with relapsing forms of multiple sclerosis compared to placebo. Aubagio® is the first and only oral MS therapy to significantly slow the progression of disability in two Phase III trials.

Aubagio® received FDA approval in the United States in September 2012 for patients with relapsing forms of MS. The product also received regulatory approval in Australia in November 2012. Marketing applications for Aubagio® are currently under review by the European Medicines Agency and other regulatory authorities.

The main compound currently in Phase III clinical development in the multiple sclerosis field is Lemtrada (alemtuzumab), 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. The two pivotal Phase III studies demonstrating the safety and efficacy of alemtuzumab were completed in 2011 and the results were published in the *Lancet* in November 2012. The first study, CARE-MS I, demonstrated strong and robust treatment effect on the relapse rate co-primary endpoint vs Rebif in treatment-naive MS patients. The co-primary endpoint of disability progression (time to sustained accumulation of disability: SAD) did not meet statistical significance. The second study, CARE-MS II, demonstrated that relapse rate and SAD were significantly reduced in MS patients receiving alemtuzumab as compared with Rebif in MS patients who had relapsed on prior therapy. Results from CARE-MS II also showed that patients treated with Lemtrada were significantly more likely to experience improvement in disability scores than those treated with Rebif, suggesting a reversal of disability in some patients. In both pivotal studies, safety results were consistent with previous alemtuzumab use in MS and adverse events continued to be manageable. Marketing applications for Lemtrada are currently under review by regulatory authorities.

Oncology

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

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 in death in many cancer cells.

Taxotere® is available in more than 90 countries as an injectable solution. The single vial formulation (one vial IV route 20-80mg) was launched in the U.S. and in the European Union in 2010. It has been approved for use in eleven 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 2012 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).

Eloxatine®

Eloxatine® (oxaliplatin) is a platinum-based cytotoxic agent. Eloxatine®, in combination with infusional (delivered through the bloodstream) 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 (original) tumors surgically removed. This approval was based on evidence of an improvement in disease-free survival after four years.

Eloxatine® is in-licensed from Debiopharm and is marketed in more than 70 countries worldwide. The top four countries contributing to sales of Eloxatine® in 2012 were the United States, Canada, China, and South Korea.

Following the end of Eloxatine® 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 Eloxatine® still has exclusivity.

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.

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 seen 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 78 countries.

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, second-line treatment of small-cell lung cancer patients, and pediatric patients with brain cancer.

The top four countries contributing to sales of Jevtana® in 2012 were the U.S., Germany, Italy and Brazil.

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 2012 were the U.S., Germany, France, the U.K. and Italy.

Zaltrap®

Zaltrap® (aflibercept) is a recombinant fusion protein which acts as a soluble decoy receptor that binds to Vascular Endothelial Growth Factor-A (VEGF-A), VEGF-B and placental growth factor (PlGF), preventing the bound VEGF from binding to their native receptors. VEGF-A is one of the mediators contributing to angiogenesis. VEGF-B and PlGF, related growth factors in the VEGF family, may contribute to tumor angiogenesis as well. In the U.S., Zaltrap® is a registered trademark of Regeneron Pharmaceuticals, Inc.

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® is marketed in the U.S. in August 2012.

In the European Union, Zaltrap® (aflibercept) 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.

The marketing of Zaltrap® is organized through our collaboration with Regeneron (see "Item 5 Alliance Arrangements with Regeneron").

Concerning the development program for the treatment of metastatic prostate cancer, the Phase III VENICE trial (First-line treatment for androgen-independent (hormone-refractory) metastatic prostate cancer in combination

with docetaxel and prednisone) did not meet the pre-specified criterion of improvement in overall survival. The safety profile was generally consistent with previous studies of Zaltrap® in combination with docetaxel.

The oncology R&D pipeline includes a broad spectrum of novel agents with a variety of mechanisms of action for treating cancer, including cytotoxic agents, anti-mitotic agents, anti-angiogenic agents, targeted therapies and monoclonal anti-bodies (unconjugated or conjugated with cytotoxics). Projects are presented from the most advanced to the least advanced stage of development.

The main compounds currently in Phase II or III clinical development in the Oncology field are:

Iniparib (SAR240550; BSI-201) is an agent with novel mechanism of activity that is currently being studied in advanced squamous non-small cell lung cancer (Phase III, fully accrued) as well as ovarian and breast cancers (Phase II). While the initial dosing regimen was based on the putative PARP inhibitory activity, current efforts are aimed at elucidating the mechanism of action and exploring the maximal tolerated dose both as a single agent and in combination with chemotherapy.

SAR302503 (TG101348) was acquired when we purchased TargeGen, Inc. in 2010 and is being developed exclusively by Sanofi. SAR302503 is a selective oral, small molecule inhibitor of the JAK2 kinase. JAK2 and the JAK/stat pathway have been identified as key regulators of growth and differentiation of normal hematopoeitic cells, and are commonly dysregulated in multiple myeloproliferative disorders, including myelofibrosis (MF), polycythemia vera (PV), and essential thrombocytosis (ET). SAR302503 is now in Phase III, being investigated in the JAKARTA trial for the treatment of primary and secondary myelofibrosis. Enrollment in this study has been completed. The unique ability of SAR302503 to decrease bone marrow fibrosis will be further explored in the JAKARTA trial. In addition, a Phase II study in MF has recently been completed and results were presented at the December 2012 conference of the American Society of Hematology (ASH). A trial in myelofibrosis patients who have failed treatment with the JAK2 kinase inhibitor, JAKAFI /JAKAVI , has been initiated and enrollment is ongoing. Also ongoing is a Phase II trial in hydroxyurea-resistant PV and ET.

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 blocks Heregulin binding to ErbB3, and formation of pErbB3 and pAKT. Given SAR256212's mode of action, it has the potential to be used in a wide number of tumors and settings. SAR256212 is in Phase II stage of development in Breast, Lung and Ovarian cancers in order to achieve Proof of Concept of its activity at reversing resistance to hormones, chemotherapy and agents targeting EGFR. During 2012, over 450 patients were enrolled in this phase II program that will complete by the second half of 2013. Biopsies at study entry are being performed for all patients to identify biomarkers predictive of response to MM-121. A companion diagnostic tool will be developed during the clinical program.

In addition, a phase 1 combination of **SAR256212 and SAR245408** has been ongoing throughout 2012 in three U.S. sites, based on the rationale that dual blockade of the PI3K pathway prevents feedback loop for reactivating the pathway. The last dose escalation cohort at full dose of both drugs will start in January 2013; so far the safety of the 2 agents together is excellent with no DLTs reported.

SAR245408 (XL147) was in-licensed from Exelixis, Inc. and is being developed by Sanofi. This oral phosphoinositide-3-kinase (PI3K) inhibitor is under evaluation in a Phase Ib study in combination with MM121 (see above) and a Phase II study in patients with hormone receptor positive breast cancer in combination with letrozole. Development in endometrial cancer has been discontinued due to insufficient evidence of activity. Development of the combination of SAR245408 in combination with pimasertib (also known as MSC1936369B) in Phase 1b (under collaboration with Merck Serono, a division of Merck KGaA, Darmstadt, Germany) was discontinued in order to focus on the SAR245409 pimasertib combination.

SAR245409 (XL765) was also 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. As indicated above, a

Phase I trial of a novel combination with MSC1936369B (under collaboration with Merck Serono, a division of Merck KGaA, Darmstadt, Germany) is ongoing. Combinations with bendamustine and rituximab are also being evaluated. Development in metastatic hormone-receptor-positive breast cancer has been discontinued due to insufficient evidence of activity.

SAR3419 (Antibody Drug Conjugate (ADC) maytansin-loaded anti-CD19 mAb; B-cell malignancies: B-Non Hodgkin's Lymphomas (NHL), B-Acute Lymphoblastic Leukemias (ALL). License from Immunogen Inc.). The clinical development program is in the Phase II stage in 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). A second indication is being developed with a Phase II study in adult patients with R/R ALL.

Three further projects (semuloparin, ombrabulin and clofarabine) that were under regulatory review and in Phase III respectively in 2012, have experienced the following changes:

Semuloparin: Following the June 20, 2012 semuloparin data review by the FDA Oncologic Drugs Advisory Committee, and its vote against the approval of semuloparin for prophylactic prevention of venous thromboembolism (VTE) in cancer patients undergoing chemotherapy, as well as other comments released by some regulatory authorities, Sanofi has decided to withdraw all applications concerning semuloparin.

Ombrabulin (AVE8062) combretastatin derivative, a new anti-vascular agent in-licensed from Ajinomoto; sarcoma; Phase III). The ombrabulin project has been discontinued for the following reasons: the results of the phase III study in sarcoma which despite reaching its primary PFS (progression free survival) endpoint, did not demonstrate sufficient clinical benefit to support regulatory submissions; the negative outcome of a phase II trial in NSCLC; and the early termination of the phase II study in ovarian cancer based on the results of a pre-specified interim analysis. In all these trials there were no substantial safety concerns.

Clofarabine (Clolar® / Evoltra®) (Genzyme) (Purine-nucleoside analog). No additional indications are being developed via corporate-sponsored studies for clofarabine in either i.v. or oral formulations, although investigator-initiated studies are continuing.

Other Prescription Products

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.

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

In 2012, Lovenox® was the leading anti-thrombotic in Germany, France, Italy, Spain, and the United Kingdom (source: IMS 2012 sales).

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 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 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 acetylsalicylic acid (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 BMS which was restructured in 2012 with effect on January 1, 2013 (see "Item 5 Alliance Arrangements with Bristol-Myers Squibb"). Sales of Plavix® in Japan are outside the scope of our alliance with BMS. Exclusivity for Plavix® in the U.S. expired on May 17, 2012 and a number of generics have been launched. Previously, generics had also been launched in Europe.

Plavix® is the leading anti-platelet in the Chinese and Japanese markets (source: IMS 2012 sales).

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/sub-licensed to Shionogi Co. Ltd and Dainippon Sumitomo Pharma Co. Ltd, respectively. Aprovel® U.S. market exclusivity expired in March 2012 and a number of generic versions have been launched.

Multaq®

Multaq® (dronedarone) is the most extensively studied anti-arrhythmic drug (AAD) in Atrial Fibrillation (AF) and has demonstrated a unique cardiovascular (CV) outcome benefit in the ATHENA study in addition to effective rhythm control in the EURIDIS and ADONIS studies.

Multaq® is a multichannel blocker with both rhythm (prevention of atrial fibrillation 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 cardiovascular hospitalization and death in patients with paroxysmal and persistent Atrial Fibrillation/Atrial Flutter .

Following reports in January 2011 of hepatocellular liver injury and hepatic failure in patients receiving Multaq®, including two post-marketing reports of acute hepatic failure requiring transplantation, Sanofi has collaborated with health authorities agencies to update prescribing information and include liver function monitoring. Sanofi coordinated the implementation of the updated label by disseminating proactively relevant educational materials to prescribers.

The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) confirmed in September 2011 that the benefits of Multaq® continue to outweigh the risks with a revised indication for the treatment of a limited, newly defined population: Multaq® is indicated for the maintenance of sinus rhythm after successful cardioversion in adult clinically stable patients with paroxysmal or persistent atrial fibrillation. Due to its safety profile, Multaq® should only be prescribed after alternative treatment options have been considered and should not be given to patients with left ventricular systolic dysfunction or to patients with current or previous episodes of heart failure.

The FDA approved a label update in December 2011 to ensure its use in the appropriate patient population, specifically in patients in sinus rhythm with history of paroxysmal or persistent atrial fibrillation (AF), and also reinforcing warnings and precautions for use.

In Europe, updated guidelines were issued by the European Society of Cardiology (ESC) confirming Multaq®'s crucial role in the AF treatment armamentarium as a first line option in a broad range of patients. Multaq® is the only recommended first line AAD for AF patients with hypertensive heart disease and left ventricular hypertrophy. Multaq® is still the only AAD recommended in non-permanent AF with CV risk factors to reduce CV hospitalization.

The main countries contributing to Multaq® sales in 2012 were the U.S., Germany and Italy.

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 EU and 65,000 in Brazil. In the EU, 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, Genzyme and generic manufacturers have settled pending litigation with regard to the production and sale of generic formulations of Renvela® tablets, Renvela® for oral suspension and Renagel®. According to the terms of the settlements, the first-filer for each product can enter the U.S. market on March 16, 2014 and second-filers can enter the market on September 16, 2014, or earlier under certain circumstances, pending approval of their generic application.

The top five countries contributing to the sales of Renagel® and Renvela® in 2012 were the U.S., Italy, France, the UK, and Brazil.

Synvisc®/Synvisc-One®

Synvisc® and Synvisc-One® (hylan G-F 20) are viscosupplements used to treat pain associated with osteoarthritis of certain joints. Synvisc is indicated for the treatment of pain associated with osteoarthritis 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. 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.

Synvisc® and Synvisc-One® are primarily marketed through Sanofi's employee sales force directly to physicians, hospitals, and pharmacies, while in some countries the products are still promoted by independent distributors.

In 2012, Sanofi initiated a pivotal clinical trial of Synvisc-One® for treatment of pain associated with mild to moderate primary osteoarthritis of the hip. The trial is a double-blind, randomized, placebo-controlled study in 350 patients recruited from 26 sites in the United States.

In 2012, the top five countries contributing to Synvisc® and Synvisc-One® sales were the U.S., Canada, France, Mexico and Germany.

LeGoo®

At the end of 2012, Sanofi launched LeGoo®, a gel for temporary endovascular occlusion of blood vessels during surgical procedures in the U.S. LeGoo® is an innovative technology that is expected to enhance the Sanofi Biosurgery portfolio.

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.

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.

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 all types of epileptic seizures and epileptic syndromes, and is generally well tolerated. Consequently, Depakine® remains a reference treatment for epilepsy worldwide.

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

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 Intellijject,Inc.

Main compounds currently in Phase II or III clinical development:

In the Metabolic field:

Phase II results for **SAR236553**, co-developed with Regeneron (REGN727: anti-PCSK9 mAb), have been obtained confirming a significant reduction in mean LDL-C by 40% to 72% over 8 to 12 weeks in patients with elevated LDL-C in patients on stable dose of statins.

A large phase III clinical program has been initiated (11 trials, 22,000 patients), and the first results are expected during the third quarter of 2013.

In the Ophthalmology field:

Sanofi started establishing its footprint in ophthalmology through the acquisition of Fovea, a French ophthalmology specialist (in October 2009), the ophthalmology assets of Genzyme (acquired in 2011), and a collaboration agreement with Oxford BioMedica (April 2009) that led to the exercise of two opt-in options in August 2012.

One project in Phase II (**FOV2304** eye-drop formulation of a bradykinin B1 receptor antagonist evaluated in diabetic macular edema) was discontinued in October 2012, and the review of Phase IIb results for **FOV-1101** (eye-drop fixed dose combination of prednisolone acetate and cyclosporine A for the treatment of allergic conjunctivitis) led to a reassessment of the commercial prospects for this compound and a decision to continue development under a sublicense agreement with an as yet unidentified third party.

In the Thrombosis and Cardiovascular field:

Otamixaban (direct factor Xa inhibitor, interventional cardiology; Phase III). Otamixaban is an injectable, selective direct inhibitor of coagulation factor Xa. It is a synthetic small molecule. Otamixaban exhibits a fast on- and off-set of action. A Phase III program to confirm the positive outcome from the SEPIA-ACS Phase II study was initiated in 2010 and is now ongoing; results are expected in the 2nd quarter of 2013.

In the Internal Medicine field:

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 is underway with three ongoing clinical studies:

SARIL-RA-MOBILITY study, investigating the effects of sarilumab, (when added to Methotrexate (MTX) in patients with active RA who are inadequate responders to MTX therapy), on the reduction of signs and symptoms of rheumatoid arthritis at 24 weeks, inhibition of progression of structural damage at 52 weeks and improvement in physical function over 52 weeks;

SARIL-RA-TARGET study, investigating the effects of Sarilumab when added to DMARD 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;

SARIL-RA-EXTEND study, which is enrolling participants by invitation from currently ongoing studies and aims to evaluate in this uncontrolled extension the long term safety and efficacy of Sarilumab on top of DMARDs in patients with active RA.

Additional studies in the SARIL-RA phase III clinical program are to be implemented in 2013.

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. Asthma will enter Phase IIb in 2Q2013. The asthma PoC study results demonstrated broader efficacy (exacerbations, lung function and symptoms) than the competition. Atopic dermatitis will also enter Phase IIb in 2Q2013. The atopic dermatitis PoC study results demonstrated improvement in signs and symptoms of active disease, with very effective and rapid onset of action compared to systemic therapies currently used in AD.

Consumer Health Care (CHC)

Consumer Health Care is a growth platform identified in our broader strategy. In 2012, we recorded CHC sales of €3,008 million, an increase of 9.9%. Nearly half of our CHC sales were in emerging markets, 22% in Europe, and 21% in the United States.

In March 2011, the Allegra® family of allergy medication products was commercially launched in the U.S. for over-the-counter (OTC) use in adults and children two years of age and older. The Allegra® family of OTC products is available in drug, grocery, mass merchandiser, and club stores nationwide. In November 2012, Sanofi launched Allegra® OTC in Japan, for patients suffering allergic rhinitis (15 years and older).

CHC sales are also supported by our legacy CHC brands, which provide us with a strong presence in the fever & pain and digestive health areas.

Doliprane® is a range of paracetamol formulas to fight pain and fever. Thanks to a wide offer both in terms of dosages (from 2.4% paracetamol suspension up to 1g formulas) and pharmaceutical forms (suspension, tablets, powder, suppositories), Doliprane® covers the needs of patients from baby to elderly. Doliprane® is sold mainly in France and in some African countries.

NoSpa® is a product containing drotaverine hydrochloride. NoSpa® is indicated in abdominal spastic pain such as intestinal spasm, menstrual pain, or vesical spasm. NoSpa® is sold mainly in Russia and Eastern Europe.

Enterogermina® is composed of two billion Bacillus clausii spores in a ready-to-drink oral suspension in vials of 5ml and in capsules. Enterogermina® is indicated in the prevention and the treatment of intestinal imbalance during acute or chronic intestinal disorders (from babies to adults). Enterogermina® is sold mainly in Europe and has been enjoying strong growth in Latin America, India and Central Asia.

Essentiale® is a herbal preparation for liver therapy, made of highly purified essential phospholipids extracted from soybeans and containing a high percentage of phosphatidylcholine, a major constituent of cellular membrane. Essentiale® is used to treat symptoms such as lack of appetite, sensation of pressure in the right epigastrium, toxico-nutritional liver damage and hepatitis. Essentiale® is sold mainly in Russia, Eastern Europe, and some South East Asian countries.

Maalox® is a well-established brand containing two antacids: aluminium hydroxide and magnesium hydroxide. Maalox® is available in several pharmaceutical forms tablets, suspension, and stick packs to provide consumer choice. Maalox® is present in 55 countries: in Europe, Latin America, Russia, Africa, Middle East, and in some Asian countries.

Magne B6® is a product containing magnesium and vitamin B6. MagneB6® has various therapeutic indications from irritability, anxiety and sleep problems to women's health issues like premenstrual syndrome or menopause discomfort. MagneB6® is present in Europe and Russia.

Lactacyd® is a range of products for feminine hygiene. Lactacyd® is sold mainly in Brazil and Asia. Lactacyd® was launched in China in May 2011.

Complementary to our legacy CHC business, our other products include:

Chattem's products in the United States (other than the Allegra® family of OTC products), mainly comprising branded consumer healthcare products, toiletries and dietary supplements across niche market segments. Chattem's well-known brands include Gold Bond®, Icy Hot®, ACT®, Cortizone-10®, Selsun Blue® and Unisom®. In January 2013, Chattem completed the acquisition of the worldwide rights to the Rolaids® brand from McNeil Consumer Healthcare Division of McNeil-PPC, Inc. Rolaids® is an over-the-counter antacid that helps relieve heartburn and acid indigestion.

Oenobiol's products in France: dietary supplements to promote beauty (sun care, weight, hair care, skin care) and well-being (digestive comfort, anti-stress) and to help manage menopausal problems.

BMP Sunstone products in China, including the leading pediatric cough and cold brand Haowawa®.

Minsheng products in China, including 21 Super Vita®, one of the leading vitamins & mineral supplements.

Universal Medicare brands in India, comprising a wide range of nutraceutical and lifestyle management products vitamins, antioxidants, mineral supplements and anti-arthritics such as Seacod®, CoQ®10, Collaflex® and Multivit®.

The top three countries contributing to our CHC sales in 2012 were the United States, France, and Russia.

Generics

In 2012, sales of the generics business reached €1,844 million, an increase of 5.0%. Performance was impacted by lower sales of the authorized generic of Lovenox® in the U.S. and less favorable market conditions in Brazil (heightened competition coupled with once-off tax

changes in Sao Paulo State which influenced the generics market).

In Latin America, Medley®, Sanofi's Brazilian brand of affordable medicines, was rolled out in Mexico and Venezuela at end of 2011 and in Colombia and Central America during 2012. In October 2012, Sanofi announced that it had signed an agreement to acquire Genfar S.A., a leading pharmaceuticals manufacturer headquartered in

Bogota, Colombia, and a major player in Colombia and the other countries in Latin America. The closing of the transaction is subject to certain conditions precedent and is expected to occur in the first quarter of 2013.

In 2012, Sanofi sales of generic products in Emerging Markets exceeded €1 billion. See "Item 5. Operating and Financial Review and Prospects Results of Operations Year Ended December 31, 2012 Compared with Year Ended December 31st, 2011 Net Sales by Product Pharmaceuticals segment".

In March 2009 we created our European Generics Platform, covering generics activities across Western and Eastern Europe, Russia and Turkey. The rebranding of Sanofi Generics activities under the Zentiva® brand in Western Europe, initiated in 2010, is nearly complete.

Vaccine Products

Sanofi Pasteur is a fully integrated vaccines division offering a broad range of vaccines. In 2012, Sanofi Pasteur provided more than 1 billion doses of vaccine, making it possible to immunize more than 500 million people across the globe against 20 serious diseases, and generated net sales of €3,897 million. Sales were favorably impacted by strong growth in markets outside North America and Europe, including sales of the IPV (inactivated polio vaccine) Imovax® Polio in Japan, continued growth of Pentaxim® sales and successful seasonal influenza vaccine campaigns in both the Northern and Southern hemispheres. See "Item 5. Operating and Financial Review and Prospects Results of Operations Year Ended December 31, 2012 Compared with Year Ended December 31, 2011 Net Sales Human Vaccines (Vaccines) segment."

Sanofi Pasteur is a world leader in the vaccine industry in terms of sales. In the United States, Sanofi Pasteur is the market leader in the segments where we compete (source: based on internal estimates).

In Europe, Sanofi Pasteur vaccine products are developed and marketed by Sanofi Pasteur MSD, a joint venture created in 1994 and held equally by Sanofi Pasteur and Merck & Co. Inc., which serves 19 countries. Sanofi Pasteur MSD also distributes such Merck & Co. vaccine products as Gardasil® and Zostavax®, in the joint venture's geographic scope. In 2012, Sanofi Pasteur MSD net sales, which are accounted for using the equity method, amounted to €845 million.

Sanofi Pasteur has been expanding in Asia (China, India and Japan), Latin America (Mexico and Brazil), Africa, the Middle-East and Eastern Europe. Sanofi Pasteur is very active in publicly-funded international markets such as UNICEF 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 shows net sales of vaccines by product range:

	2012
(€ million)	**Net Sales**
Polio/Pertussis/Hib Vaccines	1,184
Influenza Vaccines *	884
Meningitis/Pneumonia Vaccines	650
Adult Booster Vaccines	496
Travel and Other Endemics Vaccines	364
Other Vaccines	319
Total Human Vaccines	**3,897**

* *Seasonal and pandemic influenza vaccines.*

Pediatric, Combination and Poliomyelitis (Polio) Vaccines

These vaccines vary in composition due to diverse immunization schedules throughout the world.

Sanofi Pasteur is one of the key players in pediatric vaccines in both emerging and mature markets with a broad portfolio of standalone and combination vaccines protecting against up to six diseases in a single injection.

Pentacel®, a vaccine protecting against five diseases (pertussis, diphtheria, tetanus, polio and *Haemophilus influenzae* type b), was launched in the United States in 2008.

Pediacel®, a fully liquid pentavalent vaccine, has been the standard of care in the United Kingdom since 2004 for protecting against diphtheria, tetanus, pertussis (whooping cough), polio and *Haemophilus influenzae* type b infections. As of December 31, 2011, Pediacel® was approved in 29 countries across Europe in a new syringe presentation.

Pentaxim®, a combination vaccine protecting against diphtheria, tetanus, pertussis, polio and *Haemophilus influenzae* type b, was first marketed in 1997 and was launched in China in May 2011. To date, more than 150 million doses of Pentaxim® have been distributed in over 100 countries, and the vaccine has been included in the national immunization programs in more than 23 countries.

Act-HIB®, for the prevention of *Haemophilus influenzae* type b (Hib) infections, 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.

Hexaxim® is the only fully liquid, ready to use 6-in-1 (hexavalent) pediatric vaccine providing protection against diphtheria, tetanus, pertussis, polio, *Haemophilus influenzae* type b infections and hepatitis B. In June 2012, Sanofi Pasteur received a positive scientific opinion for Hexaxim® from the European Medicines Agency (EMA) as part of the Article 58 procedure designed to evaluate medicinal products intended for international markets outside the European Union. As a second step, to ensure continuity of supply as well as expanded access to hexavalent vaccines throughout the 27 E.U. member states, the vaccine was submitted to the European Medicines Agency for license review in Europe. In February 2013, the EMA recommended market approval for the 6 in 1 pediatric vaccine. This innovative vacine will be 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.

PR5I is a combination vaccine designed to help protect against six diseases: diphtheria, tetanus, pertussis, polio (poliovirus type 1, 2 and 3), invasive disease caused by *Haemophilus influenzae* type b, and hepatitis B. This product is jointly being developed between Sanofi Pasteur and Merck in the U.S. and Europe. Phase III studies in the U.S. and Europe began in April 2011.

Sanofi Pasteur is one of the world's leading developers and manufacturers of polio vaccines, in both oral (OPV) and enhanced injectable (eIPV) form. The worldwide polio eradication initiative led by the World Health Organization (WHO) and UNICEF has positioned Sanofi Pasteur as a global preferred partner with both OPV and eIPV vaccines.

Sanofi Pasteur is also supporting the introduction of eIPV internationally. With recent progress towards polio eradication in countries such as Brazil and Japan in 2012, Sanofi Pasteur expects the use of eIPV to gradually increase. 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, hepatitis B and *Haemophilus influenzae* type 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 back to obtaining prequalification status has been discussed extensively with the WHO and local Indian regulators. Based on the successful completion of clinical studies, Shan5® is expected to regain WHO prequalification in 2014.

Influenza Vaccines

Sanofi Pasteur is a world leader in the production and marketing of influenza vaccines. Sales of the influenza vaccines Fluzone® and Vaxigrip®/Mutagrip® have more than tripled since 1995 and annual supply reached more than 200 million doses in 2012 to better meet increasing demand. In recent years, influenza vaccine demand has experienced strong growth in many countries, particularly in the U.S., Brazil and Mexico. Sanofi Pasteur expects

the global demand for influenza vaccines to continue to grow within the next decade due to increased disease awareness, growth in emerging markets and wider government immunization recommendations.

Sanofi Pasteur remains focused on maintaining its leadership in the influenza market and on meeting the increasing demand for both pandemic and seasonal influenza vaccines through the launch of innovative vaccines.

In 2012, Sanofi Pasteur expanded its launch of Fluzone® ID in the U.S. in adults. The advantages of this vaccine are particularly its convenience and ease of administration. Fluzone ID® and Intanza®/IDflu® vaccines are now approved in the United States, European Union, Canada, Australia and other countries for the prevention of seasonal influenza in adults from 18 to 64 years of age.

Fluzone® High-Dose vaccine, launched in the United States in 2010, was specifically designed to generate a more robust immune response against influenza in people 65 years of age or older. This age group, which typically shows a weaker immune response, has proven to respond better to the Fluzone® High-Dose vaccine. It continued its strong growth in 2012.

Fluzone® QIV candidate vaccine is a quadrivalent inactivated influenza vaccine containing two antigens of type A (H1N1 and H3N2) and two antigens of type B (one each from Yamagata and Victoria lineage). Selecting the prevailing influenza strains for upcoming seasons is an incredibly difficult task. In the recent past, there have been a number of mismatches of the B strain component in the trivalent vaccine compared with the circulating B lineage. Sanofi Pasteur expects that increasing the number of strains in the vaccine will give increased protection against the most prevalent strains. Sanofi Pasteur filed a supplemental Biologics License Application (sBLA) with the FDA for Fluzone® QIV in October 2012. The sBLA file has been accepted by the FDA for full review, and an action date is anticipated in the second quarter of 2013.

Adult and Adolescent Boosters

Pertussis (whooping cough) affects children, adolescents and adults. Resurgence, in particular in the U.S. and other parts of the world, combined with increased awareness of the dangers of vaccine-preventable diseases in general, has led to higher sales of 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 United States in 2005. 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 50 countries.

Quadracel®, a quadrivalent booster vaccine (fifth dose) including diphtheria, tetanus, acellular pertussis and IPV, is being developed for the U.S. market. It would allow a child to complete the entire childhood series with the fewest doses possible. It is currently in Phase III trials.

Meningitis and pneumonia vaccines

Sanofi Pasteur is at the forefront of the development of vaccines to prevent bacterial meningitis. In 2005, Sanofi Pasteur introduced Menactra®, the first conjugate quadrivalent vaccine against meningococcal meningitis, considered by many as the deadliest form of meningitis in the world. By April 2011, the FDA had granted Sanofi Pasteur a license to expand the indication of Menactra® to children as young as 9 months of age. Menactra® is now indicated for people aged 9 months through 55 years in the United States, Canada, Saudi Arabia and numerous other countries in Latin America, the Middle East and Asia Pacific regions.

Meningitis A, C, Y, W-135 conj. Second Generation is a project targeting a second generation meningococcal vaccine that uses an alternative conjugation technology. In 2011, interim Phase II clinical trial results were obtained and indicated that the product is sufficiently immunogenic for further development in infants.

Travel and Endemics Vaccines

Sanofi Pasteur provides a wide range of travel and endemic vaccines including hepatitis A, typhoid, rabies, yellow fever, cholera vaccines and anti-venoms. These vaccines are used in endemic settings in the developing

world and are the basis for important partnerships with governments and organizations such as UNICEF. They are also used by the military and travelers to endemic areas. As the global leader in the majority of these vaccine markets, Sanofi Pasteur's Travel/Endemics activity has demonstrated stable growth.

IMOJEV , a Japanese encephalitis vaccine, is also in development. The Australian healthcare authorities granted approval of the latest variations of the IMOJEV file on September 24, 2012 for individuals aged 12 months and over, followed by the Thai Food and Drug Administration on November 14, 2012. IMOJEV has now been launched in these two countries.

A new generation Vero serum-free vaccine (VerorabVax) will provide a worldwide, single rabies vaccine as a replacement to our current rabies vaccine offerings. Results from the 2009 Phase II clinical trial demonstrated non-inferiority of VRVg versus Verorab® in pre-exposure prophylaxis. VRVg was approved in France as a line extension of VeroRab in January 2011 and clinical development is finalized in China with completion of Phase III confirming non-inferiority vs. Verorab® in simulated post-exposure prophylaxis.

In December 2009, Shantha launched ShanChol™, India's first oral vaccine to protect against cholera in children and adults. ShanChol was World Health Organization pre-qualified in 2011 and more than 1 million doses of ShanChol™ were sold worldwide in 2012.

Other Products

Sanofi Pasteur acquired Topaz Pharmaceuticals in October 2011. The integration of Topaz was completed in 2012. The FDA licensed Sklice® (ivermectin) lotion, 0.5%, on February 7, 2012 as a one-time treatment for head lice in persons aged 6 months and older, and commercial launch commenced in July 2012.

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. It 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 2012 amounted to €2,179 million.

Merial became Sanofi's dedicated animal health division following the joint statement issued by Merck and Sanofi in March 2011 announcing the end of their agreement to create a new animal health joint venture by combining their respective animal health segments. Consequently all Merial financials are consolidated in Group reports. 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, protects 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).

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 at the latest 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), expiring March 2018. As for human

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

As regards regulatory exclusivity, the position of veterinary medicinal products in Europe is similar to that of human pharmaceutical products: eight-year data exclusivity and ten-year market exclusivity. In the United States, there is ten-year data exclusivity for products approved by the Environmental Protection Agency and an additional five years during which a generic applicant has to compensate the originator if it cites the originator's data. For FDA approved veterinary medicinal products, a regulatory exclusivity period of five years is granted for a new chemical entity and three years for a previously-approved active ingredient. No data exclusivity exists at present for veterinary vaccines in the United States.

In April 2012, Merial acquired Newport Laboratories (Newport), a privately held company based in Worthington, Minnesota (United States), a leader in autogenous vaccines with a focus on swine and bovine production markets.

On December 20, 2012, Merial entered into a binding agreement to acquire 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. The agreement is subject to regulatory approval and is expected to finalize sometime in the first half of 2013.

The 2012 performance of the companion animals franchise was driven by the growth of pet vaccines worldwide and by the performance of Heartgard® in the U.S. For production animals, the performance was mainly driven by the avian segment (notably Vaxxitek®) and the swine segment, thanks to Circovac® sales and the acquisition of Newport.

Merial's major markets are the United States, France, Brazil, Italy, the United Kingdom, Australia, Germany, Japan, Spain, China, and Canada. Emerging Markets contributed double digit sales growth in 2012, and now account for 26.6% of total Merial sales.

Merial operates through a network of 17 production sites, with major sites located in France, the United States, Brazil and China. The major R&D sites are located in France and in the United States. Merial employs approximately 6,060 people worldwide (see Item 4D "Property, Plant & Equipment").

Global Research & Development

The mission of Sanofi's Global Research & Development organization is to discover and develop therapies that prevent, treat and cure diseases. Our day-to-day commitment is to respond to patients' real needs and to provide them with adapted therapeutic solutions in order to improve their well-being and extend their life.

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 trends and the most pressing health needs.

These include:

Diabetes. Diabetes is 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 subjects 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 health care systems all over massive costs.

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 Multiple Sclerosis).

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 cope with the growing needs of 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, people predominantly die of 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.

Vaccines. See " Vaccines Research and Development" 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.

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.

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 decentralized organization, consisting of two divisions (Oncology and Diabetes), five therapeutic Units (TSUs), several Distinct Project Units (DPUs) and five Scientific platforms, responsible for the operational aspects of development.

Genzyme R&D, which has strong expertise in rare diseases, is now fully integrated into Sanofi Pharma R&D. It consists of two different departments covering early and late stage products (according to the development phase of each project).

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 are constantly adapting our R&D approach, combining global and local action, leveraging local innovative research ecosystems and global high quality development capabilities in order to achieve the greatest possible impact.

We are creating geographically-focused integrated research innovation centers also called "hubs" in four areas: North America, Germany, France and Asia. In the Boston area (United States), which has a high concentration of universities and innovative biotechnology companies, our R&D has been reorganized to support the increasing presence of the Group.

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.

Portfolio

As in 2011, 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 include:

- relative medical value: which encompasses the extent of the unmet need, the market dynamics and the likelihood of achieving the desired price and reimbursement based on the health authorities' positioning and Sanofi competencies.

- 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 research and development or through acquisitions and strategic alliances." our product development efforts are subject to the risks and uncertainties inherent in any new product development program.

The clinical portfolio for new medical entities can be summarized as follows:

	Phase I	Phase II	Phase III /registration
Diabetes Solutions			lixisenatide(AVE0010)
Cardiovascular diseases	SAR164653 GZ402669 SAR126119 SAR127963		SAR236553 mipomersen otamixaban(XRP0673)
Oncology	SAR125844 SAR153192 SAR260301 SAR307746 GZ402674 SAR405838 SAR566658 SAR650984	SAR245408 SAR245409 SAR256212 SAR3419	iniparib(BSI-201) SAR302503
Immune Mediated diseases (including MS)	SAR100842 SAR113244 SAR252067	SAR156597 SAR339658 dupilumab	alemtuzumab teriflunomide sarilumab(SAR153191)
Age related degenerative diseases	SAR228810 SAR391786 SAR399063 SAR404460	SAR110894 SAR113945 SAR292833	
Infectious Diseases		ferroquine SAR97276 SAR279356	
Rare Diseases	GZ402665 GZ402671 GZ404477		eliglustat tartrate
Ophtalmology	GZ402663 StarGen UhsStat RetinoStat®	FOV1101	

Phase I studies are the first studies performed in humans, in 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 made to provide an adequate basis for registration.

Our Phase II & III compounds are described in the section " Pharmaceutical Products Main Pharmaceutical Products" above. A table summarizing selected key facts concerning our late stage experimental pharmaceutical products follows, at the end of this section.

The remainder of this section focuses on compounds entering Phase I or in Phase II and also lists projects that were terminated in 2012.

Diabetes/Other Metabolic Disorders portfolio

SAR164653, an inhibitor of Cathepsin A, entered Phase I development. The product is being developed to prevent heart failure for patients having experienced episodes of acute heart failure.

The network of R&D collaborations with world leading academic institutions was significantly extended in 2012. A collaboration with the Charité in Berlin that began in 2010 was further extended to include Diabetes as an additional focus. In addition we entered into a research alliance with the Helmholtz Zentrum in Munich, and a new collaboration with the Joslin Diabetes Center (affiliate of Harvard Medical School) was formed to promote the development of new medicines for the treatment of diabetes and related disorders.

Oncology portfolio

Two compounds, SAR260301 (PI3Kβ selective inhibitor) and SAR405838 (P53/HDM2 antagonist) were added to the Sanofi Phase I pipeline.

GC 1008, an anti-TGFß monoclonal antibody, is not being further developed for oncology indications via corporate-sponsored studies, although investigator-initiated studies are continuing.

In 2012, we established further collaborations with other companies, universities and institutes to investigate novel oncology agents with partners including the Massachusetts General Hospital (MGH) in the United States and the Institut Gustave-Roussy (IGR) in France.

Sanofi Genzyme early stage portfolio

rhASM Enzyme replacement therapy targeting the treatment of Niemann-Pick B disease. A Phase Ib study should start early 2013.

Fresolumimab TGF-ß antagonist targeting the treatment of Focal Segmental Glomerulosclerosis (FSGS). The Phase II program was launched early 2013.

AAV-AADC Gene therapy based on AAV vector targeting the treatment of moderate to severe Parkinson's disease. Phase I is to be completed.

SAR339658 (also known as 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.

TSU Aging portfolio

Two compounds have completed their Phase II clinical program with data analysis ongoing:

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

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

One compound has progressed into phase II clinical development:

SAR292833 GCR-15300, licensing agreement with Glenmark Pharmaceutical (TRPV3 antagonist for the oral treatment of chronic pain).

Two compounds have entered Phase I clinical development:

SAR228810 (anti-protofibrillar AB mAb for the treatment of Alzheimer's dementia).

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

One nutraceutical project has entered a clinical program:

SAR399063 (DHA-GPL & Vit D) for the treatment of sarcopenia.

Three compounds have entered preclinical development:

SAR396049 (CDRAP-MIA in osteoarthritis), licensing agreement with SCIL.

SAR244181 (P75 dimerization inhibitor in Overactive Bladder).

SAR296968 (NCX inhibitor in Chronic Heart Failure).

Two compounds have been terminated:

SAR114137 (CathepsinS/K inhibitor for the oral treatment of chronic pain).

SAR407899 (Rho-Kinase inhibitor).

Discovery/development partnerships:

The agreement with Audion Therapeutics (research in hearing disorders) has been terminated.

An agreement was signed in March 2012 with CNRH, INRA, ASL, 3iNature (Biotechs in Auvergne, France) on the development of products for treatment of sarcopenia.

TSU Infectious Diseases portfolio

Ferroquine/OZ439 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. Ferroquine is active against chloroquine-sensitive and chloroquine-resistant Plasmodium strains, and due to its long half-life has the potential to be part of single dose cure regimens and the unified global treatment of both vivax and falciparum malaria.

OZ439 is a synthetic peroxide antimalarial drug candidate from MMV designed to provide a single dose oral cure in humans. An IND was filed with the FDA in November 2012 and a phase I study of combinations of the two compounds is planned to start in February 2013.

SAR279356 (first-in-class human monoclonal antibody for the prevention and treatment of *S. aureus, S. epidermidis, E. coli, Y. pestis* and other serious infections) The option to acquire an exclusive worldwide license from Alopexx Pharmaceuticals LLC for the development and commercialization of SAR279356 was exercised in October 2010. Following the successful completion of a Phase I study in early 2011, a Phase II PK/PD study was initiated. This study was terminated in 4Q2012 in favor of a revised development plan to include more extensive preclinical credentialing prior to conduct of a future phase II proof of concept study.

SAR97276 (in licensed from CNRS) is an antimalarial drug belonging to a new chemical class with an innovative mechanism of action, being developed for the treatment of severe malaria. Clinical development of monotherapy treatment is on hold while the potential for the product as a combination therapy with other antimalarials is evaluated.

The Sanofi Fovea ophthalmology pipeline now includes four projects in clinical-stage development:

sFlt01 (Phase I): a gene therapy to deliver 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® (Phase I): a gene therapy to treat wet Age-related Macular Degeneration (AMD);

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

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

Other Projects portfolio

The Phase I program for **SAR126119**, an injectable synthetic inhibitor of TAFI (thrombin-activable fibrinolysis inhibitor) has been successfully conducted. We are looking for a partnership to pursue the development of this molecule and set up a phase II study in the treatment of acute ischemic stroke (AIS).

The development of **SSR411298** (an oral fatty acid amide hydrolase (FAAH) inhibitor) as a treatment of chronic pain in cancer patients has been discontinued in light of our positioning in pain treatment and the priorities for our R&D portfolio.

R&D expenditures for late stage development

Expenditures on research and development amounted to €4,922 million in 2012, of which €4,219 million in the Pharmaceuticals segment, €539 million in Human Vaccines and €164 million in Animal Health. Research and development expenditures were the equivalent of 14.1% of net sales in 2012, compared to 14.4% in 2011, 14.1% in 2010 and 15.5% in 2009. The stability of R&D expenditure as a percentage of sales over the past three years is explained by the management of the portfolio and close control over expenditures, despite the increasing proportion of products in late stage development. Preclinical research in the Pharmaceuticals segment amounted to €1,038 million in 2012, compared to €1,113 million in 2011 and €1,037 million in 2010. Of the remaining €3,181 million relating to clinical development in the pharmaceutical sector (€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 late stage compounds in the Pharmaceutical segment that were in Phase III in 2012, 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, and 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]	May 2008 [4]	2020	2020	2020	Dossier approved in Europe in February 2013 and submitted in the U.S. in December 2012. The FDA accepted the file for review on February 19, 2013
Zaltrap® (aflibercept)	July 2006	2020	2020	2020	2nd line colorectal cancer, approved and launched in the U.S. in August 2012, and approved in the E.U. in February 2013
iniparib (BSI-201)	June 2009	2013	2014	N/A	Phase III program ongoing in 1st line squamous Non Small Cell Lung Cancer Phase II program in 2nd line ovarian cancer ongoing

Phase III	Entry into Phase III [1] (month/year)	Compound Patent Term [2] U.S.	E.U.	Japan	Comments
otamixaban	April 2010	2016	2016	2016	Phase III results in Acute Coronay Syndrome (ACS) expected in the second quarter of 2013
Aubagio® (teriflunomide) [3]	September 2004	2014	expired	expired	In the monotherapy treatment of multiple sclerosis, dossier approved in September 2012 in the U.S., launched in October and submitted in February 2012 in Europe.
SAR236553 (REGN727) (anti PCSK-9 mAb)	July 2012	2029	2029	2029	Phase III program on going in hypercholesterolemia
SAR302503 (TG101348)	January 2012	2026	2026 [3]	2026 [3]	Phase III program ongoing in the treatment of myelofibrosis
Lemtrada (alemtuzumab)	September 2007 (MS)	2015 [5]	2014	expired	Dossier submitted in Europe and U.S. for the treatment of relapsing forms of Multiple Sclerosis in May and November 2012, respectively
New formulation Insulin glargine	December 2011	2015 [6]	2014	2014	Phase III program ongoing
Kynamro (mipomersen) [3]	August 2007	2025	pending	2023	Dossier submitted in July 2011 in Europe and approved in the U.S. on January 29, 2013 in the treatment of homozygous familial hypercholesterolemia (HoFH)
eliglustat tartrate	September 2009	2022	2022	2022	Phase III program ongoing in the treatment of Gaucher Disease type 1
sarilumab	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) *Development of lixisenatide as stand alone entity. A program evaluating the benefit of a combination of lixisenatide / Lantus® is in development.*

(5) *Regulatory exclusivity: May 2013.*

(6) Including a 6-month pediatric extension.

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.

Vaccines Research and Development

Our human vaccine research and development (R&D) remains focused on improving existing vaccines, as well as on the development of new prophylactic vaccines.

Portfolio

The Sanofi Pasteur R&D portfolio includes 14 vaccines currently in advanced development as shown in the table below. The portfolio includes five vaccines/antibody products for novel targets and nine vaccines which are enhancements of existing vaccine products.

Phase I	**Phase II**	**Phase III**	**Submitted**
***Streptococcus pneumonia* *** Meningitis & pneumonia vaccine	**Meningitis A,C,Y,W conj. 2nd generation** meningococcal conjugate infant vaccine	**Quadracel®** DTP [(1)] IPV vaccine 4-6 years U.S.	**Hexaxim®/New hexavalent vaccine** DTP-HepB-Polio-Hib vaccine [(1)]
Tuberculosis * Recombinant subunit vaccine	**Rabies VRVg** Purified vero rabies vaccine	**Dengue *** Mild-to-severe dengue fever vaccine	**Fluzone® QIV ID** Quadrivalent inactivated influenza vaccine intradermal
Rotavirus Live attenuated tetravalent rotavirus oral vaccine	**ACAM C. diff *** *Clostridium difficile* Toxoid vaccine	**Fluzone® QIV IM** Quadrivalent inactivated influenza vaccine	
***Pseudomonas aeruginosa* *** Antibody fragment product Prevention of ventilator-associated pneumonia		**Vaxigrip® QIV IM** Quadrivalent inactivated influenza vaccine	
		DTP-HepB-Polio-Hib [(1)] Pediatric hexavalent vaccine	

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

* *New targets*

Project highlights

This section focuses on Phase I compounds and novel targets. Other vaccines in Phase II or III are described in the section " Vaccine Products" above.

Influenza

To sustain our global leadership in the development of influenza vaccine, our R&D efforts are focused on innovative approaches for assessing new formulations and alternative delivery systems, as well as quadrivalent flu vaccine development (see " Vaccine Products").

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, poliomyelitis (polio), *Haemophilus influenzae* type b infections and hepatitis B (see " Vaccine Products").

Meningitis

Neisseria meningitidis bacteria is a leading cause of meningitis in the United States, Europe and elsewhere, affecting infants and children as well as adolescents. The primary focus of several ongoing projects related to Menactra® is to decrease the age at which this vaccine can first be administered. (see " Vaccine Products").

Pneumococcal Vaccine

Streptococcus pneumoniae bacteria is the leading etiological agent causing severe infections such as pneumonia, septicemia, meningitis and otitis media, and is responsible for over three million deaths per year worldwide, of which one million are children. 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 as compared to current polysaccharide or conjugate based vaccines and should not induce nor be sensitive to serotype replacement. Results from the first Phase I clinical trial of a bi-component formulation demonstrated safety and immunogenicity. Results from a second Phase I clinical trial to evaluate a third antigen also demonstrated safety and immunogenicity (ability to induce an immune response). A third Phase I clinical trial of a tri-component formulation began in September 2011 in adults, adolescents, and infants in Bangladesh.

Rabies Vaccine

Rabies mAb Post Exposure Prophylaxis This product consists of two rabies monoclonal antibodies (mAbs) that will be used in association with the rabies vaccine for post-exposure prophylaxis. In 2011, Sanofi Pasteur reviewed the rabies mAb project, developed in partnership with Crucell. Crucell, acquired by Johnson & Johnson in 2011, has taken over full responsibility for the development of the product and Sanofi Pasteur will market it, when the vaccine is available.

New Vaccine Targets

Dengue Dengue fever has increasing epidemiological importance due to global socio-climatic changes. It is a major medical and economic burden in the endemic areas of Asia-Pacific, Latin America and Africa. It is also one of the leading causes of fever among travelers. Multiple approaches have been tested to develop a vaccine covering the four viral serotypes of dengue fever in order to prevent this disease and its severe complications (hemorrhagic fever). Sanofi Pasteur's dengue vaccine research program includes ongoing clinical studies (adults and children) in several countries in endemic regions. The complexity of dengue virus infection has hampered vaccine research for decades and it is the first time in 50 years of dengue research that a vaccine was seen that protected a large group of children from clinical disease caused by dengue viruses. The results of the world's first efficacy study confirmed the excellent safety profile of Sanofi Pasteur's dengue vaccine candidate. The full analysis of vaccine efficacy against each serotype, reflecting real-life conditions (intent to treat analysis) showed vaccine efficacy to be 61.2% against dengue virus type 1, 81.9% against type 3 and 90% against type 4. One of the

dengue virus types (serotype 2) eluded the vaccine. Analyses are ongoing to understand the lack of protection for serotype 2. Phase III efficacy studies are ongoing in several Latin American and South East Asian countries.

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 license from SSI includes access to the Intercell IC31® adjuvant. The candidate vaccine is made up of recombinant protein units. Results from the 2008 Phase I trial found that the H4/IC31 candidate was safe when administered to healthy adults living in a region of high endemic tuberculosis. Rapid and poly-functional antigen-specific T cell responses were induced following a single dose of the investigational vaccine. A second Phase I trial was initiated in Switzerland in December 2010. A Phase I/II study will be initiated in the Republic of South Africa in infants primed with BCG.

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 with Novartis Vaccines, the Bill & Melinda Gates Foundation, the U.S. National Institutes of Health (NIH), the HIV Vaccine Trial Network, and the Military HIV Research Program to substantiate and extend the vector prime/protein subunit boost regimen used in Thailand. Plans are being made to also study the regimen in the Republic of South Africa. 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, Replivax, by participating in international consortium and under the Collaboration for AIDS Vaccine Discovery (CAVD).

ACAM-Cdiff *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 (CDAD) 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 the only vaccine candidate currently in development is ACAM-Cdiff. ACAM-Cdiff is a toxoid-based vaccine. Toxoids have been used as the basis of a number of highly successful licensed vaccines. This vaccine candidate has successfully completed Phase I clinical trials with more than 200 participants in which safety and immunogenicity were evaluated. Sanofi Pasteur received a positive response from the United States FDA's Center for Biologics Evaluation & Research (CBER) on the Fast Track Development Program submission in 2010. In November 2010, our *Clostridium difficile* vaccine started Phase II of clinical study in the U.S. This trial is focused on evaluating prevention of the first episode of *Clostridium difficile* infection (CDI) in at-risk individuals, which includes adults with imminent hospitalization or current or impending residence in a long-term care or rehabilitation facility. Results from the first stage of this study showed the vaccine was safe and immunogenic and provided important information for dose selection. Phase II study results are under review. A multinational Phase III trial is planned to start in the third quarter of 2013.

Pseudomonas aeruginosa In February 2010, Sanofi Pasteur entered into an agreement with KaloBios Pharmaceuticals, a U.S.-based, privately held biotech company, 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 primarily affecting the respiratory system in susceptible individuals and are a serious clinical problem due to their resistance to antibiotics. The two primary target indications for the antibody are prevention of *Pa* associated pneumonia in mechanically ventilated patients in hospitals, and prevention of relapses and potential improvement of treatment outcomes in patients with an ongoing *Pa* infection. Under the terms of the agreement, 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 one in healthy volunteers and one in cystic fibrosis patients and a small proof of concept Phase II clinical trial in mechanically ventilated patients using an *E. coli-derived* antibody fragment. A Phase I study in healthy adult volunteers has been initiated in December 2012 with a Chinese hamster ovary cell-derived antibody fragment.

Rotavirus Rotavirus is the leading cause of severe, dehydrating diarrhea in children aged under five globally. Estimates suggest that rotavirus causes over 25 million outpatient visits, over 2 million hospitalizations and over 500,000 deaths per year. The burden of severe rotavirus illness and deaths falls heavily upon children in the poorer countries of the world, with more than 80% of rotavirus-related deaths estimated to occur in lower income countries of Asia, and in sub-Saharan Africa. Two vaccines (RotaTeq® and Rotarix®) are licensed worldwide, but production of local vaccines is necessary to achieve wide coverage. Shantha has a non-exclusive license of rotavirus strains from the U.S. NIH and is developing a live-attenuated human bovine (G1-G4) reassortant vaccine. The license excludes Europe, Canada, United States, China and Brazil. The project is currently in Phase I/II (dose finding study).

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 chemical entity 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 significant 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 2012, 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.

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 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

56

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 (generally 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-

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 Our Business 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"). Our main products which have received FDA grants of pediatric exclusivity at some point are Aprovel®, Lantus®, Allegra®, Ambien®/Ambien® CR, Plavix®, Taxotere®, and Actonel®.

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 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 or the equivalent of these patents in other countries (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® and Actonel®.

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	Compound: November 2014 in most of Western Europe requests for pediatric exclusivity until May 2015 are pending	Compound: November 2014

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

Taxotere® (docetaxel)

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

Eloxatine® (oxaliplatin) [(1)]

U.S.	**E.U.**	**Japan**
Compound: expired Generics on the market [(2)]	Compound: expired Generics on the market	Compound: N/A [(3)]

(1) *We do not own most Eloxatin® patents but license them from Debiopharm for marketing.*

(2) *See "Item 8 A. Consolidated Financial Statements and Other Financial Information Patents Eloxatin® (oxaliplatin) Patent Litigation".*

(3) *No rights to compound in Japan.*

59

Jevtana® (cabazitaxel)

U.S.	E.U.	Japan
Compound: March 2016 (up to March 2021 if PTE is granted)	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	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	Compound: expired	Compound: expired
Generics on the market		Regulatory exclusivity: January 2016

Plavix® (clopidogrel bisulfate)

U.S.	E.U.	Japan
Compound: Expired	Generics on the market	Compound: expired
Generics on the market		Regulatory exclusivity: January 2014

Aprovel® (irbesartan)

U.S.	E.U.	Japan
Compound: expired	Compound: expired in most of the EU; exceptions: May 2013 in Lithuania. No compound patent in force in Spain, Portugal, Finland, Norway and much of Eastern Europe	Compound: March 2016
Generics on the market	Generics on the market	Regulatory exclusivity: April 2016

Tritace® (ramipril)

U.S.	E.U.	Japan
N/A [(1)]	Compound: expired	Compound: expired
	Generics on the market	

(1) *No rights to compound in the U.S.*

Multaq® (dronedarone hydrochloride)

U.S.	E.U.	Japan
Compound: July 2013 with interim petition granted (July 2016 if PTE petition is granted)	Compound: expired	Compound: expired
Later filed patent: formulation (June 2018)	Later filed patent: formulation June 2018 extended with SPC up to June 2023 in most of the countries	
Regulatory exclusivity: July 2014	Regulatory exclusivity: November 2019	

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.*

Nasacort® (triamcinolone acetonide) [(1)]

U.S.	E.U.	Japan
Compound: expired	Compound: expired Later filed patent: formulation July 2017	Compound: expired

Later filed patents: formulation and method of use July 2016
Generics on the market

(1) *A license was granted to Barr Laboratories, Inc. in settlement of patent litigation.*

Xatral® (alfuzosin hydrochloride)

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

Actonel® (risedronate sodium) [(1)]

U.S.	E.U.	Japan
Compound: December 2013, Extended to June 2014 by Pediatric extension Later filed patents: coverage ranging through June 2018	Compound: expired Later filed patents: coverage ranging through June 2018	Compound: Expired

(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 Later filed patents: coverage ranging through September 2015 Biologics Regulatory Exclusivity: April 2015	Compound: N/A	Compound: N/A Later filed patents: November 2013 Orphan regulatory exclusivity: January 2014

Cerezyme® (imiglucerase)

U.S.	E.U.	Japan
Compound: August 2013	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 Orphan Drug Exclusivity: April 2013 Biologics Regulatory Exclusivity: April 2018	Later filed patents: coverage ranging from March 2021 to May 2023 Orphan Regulatory Exclusivity: March 2016 Biologics Regulatory Exclusivity: March 2016	Later filed patents: 2021 Orphan Regulatory Exclusivity: April 2017

Renagel® (sevelamer hydrochloride)

U.S.	E.U.	Japan
Compound: N/A Later filed patent: coverage ranging through August 2013 and September 2014	Compound: N/A Later filed patent: August 2014 SPC coverage to January 2015 in certain EU countries	Compound: N/A Later filed patent: August 2014 PTE protection to December 2016

Renvela® (sevelamer carbonate)

U.S.	E.U.	Japan
Compound: N/A Later filed patent: coverage ranging through August 2013 and 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 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 Later filed patent: January 2028	Compound: N/A	Compound: expired

Lyxumia® (lixisenatide)

U.S.	E.U.	Japan
Compound: July 2020	Compound: July 2020	Compound: July 2020

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 (2019 if PTE is granted) Regulatory Exclusivity: September 2017	Compound: expired	Compound: expired

Kynamro (mipomersen)

U.S.	E.U.	Japan
Compound: December 2025	Compound: pending	Compound: 2023

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 have 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 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.

Procedures comparable to the ANDA exist in other major markets.

In the European Union, a generic drug manufacturer may only reference the data of the regulatory file for the original approved product after data exclusivity has expired. However, there is no patent listing system in Europe comparable to the Orange Book, which would allow the patent holder to prevent the competent authorities from granting marketing approval by bringing patent infringement litigation prior to approval. As a result, generic products may be approved for marketing following the expiration of marketing exclusivity without regard to the patent holder's rights. Nevertheless, in most of these jurisdictions once the competing product is launched and in some jurisdictions, even prior to launch (once launch is imminent), the patent holder may seek an injunction against such marketing if it believes its patents are infringed. See Item 8 of this annual report.

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 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.

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, Haupt, Patheon, Catalent and Sofarimex. 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".

We also depend on third parties for the manufacture of certain products. Under our alliance with BMS, multi-vendor supply and safety stock arrangements are in place for Plavix® (clopidogrel bisulfate) and Aprovel® (irbesartan).

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. A new antigen production facility in Mexico for seasonal and pandemic influenza vaccines was approved by the Mexican authorities early in 2012, and began commercial production in time for the Mexican influenza vaccination campaign in September 2012.

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 17 production sites spread across nine countries.

All of our pharmaceutical and vaccine facilities are Good Manufacturing Practices (GMP) compliant, in line with international guidelines. Our principal sites are approved by the U.S. Food & Drug Administration (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, Dagenham and Fawdon, the last two of which are due to close in 2013 and 2015, respectively); in Ireland (Waterford); in Germany (Frankfurt); in Hungary (Veresegyhaz); in Italy (Anagni); and in the United States (Saint Louis). 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) 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.

In February 2011, we received an FDA warning letter concerning our Frankfurt facility following a routine FDA inspection in September 2010. The warning letter cited GMP compliance issues in certain manufacturing processes, without referring to specific products. While believing that the points raised in the letter did not compromise the quality of our marketed products, we acted on this warning and worked towards satisfying the recommendations through a "compliance first" action plan at the Frankfurt facility. In October 2011, we notified the FDA that we had completed this plan. The FDA reinspected the site in April 2012, and issued an unqualified report on Form FDA 483. This was confirmed in the FDA Establishment Inspection Report, received August 14, 2012, which officially closed the warning letter procedure.

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 take a further three years to complete. It includes a timetable of specified milestones. If the milestones are not met in accordance with the timetable, the FDA can require us to pay $15,000 per day, per affected drug, until these compliance milestones are met. Upon satisfying all compliance requirements in accordance with the terms of the consent decree, Genzyme will be required to retain an auditor to monitor and oversee ongoing compliance at the Allston facility for an additional 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®.

On July 12, 2012, Sanofi Pasteur received a warning letter from the FDA following routine inspections conducted during 2012 at its facilities in Toronto (Canada) and Marcy l'Étoile (France). The warning letter contains observations about products intended for the U.S. market, and the premises in which they are produced. Sanofi Pasteur takes these observations extremely seriously, and 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.

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

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 €100 million in 2012.

The applicable environmental laws and regulations may require Sanofi to eradicate or reduce the effects of chemical substance usage and release at its various sites. The sites in question may belong to the Group, be currently operational, or they may have been owned or operational in the past. Under some of these laws and regulations, a current or previous owner or operator of a property may be held liable for the costs of removal or remediation of hazardous substances on, under or in its property, or transported from its property to third party sites, without regard to whether the owner or operator knew of, or under certain circumstances caused the presence of the contaminants, or at the time site operations occurred, the discharge of those substances was authorized.

Moreover, as is the case for a number of companies involved in the pharmaceutical, chemical and agrochemical industries, soil and groundwater contamination has occurred at some Group sites in the past, and may still occur or be discovered at others. In the Group's case, such sites are mainly located in the United States, Germany, France, Hungary, the Czech Republic, Slovakia, 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, Ambler and Portland in the United States; Frankfurt in Germany; Beaucaire, Valernes, Limay, Rousset,

Romainville, Neuville, Vitry and Toulouse in France; Dagenham in the United Kingdom; Brindisi and Garessio in Italy; Ujpest in Hungary; Hlohovec in Slovakia; 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, in 2007 the State of New Jersey initiated a claim against Bayer CropScience seeking compensation for damages caused to natural resources (NRD) at a former Rhône-Poulenc site in the United States, resulting in indemnification claims by Bayer CropScience against the Group 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 2012, Sanofi spent €45 million on rehabilitating sites previously contaminated by soil or groundwater pollution. During the year ended December 31, 2012, 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 €728 million as at December 31, 2012; this figure includes the provisions related to Genzyme.

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 is not currently subject 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 (53 in 2012) 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, nine specialized audits covering contractors or biosafety and 163 loss prevention technical visits were carried out by our teams in 2012.

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".

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, Neuville-sur-Saône, Sisteron and Vertolaye, as well as the plants located in the Hoechst Industry Park in Frankfurt, Germany, the Zentiva site in Hlohovec, Slovakia, 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, 60 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 2012, seven of our European sites were included in the scope of the European CO_2 Emissions Credit Trading Scheme aimed at helping to reach the targets set by the Kyoto protocol.

Our recent efforts in terms of environmental protection have mainly targeted reductions in energy consumption, greenhouse gas emissions control, improvements in the performance of water treatment installations, reduction of volatile organic compound emissions, raw material savings and recycling, and reductions in waste materials or increases in the percentage being recycled. In 2012, we reduced carbon dioxide emissions caused by our sales representation car fleet by 10% versus 2011, due to the policy of using energy efficient cars as well as a reduction in the number of cars. Measured against the benchmark year for our new targets (2010), direct and indirect emissions from our production and research facilities (excluding vehicle fleets) have fallen by 7.2% 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.

Markets

A breakdown of revenues by business segment and by geographic region for 2012, 2011 and 2010 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 2011, 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).

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 31.9% of our net sales, the largest contribution to net sales of any region. We are the leading healthcare company in emerging markets. In 2012, sales in emerging markets grew by 8.3% at constant exchange rates (or +7.2% including the non consolidated sales of Genzyme in the first quarter of 2011). Latin America, Asia and Middle East recorded double-digit sales growth in 2012. Sales in BRIC countries were up 12.0%, accounting for 35.0% of Emerging Markets sales. Sales in China, Brazil, Russia were up 15.0%, 7.7% and 13.6% respectively. In 2012, sales in Africa and the Middle East each exceeded €1 billion for the first time.

The United States represent 31.1% of our net sales; we rank twelfth with a market share of 3.7% (3.1% in 2011). Sales in the U.S. were up 0.7% at constant exchange rates in 2012 (or -2.8% including the non consolidated sales of Genzyme in the first quarter of 2011), driven by strong performances for Diabetes and Generics but impacted by the loss of exclusivity of Eloxatine® and generic competition for Lovenox®.

Western Europe represents 23.8% of our net sales; we are the leading pharmaceutical company in France where our market share is 9.3% (9.9% in 2011), and we rank fourth in Germany with a 4.7% market share (after the Copaxone® transfer and without taking into account parallel trade). In 2012, sales in Western Europe were down 9.3% at constant exchange rates (or -7.5% including the non consolidated sales of Genzyme in the first quarter of 2011 and excluding Copaxone®), impacted by the transfer of the Copaxone® business to Teva, generic competition for Plavix®, Aprovel® and Taxotere® and the impact of austerity measures.

Other countries represent 13.1% of our net sales; our market share in Japan is 3.5% (3.4% in 2011). Full-year 2012 sales in Japan were up 6.6% at constant exchange rates (or +4.7% with Genzyme on a full-year basis in 2011).

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

Although specific distribution patterns vary by country, we sell prescription drugs primarily to wholesale drug distributors, independent and chain retail drug outlets, hospitals, clinics, managed care organizations and government institutions. Rare disease, renal, and biosurgery products are also sold directly to physicians. With the exception of Consumer Health Care 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, 2012, we had a global sales force of 32,874 representatives: 9,866 in Europe, 4,866 in the United States, and 18,142 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.

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 like: Novo Nordisk in diabetes; Eli Lilly in diabetes and oncology; Bristol-Myers Squibb in diabetes and oncology; Merck & Co in diabetes and hypertension; GlaxoSmithKline in diabetes, oncology and thrombosis; Novartis in diabetes, multiple sclerosis, oncology and hypertension; 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, hypertension and oncology; Boehringer-Ingelheim in diabetes; Fresenius Medical Care in renal diseases.

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

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

In our 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 selected 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, which are leveraging their cost/volume advantage and raising their level of technical capability and quality standards to compete on 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 on existing vaccines across the middle to low income segments.

In our Animal Health business, we compete primarily with international companies like Pfizer in both production and companion animals; with Merck and Boehringer Ingelheim in production animals; with Boehringer Ingelheim mainly in the vaccines segment; with Novartis and Bayer for pets and particularly for pets parasiticides; and with Virbac, Ceva and Vetoquinol, French companies with global presence, for pharmaceuticals and vaccines (except for Vetoquinol, which operates only in the pharmaceutical segment).

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 to more than 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.

The WHO also estimates that 50% of drugs sold on illegal websites have been found to be counterfeit.

A counterfeit medicine is deliberately and fraudulently mislabeled with respect to its identity and/or its source. Counterfeiting can apply to both branded and generic products, and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients, or with fake packaging.

Sanofi acts ethically and responsibly to protect patient health worldwide. We become involved in any efforts made to overcome drug counterfeiting and have implemented the following actions:

- Ever closer collaboration with international organizations and with customs and police to reinforce regulatory frameworks (Medicrime Convention, European Directive on Falsified Medicines, etc.), to investigate suspected counterfeiters and to deliver information and educational programs to raise awareness about the risk related to falsified medicines;

- Centralization and analysis in a specialized laboratory of all suspect Sanofi drugs, to detect falsified medicines and inform health and enforcement authorities; and

- Development of technologies to make drugs more difficult to copy through packaging protection programs and traceability programs.

Regulatory Framework

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

The submission of an application to a regulatory authority does not guarantee that a license to market will be granted. Furthermore, each regulatory authority may impose its own requirements during the course of the product development and application review. It may refuse to grant approval and require additional data before granting approval, even though the same product has already been approved in other countries. Regulatory authorities also have the authority to request product recalls, product withdrawals and penalties for violations of regulations based on data that are made available to them.

Product 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 submitted, 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 the ICH (International Conference on Harmonization) participants to harmonize product development and regulatory submission requirements. The ICH consists of the regulatory agencies of the three founding members (European Union, Japan, United States), plus Health Canada and

Swissmedic as observers. An example of these efforts is the Common Technical Document (CTD), which can be used in different ICH regions for a product application review, with only local or regional adaptation. Electronic CTD is becoming the standard for worldwide product submission. Interestingly, emerging countries are starting to participate in ICH standardization discussions, and could be more involved in the near future.

International collaboration between regulatory authorities continues to develop with implementation of confidentiality arrangements between ICH regulatory authorities, and with 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, blood products) between the United States and the European Union. Other initiatives include the presence of permanent representatives from the FDA and the Japanese Pharmaceutical and Medical Devices Agency (PMDA) in London, and a corresponding permanent representative from EMA at the FDA.

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 certain types of medicinal products. When an application is submitted to the EMA, the scientific evaluation of the application is carried out by the Committee for Medicinal Products for Human Use (CHMP) and a scientific opinion is prepared. This opinion is sent to the European Commission which adopts the final decision and grants an E.U. marketing authorization. Such a marketing authorization is valid throughout the E.U. and the drug may be marketed within all E.U. member states.

If a company is seeking a national marketing authorization in more than one member state, the mutual recognition or decentralized procedure is available to facilitate the granting of harmonized national authorizations across member states. Both the decentralized and the mutual recognition procedures are based on the recognition by national competent authorities of a first assessment performed by the regulatory authority of one member state.

National authorizations are still possible, but are only for products intended for commercialization in a single E.U. member state or for line extensions to existing national product licenses.

Generic products are subject to the same marketing authorization procedures. A generic product must contain the same active medicinal substance as a reference product approved in the E.U. Generic applications are abridged: generic manufacturers only need to submit quality data and demonstrate that the generic drug is "bioequivalent" to the originator product (i.e., works in the same way in the patient's body), but do not need to submit safety or efficacy data since regulatory authorities can refer to the reference product's dossier. Generic product applications can be filed and approved in the European Union only after the originator product eight year data exclusivity period has expired. Further, generic manufacturers can only market their generic products after a 10- or 11-year period has elapsed from the date of approval of the originator product has elapsed.

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 on its territory and takes appropriate action where necessary and monitors the compliance of marketing authorization holders with their obligations with respect to pharmacovigilance. All relevant information is shared between the regulatory authorities and the marketing authorization holder, 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 recommendation/advice on product safety issues. This committee, which includes a patient representative, can hold public hearings. Since its introduction in the second quarter of 2012 the PRAC has initiated reviews of products with subsequent regulatory actions leading to harmonization of the labeling. For instance several Sanofi products including zolpidem, clopidogrel, and insulin glargine are currently under review.

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. As of today, no PASS or PAES has been requested to Sanofi.

The Pharmacovigilance legislation also introduces a new periodic safety report prepared by the 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.

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 (FDASIA GDUFA), an application for a generic drug product requires a user fee payment. User fees for generic drug applications are necessary to help alleviate the backlog of applications at the Office of Generics Drugs (OGD). 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, 2013, no sponsor has submitted a 351k application to the FDA for review.

On July 9, 2012, President Obama signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA), which primarily amends the Federal Food, Drug, and Cosmetic Act and Public Health Service Act. In addition to reauthorizing and amending several drug and medical device provisions that were scheduled to expire, the new law establishes new user fee statutes for generic drugs and biosimilars. FDASIA also provides the FDA with tools intended to expedite the development and review of innovative new medicines that address certain unmet medical needs, and with new authority concerning drug shortages, among other things. The law significantly changes the FDC Act and the PHS Act in several respects that will have considerable short- and long-term effects on the regulated industry.

FDASIA includes 11 titles, the first five of which concern drug and medical device user fee and pediatric-related programs. FDASIA § 501 makes permanent both the Best Pharmaceuticals for Children Act and Pediatric Research Equity Act by eliminating the "sunset" provision of the BPCA and a related PREA provision. Title VI includes changes to the law styled as medical device regulatory improvements. Title VII makes significant changes to enhance the FDA's inspection authority and the drug supply chain. Title VIII creates incentives to encourage the development of products for antibiotic-resistant infections. Title IX expands the scope of products that qualify for accelerated approval and creates a new "breakthrough therapy" program, among other things. Title X is intended to legislatively address the current drug shortage crisis. Finally, Title XI reauthorizes certain provisions created by the FDA Amendments Act of 2007, provides for the regulation of medical gases, and includes several miscellaneous provisions, such as provisions on prescription drug abuse, 180-day generic drug marketing exclusivity, citizen petitions, controlled substances, and nanotechnology to name a few.

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. 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 unproved drugs/off-label indications with high medical needs. Pharmaceutical manufacturers are required to conduct literatures-based submission within six months or start a clinical trial for registration within one year after the official request. Otherwise, NHI prices of all products of the manufacturer would be reduced dramatically. In addition, the regulatory authorities have begun to promote multinational studies.

For new drugs and biosimilar products with approval applications submitted on or after April 2013, Japan will begin implementing a "Risk management plan", 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.

Focus on Biologics

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 2012, the EMA has initiated a revision of the majority of the existing biosimilar guidelines (general guidelines, as well as immunogenicity and product-related guidelines for recombinant insulin and LMWH). Two new guidelines on monoclonal antibodies and immunogenicity of monoclonal antibodies have also been issued; other product-related guidelines (follitropin α and β interferon) are under preparation.

In response to the European Commission's wish to stimulate the global development of biosimilars, biosimilar reference medicines sourced outside the European Economic Area will be allowed (the basis will always be a locally licensed product, but 'Bridging studies' to another product licensed in another part of the world will be allowed). Currently in the E.U., the reference product for a biosimilar has to be licensed in the E.U. and therefore clinical trials have to be repeated in all three major markets (Japan, E.U. and U.S.). This important change will enter into force after the revision of the EU so-called "over-arching" biosimilar guideline, already under review and expected for early 2013.

While the EMA has adopted so far a balanced approach for all biosimilars, which allows evaluation on a case-by-case basis in accordance with relevant biosimilar guidelines, it seems that there is 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 Japan, guidelines defining the regulatory approval pathway for follow-on biologics were finalized in March 2009. These guidelines set out the requirements on CMC (Chemistry, Manufacturing and Control), preclinical and clinical 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.

In the United States, the Patient Protection and Affordable Care Act, in particular Title VII, Subtitle A "Biologics Price Competition and Innovation Act," was signed into law by President Obama on March 23, 2010, This law 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.

On February 15, 2012, the FDA published for consultation three draft guidance documents for biosimilar development: Scientific Considerations in Demonstrating Biosimilarity to a Reference Product, Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product, and Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009. These guidance documents remain in draft format. A fourth document on clinical pharmacology has yet to be published.

The Federal Food, Drug, and Cosmetic Act, as amended by the Biosimilar User Fee Act of 2012 (Title IV of the Food and Drug Administration Safety and Innovation Act, Public Law 112-144, which was signed by the President on July 9, 2012), authorizes the FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development, for certain applications and supplements for approval of biosimilar biological products, on establishments where approved biosimilar biological product products are made, and on biosimilar biological products after approval.

At the December 2012 FDA-CMS meeting, the agency stated that they had received 50 requests for initial meetings with potential biosimilar sponsors to talk about development plans and conducted 34. The agency has now

received 12 biosimilar INDs and has many other active programs with no IND submitted. Proposals have involved 12 reference products.

Focus on Medical Devices

In the E.U., the European Commission released its legislative proposal on medical devices on September 26, 2012. The new revised framework could enter into force by 2015, if approved at first reading.

The main change of this proposal is the replacement of the current three directives by two regulations (one for medical devices and one for *in-vitro* medical devices).

The objectives of the legislation are to simplify and strengthen the current E.U. legal framework by implementing a robust and transparent regulatory framework. The revision impacts the pre-market assessment of devices by strengthening the oversight of Notified Bodies (NBs), post-market safety and continuous assessment of NB compliance, and the management of the regulatory system (better coordination, transparency and communication). A "scrutiny procedure" (via a European decentralized approach) would be used for high-risk Class III devices (novel technologies or specific public health threats). 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.

In addition, enhanced vigilance and post-market surveillance systems for medical devices, with greater harmonization of E.U. member states' market surveillance activities, are expected.

In the U.S., in January 2011, the FDA announced a Plan of Action, which includes 36 specific actions, to modernize and improve the FDA's premarket review of medical devices. In the two years since the FDA began implementing the plan, the speed and predictability of device review have improved for the first time in almost a decade, including significant reductions in the time it takes the FDA to review applications and the size of application backlogs. These results have been achieved even though the Plan of Action has not yet been fully implemented.

The FDA has met almost all of its early implementation timelines. As implementation continues and the impact of the Plan grows over the next several years, the FDA expects performance on review times and reductions in backlogs to continue to improve. The new process improvements and resources made available by this year's reauthorization of the Medical Device User Fee Act (MDUFA III) will accelerate the FDA's ability to make premarket review of devices predictable, consistent, transparent, efficient, and timely.

Recent biomedical breakthroughs are pushing medicine toward tailored therapeutics, or personalized medicine. This means an increase in the development of companion diagnostics. To address this issue, the FDA issued the draft guidance In Vitro Companion Diagnostic Devices on July 12, 2011, to communicate to industry how the FDA defines these devices and what the Agency's regulatory requirements are for them. The finalization of this guidance has been delayed.

Focus on transparency and public access to documents

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 disclosure about the rationale and basis of regulatory decisions on medicinal products, so as to enhance the credibility of the regulatory process. This is a significant driver of the transparency initiatives undertaken in several countries.

Pharmaceutical manufacturers have committed to publishing protocols and results of clinical studies performed with their products in publicly accessible registries. In addition, both ICH and non-ICH countries often impose mandatory disclosure of clinical trials information.

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

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

The European regulators recently took a major step towards more openness and transparency by giving much wider access to documents originated by pharmaceutical companies and submitted to the regulatory authorities for scientific evaluation after a regulatory decision is taken. Whilst it is anticipated that these documents would be redacted before disclosure in order to protect information contained therein that cannot be disclosed (commercial confidential information or personal data), the draft document released in June 2011 for public consultation by the EMA and the Head of Medicines Agencies (HMA) gives a narrower definition of commercially confidential information and personal data within the context of the marketing authorization dossier. Consequently, the scope of the information accessible to the public has been considerably widened (e.g., clinical study reports in a marketing authorization dossier, but also a significant portion of non-clinical test data).

During the second half of 2012 the EMA informed stakeholders about its intention to implement by January 2014 the previously announced proactive policy for public disclosure of raw data from clinical trials that are included in marketing authorization dossiers of approved medicinal products.

Protection of patients' personal data, data format definition and document redaction, rules of engagement for third parties willing to conduct new analyses on data files, legal aspects about risk of infringement of commercially confidential information are among the main ethical and technical issues to be overcome before the new transparency policy is enforced, and are to be discussed between the EMA and its stakeholders over the first part of 2013.

The EMA does not routinely require raw data files as part of the submitted dossier, implying that this new policy will apply in particular to prospective submissions.

In the highly competitive field of medicinal products, it is still necessary to reinforce the principle that non-innovators cannot obtain marketing authorization based solely on the originator's data released in the E.U. for as long as the data protection period is in force.

As of the end of 2012, the E.U. disclosure policy appears more advanced than that in other major markets.

In the U.S., FDA Commissioner, Dr. Margaret A. Hamburg, launched FDA's Transparency Initiative in June 2009, in response to President Obama's January 2009 "Open Government Initiative". 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 FDA basics (completed with ongoing updates); Phase II Improving FDA's disclosure of information to the public (ongoing); and Phase III Improving FDA's transparency to regulated industry (ongoing). Proposals to improve transparency and access to information were released for consultation for both Phase II (May 19, 2010) and Phase III (January 6, 2011). 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.

Other new legislation proposed or pending implementation

Clinical trials applications: 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 released in July 2012 with the following objectives:

1) To establish a modern regulatory framework for submission, assessment and regulatory follow-up of applications for clinical trials, taking into account the multinational research environment. The goal is to reduce administrative burdens and operational costs, and cut lead times to launch clinical trials, insofar as they are caused by regulation.

2) Regulatory requirements which are adapted to practical considerations, constraints and needs, without compromising the safety, wellbeing and rights of participants in clinical trials and without compromising data robustness, with a goal of reducing administrative burdens and operational costs as regards two key regulatory requirements: the annual safety report and obligatory insurance/indemnification.

3) Addressing the global dimension of clinical trials when ensuring compliance with Good Clinical Practices (GCP). The operational objective is to ensure that clinical trials conducted in non-EU countries comply with GCP.

Discussions have begun on this proposal (2012/2013) and the final regulation is expected to come into force by 2016.

Overall, the replacement of Directive 2001/20/EC by a Regulation is expected to introduce a harmonized review pathway and timelines without interfering with Member States' competences in terms of ethical aspects. A single E.U. submission portal is expected to significantly streamline the review process and will also allow increased transparency over the conduct and results of clinical trials.

Falsified medicines: implementation of Directive 2011/62/EU: The European Union (E.U.) has reformed the rules for importing into the E.U. active substances for medicinal products for human use. As of January 2, 2013, all imported active substances must have been manufactured in compliance with standards of good manufacturing practices (GMP) at least equivalent to the GMP of the E.U. The manufacturing standards in the EU for active substances are those of the "International Conference for Harmonisation" ICH Q7. As of July 2, 2013, this compliance must be confirmed in writing by the competent authority of the exporting country. This document must also confirm that the plant where the active substance was manufactured is subject to control and enforcement of good manufacturing practices at least equivalent to that in the E.U.

In practice, the full implementation of Directive 2011/62/EU by July 2013 could generate temporary drug shortages in the E.U. in those cases where manufacturers will be unable to supply the required documentation.

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 changes in the Pharmaceutical/Healthcare environment emerged since 2010:

In the United States, implementation of health insurance and market reforms continued during 2012. These reforms are expected to lead to a large number of uninsured being covered by 2014, either through

state programs or mandatory enrollment in private plans. Cost-containment pressures affecting pharmaceuticals are also persisting in the public and private health care sectors.

In Europe, emergency cost containment measures and reforms introduced since 2010 in several countries (including, Germany, Greece, Spain, Portugal, and Ireland) are being implemented. These will significantly affect the size of the pharmaceutical market. A number of Central and Eastern European countries are also implementing cost containment measures (Hungary, Slovakia, Poland). In parallel, the full effect of the new German laws (end to the free-price-setting system) has only just begun to see negative dividends for the industry. In 2011, France implemented numerous changes to pharmaceutical access. In addition, health economic assessment is now officially part of the price determination in countries such as France and Spain. Details of the UK value-based pricing of drugs scheme are still to be finalized and it is not clear how or if the emphasis of the Incremental Cost Effectiveness Ratio (ICER) used by the National Institute for Clinical Excellence (NICE) will be diminished.

In Japan, along with the usual biennial price cuts (April 2012), the extension of price premiums for drug development and measures to encourage the access to new medications have been announced.

Regardless of the exact method, 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 the market accessibility of our products.

We continue to add flexibility and adaptability to our operations so as to better prepare, diagnose, and address issues in individual markets.

Keeping in mind the importance of recognizing the value of our products and the high cost of research and development, we continue to analyze innovative pricing and access strategies that balance patient accessibility 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 usually foresee that the clinical efficacy of a drug is followed after its commercialization, 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.

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 excess property, 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 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. 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.

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, 2012. 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.1.2. 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, 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 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	63%
Research	13%
Offices	12%
Logistics	7%
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	32%
Owned	68%

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

We carry out our industrial production at 112 sites in nearly 40 countries (including 40 sites in emerging markets):

82 sites for our Pharmaceuticals activity, including Genzyme;

13 sites for the industrial operations of Sanofi Pasteur in vaccines;

17 sites for the Animal Health activities of Merial.

In 2012, we produced the following quantities:

Pharmaceuticals: 3,520 million boxes produced and packaged (4,117 including outsourced production) and for Genzyme, 9.1 million vials (42.7 million including outsourced production);

Vaccines: 417 million containers prepared (451 million including outsourced production);

Animal Health: 500 million doses of vaccines for all species other than avian, 90 billion doses of avian vaccines, and 1.7 billion units of pharmaceutical products (pipettes, pills, vials, syringes).

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 the consolidated financial statements.

Industrial Sites: Pharmaceuticals

Production of chemical and pharmaceutical products is the responsibility of our Industrial Affairs function, 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), Le Trait (Lovenox®), Lyon Gerland (Thymoglobulin®, Celsior®), Maisons-Alfort (Lovenox®), Neuville (dronedarone), Quetigny (Stilnox®, Plavix®), Sisteron (clopidogrel bisulfate, dronedarone, zolpidem tartrate), Tours (Stilnox®, Aprovel®, Xatral®), Vitry-sur Seine (docetaxel/aflibercept);

Germany: Frankfurt (insulins, Ramipril®, Lantus®, Tritace®, 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®, Eloxatine®, currently being transferred to Frankfurt in Germany), 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®).

The rare diseases specialist Genzyme became a Sanofi subsidiary in April 2011. This acquisition expanded our presence in biotechnologies, especially rare diseases. 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 (alglucosidase alpha: Myozyme®/Lumizyme®);

United States: Allston (Cerezyme®, Fabrazyme®); Framingham (Fabrazyme®, Myozyme®, Thyrogen®, Seprafilm, Hyaluronic Acid); Cambridge (Carticel®, Epicel®, MACI® (Matrix-induced Autologous Chondrocyte Implantation); Ridgefield (Synvisc®, Hectorol®, Mozobil®, Jonexa®, Prevelle®); and Lynnwood, Washington (Leukine®), a former Bayer Healthcare site;

Australia: Perth (MACI®);

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, the largest ever made by Sanofi, is intended to gradually transition the existing chemical activity to vaccine production from 2013 onwards.

In 2010, Sanofi Pasteur acquired VaxDesign, a U.S. company located in Orlando, Florida. VaxDesign's Modular IMmune In-vitro Construct (MIMIC®) System is designed to capture genetic and environmental diversity and predict human immune responses. The MIMIC® platform is expected to accelerate vaccine development, reduce time to market and increase success rates in the pre-clinical and clinical stages.

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

Industrial Sites: Animal Health (Merial)

Since Merck and Sanofi announced in March 2011 that they were maintaining separate activities in the field of animal health, Merial has become a dedicated Sanofi division. Merial has 17 industrial sites in nine different countries, 9 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);

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 and vaccine 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);

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

Research & Development sites: 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 largest of which is in Frankfurt (Germany);

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

2 sites in Asia with 1 clinical research unit in Beijing, China and 1 unit in Japan.

D.3. Acquisitions, Capital Expenditures and Divestitures

The carrying amount of our property, plant and equipment at December 31, 2012 was €10,578 million. During 2012, we invested €1,351 million (see Note D.3. to our consolidated financial statements, included at Item 18 of this annual report) in increasing capacity and improving productivity at our various production and R&D sites.

Our principal capital expenditures and divestitures in 2010, 2011 and 2012 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, 2012, our firm commitments in respect of future capital expenditures amounted to €323 million. The principal sites involved were (for the Pharmaceuticals activity) the industrial facilities at Frankfurt (Germany), Framingham and Allston (United States), Vertolaye (France), and in Hungary; and for the Vaccines activity, 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 €1.4 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 2012, our industrial network actively contributed to the development of our seven growth platforms: Emerging Markets, Diabetes Solutions, Consumer Health Care, New Genzyme and Other Innovative Products (all of which are part of our Pharmaceuticals activity), 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. This investment will be operational in 2016. The Sanofi Diabetes industrial network is expanding its footprint in emerging markets, both in Russia 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®**.

Our industrial pharmaceutical operations for the **Consumer Health Care** platform are based on four growth hubs: in Europe, Asia (where a new consumer products facility at Hangzhou in China with a production capacity of 3 billion pills will be operational early in 2013), South America, and the United States (focused on the Chattem site in Tennessee, which in 2012 led preparations for the U.S. launch of the pediatric oral suspension formulation of Allegra®). The industrial development teams also contributed to over 30 new launches of consumer products during 2012, 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 2012 produced the first technical batches of **aflibercept** (the active ingredient of **Zaltrap®**); and Lyon Gerland (France), a new world center dedicated to the production of **thymoglobulin®** for the prevention and treatment of transplant rejection. During 2012, our teams at Lyon prepared a dossier for the healthcare authorities as part of the process of transferring production to this site.

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 and Consumer Health Care, a number of other projects are under way. In the Middle

87

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, we are building a dedicated hormonal products facility in Brasilia. Also during 2012, the Ankleshwar Pharma site in Gujarat State (India) handled packaging and quality control through to release of the first commercial batches of **AllSTAR** , the first high-quality affordable insulin pen specifically intended for the local market. The Goa site (India) invested to extend its solid formulation production capacity to around 2.5 billion pills a year. And in Algeria, Sanofi signed an agreement with the local authorities for a major industrial investment that will lead to the construction of our biggest industrial complex in the Africa-Middle East region.

The industrial network of our Pharmaceuticals activity continued throughout 2012 with the roll-out of the economic performance improvement plan launched in 2011. This 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 to market needs, as a result of which a number of sites are in the process of sale or closure, such as Kansas City (United States), Dagenham and Fawdon (United Kingdom), Romainville (France), and Hlohovec (Slovakia).

The industrial network of the **New Genzyme** growth platform is predominantly located in the United States where major investments are under way, especially at the Framingham Biologics site, which was approved by the FDA and the EMA in 2012 for the manufacture of Fabrazyme® (Fabry disease). 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. Finally, the Bayer Healthcare facility at Lynnwood (Washington), specializing in the manufacture of Leukine®, joined the Genzyme industrial network in 2012.

Vaccines (Sanofi Pasteur)

Sanofi Pasteur is undergoing a major investment phase, particularly the new dedicated dengue fever vaccine facility at Neuville (France), which will produce its first batches in 2014. Two new dedicated influenza vaccine facilities are in the start-up phase: Shenzhen (China) is currently testing its production processes, while Ocoyoacac (Mexico) was approved by the Mexican authorities at the start of 2012 and began production in time for the Mexican influenza vaccination program in September 2012. 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 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 China, Merial is investing in a new site in the Nanchang high-tech development zone, in order to service future growth in vaccines for avian and other species in the local market. In Europe, a substantial portion of the investment in recent years has been directed at the transfer of vaccine production from Lyon Gerland (France) to a new site nearby at Saint Priest (Lyon Porte des Alpes). At the Toulouse site (France), Merial is adapting its production capacity to new products by investing in a packaging line for use in the manufacturing of **Certifect®** (compliant with European Union Good Manufacturing Practices (GMP), and approved by the U.S. Environmental Protection Agency) and in a building for the production of the injectable form of Zactran®.

Industrial innovation was a key theme in 2012. The fourth "Innovation Trophy" awards again illustrated the striking progress being made in this area, which we regard as a top priority in our industrial strategy. The **2012 Pierre Potier Prize** was awarded to the Chemicals and Biotechnology teams, who developed an innovative industrial process for the production of artemisinin, the basis for antimalarial drugs. Investment is ongoing in the installation of an innovative biosynthesis process at two French sites, Saint-Aubin-lès-Elbeuf (Seine Maritime) and Vertolaye (Puy de Dôme), with the aim of improving the international competitiveness of our corticosteroid production.

D.4. Office Space

As part of the rationalization of our office sites in the Paris region of France, we have since mid-2009 been carrying out a medium-term review of our office space master plan for the Greater Paris area.

This review will result in all our Group support functions and operating divisions being housed on a smaller number of sites (5 in 2012 on completion of phase 1, and 3 by 2015). All of these sites will meet environmental certification standards, and offer cost-effective space solutions.

Item 4A. Unresolved Staff Comments

N/A

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, 2012.

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.

2012 Overview

During 2012, we continued to follow the strategic direction established in 2008 and to pursue the objectives for 2012-2015 announced in September 2011 and reiterated in February 2013. The thrust of these objectives is fourfold: grow a global healthcare leader with synergistic platforms, bring innovative products to market, seize value-enhancing growth opportunities, and adapt our structure for future challenges and opportunities.

Our 2012 full-year results were affected by the loss of exclusivity for Plavix® and Avapro® in the United States in the first half, and by ongoing generic competition for our former flagship products. However, the erosion in our net sales and profitability was cushioned by our growth platforms, the contribution from Genzyme, and tight cost control.

Our 2012 net sales reached €34,947 million, 4.7% higher than in 2011 (0.5% at constant exchange rates, see definition at " Presentation of Net Sales" below), driven mainly by the performance of the Emerging Markets, Diabetes, Vaccines, Consumer Health Care, Animal Health and Other Innovative Products growth platforms, by advances for the Generics business, and by the contribution from Genzyme (whose net sales have only been consolidated since April 2011). This performance was achieved in spite of the significant impact of competition from generics, which cost us €1.2 billion in lost sales (€1.3 billion at constant exchange rates, see " Impacts from generic competition" below), and the ending of the co-promotion agreement with Teva on Copaxone®. Milestones for our research efforts during 2012 included the launch of Zaltrap® (metastatic colorectal cancer) and Aubagio® (multiple sclerosis) in the United States.

The ongoing realignment of our resources cut research and development expenses by 0.4% and limited the rise in selling and general expenses to 1.8%, after including Genzyme's costs over the full year. Business net income was €8,179 million, 7.0% lower than in 2011 on a reported basis, mainly due to the loss of exclusivity for Plavix® and Avapro® in the United States and to competition from generics. Business earnings per share was €6.20, 6.8% lower than in 2011. 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 at " Business Net Income" below.

Net income attributable to equity holders of Sanofi came to €4,967 million, down 12.8% on 2011. Basic earnings per share amounted to €3.76, also 12.8% lower than in 2011; diluted earnings per share for 2012 were €3.74 (12.8% lower).

During 2012, we continued with our policy of targeted acquisitions and of alliances in research and development. In Generics, we announced in October 2012 that we had signed an agreement to acquire Genfar S.A., a Colombian pharmaceutical company which is a key generics player not only in Colombia, but also in other Latin American countries. Closing of this acquisition is subject to certain conditions, and is expected to take place during the first half of 2013. In biosurgery, we acquired the U.S. medical devices company Pluromed, Inc. in April 2012. We strengthened our Animal Health division with the April 2012 acquisition of Newport Laboratories (a U.S. American producer of autogenous vaccines for the bovine and swine markets), and by entering into an agreement to acquire the animal health division of Dosch Pharmaceuticals Pvt Ltd that will give Merial an entry point into the

Indian market. We also entered into various alliances and licensing deals to extend or strengthen our existing research fields.

In October 2012, Sanofi and Bristol-Myers Squibb announced that they were restructuring their alliance following the loss of exclusivity for Plavix® and Avapro®/Avalide® in many major markets. The new agreement, which took effect on January 1, 2013, returns the rights for Plavix® and Avapro®/Avalide® to Sanofi worldwide (except for the United States and Puerto Rico for Plavix®), thereby giving Sanofi exclusive control over these products and their commercialization.

In August 2012, we sold our interest in Société Financière des Laboratoires de Cosmétologie Yves Rocher, in line with our desire to focus on strategic activities.

As of December 31, 2012, we had reduced our debt, net of cash and cash equivalents to €7.7 billion, compared with €10.9 billion as of December 31, 2011. The Annual General Meeting of shareholders, to be held on May 3, 2013, will be asked to approve a dividend of €2.77 per share in respect of the 2012 fiscal year, representing a payout equivalent to 45% of our business net income.

While we remain focused on our objectives for 2012-2015 announced in September 2011, we expect erosion from generic competition to continue, with a negative impact on net income in 2013 (see " Impacts from generic competition" below). While we continue to save costs, we expect that part of the savings will be reinvested in product launches and late-stage clinical trials.

Our operations generate significant cash flow. We recorded €8,171 million of net cash provided by operating activities in 2012 compared to €9,319 million in 2011. During the course of 2012, we paid out €3.5 billion in dividends and repaid part of our debt. With respect to our financial position, we ended 2012 with our debt, net of cash and cash equivalents (see definition at " Liquidity and Capital Resources" below) at €7,719 million (2011: €10,859 million). Debt, net of cash and cash equivalents, is a financial indicator that is used by management to measure the Company's overall net indebtedness and to manage the Group's equity capital. In order to assess the Company's 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 13.4% at the end of 2012 versus 19.3% at the end of 2011. See " Liquidity and Capital Resources" below.

Impacts from generic competition

Some of our flagship products continued to experience sales erosion in 2012 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 net sales for the years ended December 31, 2012 and 2011 (see " Results of Operations Year Ended December 31, 2012 Compared with Year Ended December 31, 2011") shows that competition from generics was associated with a decline of €1.2 billion in net sales in 2012 (or €1.3 billion at constant exchange rates). The table below shows the impact by product.

(€ million) **Product**	**2012** **Reported**	**2011** **Reported**	**Change on a reported basis**	**Change on a reported basis (%)**
Plavix® Western Europe	285 (1)	406 (1)	(121)	-29.8%
Aprovel® Western Europe	542 (1)	718 (1)	(176)	-24.5%
Taxotere® Western Europe	53	189	(136)	-72.0%
Eloxatine® U.S.	718	806	(88)	-10.9%
Lovenox® U.S.	319	633	(314)	-49.6%
Plavix® U.S.	76 (2)	196	(120)	-61.2%
Aprovel® U.S.	45 (2)	49	(4)	-8.2%
Taxotere® U.S.	53	243	(190)	-78.2%
Ambien® U.S.	85	82	+3	+3.7%
Xatral® U.S.	20	75	(55)	-73.3%
Nasacort® U.S.	21	54	(33)	-61.1%
Xyzal® U.S.	6	13	(7)	-53.8%
Allegra® U.S.	(1)	3	(4)	-133.3%
Total	**2,222**	**3,467**	**(1,245)**	**-35.9%**

(1) *Excluding industrial sales (Plavix®: €22 million in 2012, €8 million in 2011; Aprovel®: €15 million in 2012, €35 million in 2011).*

(2) *Sales of active ingredient to the BMS majority-owned entity in the United States.*

Despite the introduction of generics in the second half of 2012, Myslee® in Japan posted a 2.8% rise in net sales in 2012 (or a fall of 4.9% at constant exchange rates), to €292 million.

We expect erosion from generic competition to continue in 2013, with a negative impact on net income. The following products are expected to be impacted by generics in 2013:

- products for which new generic competition can reasonably be expected in 2013 based on expiration dates, patents or other regulatory or commercial exclusivity: Allegra® in Japan;
- products for which generics competition began in 2012 and is expected to continue in 2013: Plavix®, Avapro® and Eloxatine® in the United States (net sales of Plavix® and Avapro® in the U.S. are not included in our consolidated net sales), Co-Aprovel® in Europe, and Myslee® and Taxotere® in Japan;
- products which already faced generic competition as of January 1, 2012, but for which 2013 sales can reasonably be expected to be subject to further erosion: Plavix®, Eloxatine®, Aprovel® and Taxotere® in Europe; and Lovenox®, Ambien®, Xyzal®, Taxotere®, Xatral® and Nasacort®in the U.S.

Eloxatine® in the U.S. is a special case. This product was subject to generic competition for part of 2010 until a court ruling prevented further sales of unauthorized generics from June 2010 until August 9, 2012.

In 2012, aggregate consolidated net sales generated by all the products in countries where generic competition currently exists or is expected in 2013 (excluding Plavix® and Avapro® in the U.S., and industrial sales of these two products worldwide) were €2,996 million, including €1,221 million in the U.S., €880 million in Europe and €

895 million in Japan (Allegra®, Myslee® and Taxotere®). The negative impact on our 2013 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 2013, the prices at which they are sold, and potential litigation outcomes.

In addition, the loss of Plavix® and Avapro® exclusivity in the U.S. in the first half of 2012 is expected to negatively impact our net income by €0.8 billion in 2013 relative to 2012. Although sales of Plavix® and Avapro® in the U.S. are not included in our consolidated net sales, these products nonetheless have an impact on our net income (see " Financial Presentation of Alliances Alliance Arrangements with Bristol-Myers Squibb" below for further explanations).

Purchase Accounting Effects

Our results of operations and financial condition for the years ended December 31, 2012, December 31, 2011 and December 31, 2010 have been significantly affected by our August 2004 acquisition of Aventis and certain subsequent transactions, mainly our acquisition of Genzyme on April 4, 2011.

The Aventis acquisition has given rise to significant amortization (€1,489 million in 2012, €1,788 million in 2011, and €3,070 million in 2010) and impairment of intangible assets (reversals of €12 million in 2012 and of €34 million in 2011, and charges of €127 million in 2010). The Genzyme acquisition has also given rise to amortization of intangible assets (€981 million in 2012 and €709 million in 2011) and impairment of intangible assets (€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", see " Business Net Income" below.

Business net income for the years ended December 31, 2012, 2011 and 2010 is presented in " 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 and human vaccines directly, through alliances, and through licensees throughout the world. When we sell products directly, we record sales revenues as part of our consolidated net sales. When we sell products through alliances, the revenues reflected in our consolidated financial statements are based on the 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 active ingredients and raw materials, 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 distribute products that are patented by other companies and license agreements under which other companies distribute products that we have patented. When we pay royalties, we record them in cost of sales, and when we receive royalties, we record them in "Other revenues" as discussed above.

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

Segment Information

Operating Segments

In accordance with IFRS 8 "Operating Segments," we have defined our segments as "Pharmaceuticals", "Human Vaccines" (Vaccines) and "Animal Health". Our other identified segments are categorized as "Other".

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". In particular, this segment included our interest in the Yves Rocher group until the date of loss of significant influence (November 2011) (see note D.6. to our consolidated financial statements included at Item 18 of this annual report); it also includes the effects of retained commitments in respect of divested businesses.

Inter-segment transactions are not material.

Business Operating Income of Segments

We report segment results on the basis of "Business Operating Income". This indicator, 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.

The following table presents our Business Operating Income for the year ended December 31, 2012.

(€ 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	(8,759)	(1,635)	(701)		(11,095)
Research and development expenses	(4,219)	(539)	(164)		(4,922)
Selling and general expenses	(7,666)	(611)	(669)	(1)	(8,947)
Other operating income and expenses	98	(7)	3	14	108
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	**9,519**	**1,148**	**673**	**13**	**11,353**

The following table presents our Business Operating Income for the year ended December 31, 2011.

(€ 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	(8,368)	(1,404)	(654)		(10,426)
Research and development expenses	(4,101)	(564)	(146)		(4,811)
Selling and general expenses	(7,376)	(542)	(617)	(1)	(8,536)
Other operating income and expenses	(13)		(7)	24	4
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	**10,496**	**985**	**627**	**36**	**12,144**

The following table presents our Business Operating Income for the year ended December 31, 2010.

(€ million)	Pharmaceuticals	Vaccines	Animal Health	Other	Total
Net sales	**26,576**	**3,808**	**1,983**		**32,367**
Other revenues	1,623	28	18		1,669
Cost of sales	(7,316)	(1,371)	(615)		(9,302)
Research and development expenses	(3,884)	(517)	(155)		(4,556)
Selling and general expenses	(6,962)	(603)	(604)	(2)	(8,171)
Other operating income and expenses	177	14	(6)	(108)	77
Share of profit/(loss) of associates and joint ventures	1,009	19		8	1,036
Net income attributable to non-controlling interests	(258)	1			(257)
Business operating income	**10,965**	**1,379**	**621**	**(102)**	**12,863**

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, 2012, 2011 and 2010:

(€ million)	Year Ended December 31, 2012	Year Ended December 31, 2011	Year Ended December 31, 2010
Business Operating Income	**11,353**	**12,144**	**12,863**
Share of profit/(loss) of associates and joint ventures [1]	(424)	(1,102)	(1,036)
Net income attributable to non-controlling interests [2]	172	247	257
Amortization of intangible assets	(3,291)	(3,314)	(3,529)
Impairment of intangible assets	(117)	(142)	(433)
Fair value remeasurement of contingent consideration liabilities	(192)	15	
Expenses arising from the impact of acquisitions on inventories [3]	(23)	(476)	(142)
Restructuring costs	(1,141)	(1,314)	(1,384)
Other gains and losses and litigation [4]		(327)	(138)
Impact of the non-depreciation of property, plant and equipment of Merial (in accordance with IFRS 5)			77
Operating Income	**6,337**	**5,731**	**6,535**
Financial expense	(553)	(552)	(468)
Financial income	93	140	106
Income before tax and associates and joint ventures	**5,877**	**5,319**	**6,173**

(1) *Excluding restructuring costs of associates and joint ventures and expenses arising from the impact of acquisitions on associates and joint ventures.*

(2) *Excluding the share of restructuring and other adjusting items attributable to non-controlling interests.*

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

(4) *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 impact of the non-depreciation of the property, plant and equipment of Merial starting September 18, 2009 and continuing through 2010 (in accordance with IFRS 5); (viii) the tax effect related to the items listed in (i) through (vii); as well as (ix) effects of major tax disputes 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 (x) the share of non-controlling interests in items (i) through (ix). Items (i), (ii), (iii), (v) and (vi) correspond to those reported in the income statement line items "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, 2012, 2011 and 2010:

(€ million)		**2012**	**2011**	**2010**
Business net income		**8,179**	**8,795**	**9,215**
(i)	Amortization of intangible assets	(3,291)	(3,314)	(3,529)
(ii)	Impairment of intangible assets	(117)	(142)	(433)
(iii)	Fair value remeasurement of contingent consideration liabilities	(192)	15	
(iv)	Expenses arising from the impact of acquisitions on inventories [1]	(23)	(476)	(142)
(v)	Restructuring costs	(1,141)	(1,314)	(1,384)
(vi)	Other gains and losses, and litigation [2]		(327)	(138)
(vii)	Impact of the non-depreciation of the property, plant and equipment of Merial (IFRS 5)			77
(viii)	Tax effects on the items listed above, comprising:	1,580	1,905	1,856
	amortization of intangible assets	*1,159*	*1,178*	*1,183*
	impairment of intangible assets	*42*	*37*	*143*
	fair value remeasurement of contingent consideration liabilities	*2*	*34*	
	expenses arising from the impact of acquisitions on inventories	*7*	*143*	*44*
	restructuring costs	*370*	*399*	*466*
	other gains and losses, and litigation		*114*	*46*
	non-depreciation of property, plant and equipment of Merial (IFRS 5)			*(26)*
(iv)/(ix)	Other tax items [3]		577	
(x)	Share of items listed above attributable to non-controlling interests	3	6	3
(iv)/(v)	Restructuring costs and expenses arising from the impact of acquisitions on associates and joint ventures [4]	(31)	(32)	(58)
Net income attributable to equity holders of Sanofi		**4,967**	**5,693**	**5,467**

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

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

(3) *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.*

(4) *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, 2012, 2011 and 2010:

(€ million)	2012	2011	2010
Business operating income	**11,353**	**12,144**	**12,863**
Financial income and expenses	(460)	(412)	(362)
Income tax expense	(2,714)	(2,937)	(3,286)
Business net income	**8,179**	**8,795**	**9,215**

The most significant reconciliation items in the table above 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 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 to cost of sales resulting from the workdown of acquired inventories remeasured at fair value, net of tax;
- charges related to the impairment of goodwill; and
- charges related to the amortization and impairment of intangible assets, net of tax and non-controlling interests.

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 €7,877 million for amortizable intangible assets (average amortization period of eight and a half years) and €2,148 million for in-progress research & development. A large part of our revenues could not be generated without owning acquired intangible assets.

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

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

We compensate for the above-described material limitations by using business net income only to supplement our IFRS financial reporting and by ensuring that our disclosures provide sufficient information for a full understanding of all adjustments included in business net income. In addition, subject to applicable law, we may in the future decide to report additional non-GAAP financial measures which, in combination with business net income, may compensate further for some of the material limitations described above.

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 2012, 2011 and 2010. 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, 2012 Compared with Year Ended December 31, 2011 Net Sales" and at " Results of Operations Year Ended December 31, 2011 Compared with Year Ended December 31, 2010 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, 2012 Compared with Year Ended December 31, 2011" and " Year Ended December 31, 2011 Compared with Year Ended December 31, 2010", in particular in " Net sales", " Other Revenues", " Share of Profit/Loss of Associates and Joint Ventures" and " Net Income Attributable to Non-Controlling Interests".

Alliance Arrangements with Bristol-Myers Squibb

Our revenues, expenses and operating income are affected significantly by the presentation of our alliance with Bristol-Myers Squibb (BMS) in our consolidated financial statements.

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

As of December 31, 2012, 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 alliance arrangements as of December 31, 2012 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 alliance arrangements as of December 31, 2012, 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.

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.

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.

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 under which Sanofi committed to funding the development costs of Regeneron's human monoclonal antibody research program until 2017, up to a maximum of $160 million a year (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 is primarily responsible for funding, and co-develops 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 are 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 are shared 80% by Sanofi and 20% by Regeneron. Once a product begins to be marketed, Regeneron will progressively repay out of its profits 50% of the development costs borne by Sanofi for all antibodies licensed by Sanofi. However, Regeneron are not 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 2012, six 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 will be entitled to receive a royalty once the antibody begins to be marketed.

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 and in the United Kingdom since January 1, 2009. 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.

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 2012, we earned 31.1% 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".

Divestments

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).

There were no material divestments in 2010.

Acquisitions

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 (Sanofi's Animal Health division) 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.

In October 2012, Sanofi signed an agreement to acquire Genfar S.A. (Genfar), a Colombian pharmaceutical company that is a major player in Colombia and other countries in Latin America. Genfar is the second-largest generics manufacturer in Colombia by sales, and the leader by volumes sold. Closing of the deal is subject to certain conditions, and is expected to take place in the first quarter of 2013.

In December 2012, Sanofi announced that an agreement had been reached to acquire the animal health division of Dosch Pharmaceuticals Pvt Ltd, an Indian company, allowing Merial to enter this strategic animal health market. Closing of the deal is subject to regulatory approval, and is expected to take place during the first half of 2013.

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 develops a portfolio of branded pharmaceutical and healthcare products in China. See Note D.1.2. 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.1.2. 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.1.2. to our consolidated financial statements included at Item 18 of this annual report. The total amount of payments (including the upfront payment) could reach $207.5 million.

In November 2011, Sanofi acquired the business of Universal Medicare Private Limited (Universal), a major producer of nutraceuticals in India. An upfront payment of €83 million was made on completion of the transaction. See Note D.1.2. to our consolidated financial statements included at Item 18 of this annual report.

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. Total program funding over the first five years could amount to up to $125 million, including an equity investment of up to $75 million.

The principal acquisitions during 2010 are described below:

In February 2010, Sanofi acquired the U.S.-based company Chattem, Inc. (Chattem) by successfully completing a cash tender offer leading to the acquisition of 100% of the share capital. Chattem is a major consumer health player in the United States, producing and distributing branded consumer health products, toiletries and dietary supplements across various market segments. Chattem manages the Allegra® brand, and acts as the platform for Sanofi over-the-counter and consumer healthcare products in the United States. See Note D.1.4. to our consolidated financial statements included at Item 18 of this annual report.

In April 2010, Sanofi acquired a controlling interest in the capital of Bioton Vostok, a Russian insulin manufacturer. Under the terms of the agreement, put options were granted to non-controlling interests. See Note D.18. to our consolidated financial statements included at Item 18 of this annual report.

In May 2010, Sanofi formed a new joint venture with Nichi-Iko Pharmaceuticals Co., Ltd (Nichi-Iko), a leading generics company in Japan, to expand generics activities in the country. In addition to forming this joint venture, Sanofi took a 4.66% equity interest in the capital of Nichi-Iko.

In June 2010, Sanofi acquired 100% of the share capital of Canderm Pharma Inc. (Canderm), a privately-held leading Canadian skincare company distributing cosmeceuticals and dermatological products. Canderm generated net sales of 24 million Canadian dollars in 2009.

In July 2010, Sanofi acquired 100% of the share capital of TargeGen, Inc. (TargeGen), a U.S. biopharmaceutical company developing small molecule kinase inhibitors for the treatment of certain forms of leukemia, lymphoma and other hematological malignancies and blood disorders. An upfront payment of $75 million was made on completion of the transaction. Future milestone payments may be made at various stages in the development of TG 101348, TargeGen's principal product candidate. The total amount of payments (including the upfront payment) could reach $560 million. See Note D.1.4. and Note D.18. to our consolidated financial statements included at Item 18 of this annual report.

In August 2010, Sanofi acquired 100% of the share capital of Nepentes S.A. (Nepentes), a Polish manufacturer of pharmaceuticals and dermocosmetics, for a consideration of PLN 425 million (€106 million).

In October 2010, Sanofi Pasteur acquired 100% of the share capital of VaxDesign Corporation (VaxDesign), a privately-held U.S. biotechnology company which has developed a technology reproducing in vitro models of the human immune system, that can be used to select the best candidate vaccines at the pre-clinical stage. Under the terms of the agreement, an upfront payment of $55 million was made upon closing of the transaction, and a further $5 million will be payable upon completion of a specified development milestone.

In October 2010, Sanofi acquired a 60% equity interest in the Chinese consumer healthcare company Hangzhou Sanofi Minsheng Consumer Healthcare Co. Ltd, in partnership with Minsheng Pharmaceutical Co., Ltd ("Minsheng"). Minsheng was also granted a put option over the remaining shares not held by Sanofi. See Note D.18. to our consolidated financial statements included at Item 18 of this annual report.

Results of Operations

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

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

(under IFRS)		**as % of**		**as % of**
(€ million)	**2012**	**net sales**	**2011**	**net sales**
Net sales	**34,947**	**100.0%**	**33,389**	**100.0%**
Other revenues	1,010	2.9%	1,669	5.0%
Cost of sales	(11,118)	(31.8%)	(10,902)	(32.7%)
Gross profit	**24,839**	**71.1%**	**24,156**	**72.3%**
Research & development expenses	(4,922)	(14.1%)	(4,811)	(14.4%)
Selling & general expenses	(8,947)	(25.6%)	(8,536)	(25.6%)
Other operating income	562		319	
Other operating expenses	(454)		(315)	
Amortization of intangible assets	(3,291)		(3,314)	
Impairment of intangible assets	(117)		(142)	
Fair value remeasurement of contingent consideration liabilities	(192)		15	
Restructuring costs	(1,141)		(1,314)	
Other gains and losses, and litigation [(1)]			(327)	
Operating income	**6,337**	**18.1%**	**5,731**	**17.2%**
Financial expenses	(553)		(552)	
Financial income	93		140	
Income before tax and associates and joint ventures	**5,877**	**16.8%**	**5,319**	**15.9%**
Income tax expense	(1,134)		(455)	
Share of profit/(loss) of associates and joint ventures	393		1,070	
Net income	**5,136**	**14.7%**	**5,934**	**17.8%**
Net income attributable to non-controlling interests	169		241	
Net income attributable to equity holders of Sanofi	**4,967**	**14.2%**	**5,693**	**17.1%**
Average number of shares outstanding (million)	1,319.5		1,321.7	
Average number of shares outstanding after dilution (million)	1,329.6		1,326.7	
Basic earnings per share (in euros)	3.76		4.31	
Diluted earnings per share (in euros)	3.74		4.29	

(1) *See Note B.20.2. to our consolidated financial statements included at Item 18 of this annual report.*

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

Net Sales

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

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

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

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

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

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

Net Sales by Product Pharmaceuticals segment

Net sales generated by our Pharmaceuticals segment were €28,871 million in 2012, up 3.5% on a reported basis but down 0.4% at constant exchange rates. The year-on-year change reflects the positive impact of consolidating Genzyme from April 2011 and the performance of growth platforms, but also the negative effects of generic competition (mainly on sales of Lovenox®, Taxotere® and Eloxatine® in the United States, and of Taxotere®, Plavix® and Aprovel® in Western Europe), the ending of the co-promotion agreement with Teva on Copaxone®, the divestiture of the Dermik business in July 2011, and austerity measures in the European Union.

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

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

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

(€ million)		2012	2011	Change on a reported	Change at constant exchange
Product	**Indication**	**Reported**	**Reported**	**basis (%)**	**rates (%)**
Lantus®	Diabetes	4,960	3,916	+26.7%	+19.3%
Apidra®	Diabetes	230	190	+21.1%	+16.8%
Amaryl®	Diabetes	421	436	-3.4%	-8.0%
Insuman®	Diabetes	135	132	+2.3%	+3.0%
Other diabetes products	Diabetes	36	10	+260.0%	+250.0%
Total: Diabetes	**Diabetes**	**5,782**	**4,684**	**+23.4%**	**+16.7%**
Eloxatin®	Colorectal cancer	956	1,071	-10.7%	-17.3%
Taxotere®	Breast, lung, prostate, stomach, and head & neck cancer	563	922	-38.9%	-41.9%
Jevtana®	Prostate cancer	235	188	+25.0%	+20.2%
Zaltrap®	Colorectal cancer	25			
Mozobil® (1)	Hematologic malignancies	96	59		
Other oncology products (1)		519	389		
Total: Oncology		**2,394**	**2,629**	**-8.9%**	**-14.3%**
Lovenox®	Thrombosis	1,893	2,111	-10.3%	-12.0%
Plavix®	Atherothrombosis	2,066	2,040	+1.3%	-4.6%
Aprovel®/CoAprovel®	Hypertension	1,151	1,291	-10.8%	-13.3%
Allegra®	Allergic rhinitis, urticaria	553	580	-4.7%	-9.5%
Stilnox®/Ambien®/Myslee®	Sleep disorders	497	490	+1.4%	-4.5%
Copaxone®	Multiple sclerosis	24	436	-94.5%	-94.7%
Depakine®	Epilepsy	410	388	+5.7%	+3.1%
Tritace®	Hypertension	345	375	-8.0%	-8.3%
Multaq®	Atrial fibrillation	255	261	-2.3%	-8.0%
Xatral®	Benign prostatic hypertrophy	130	200	-35.0%	-37.0%
Actonel®	Osteoporosis, Paget's disease	134	167	-19.8%	-21.6%
Nasacort®	Allergic rhinitis	71	106	-33.0%	-35.8%
Renagel®/Renvela® (1)	Hyperphosphatemia	653	415		
Synvisc®/Synvisc-One® (1)	Arthritis	363	256		
Aubagio®	Multiple sclerosis	7			
Sub-total Multiple sclerosis		*7*			
Cerezyme® (1)	Gaucher disease	633	441		
Myozyme®/Lumizyme® (1)	Pompe disease	462	308		
Fabrazyme® (1)	Fabry disease	292	109		
Other rare disease products (1)		391	264		
Sub-total Rare diseases (1)		*1,778*	*1,122*		
Total: New Genzyme (1)		**1,785**	**1,122**		
Other prescription products		5,513	5,927	-7.0%	-9.1%
Consumer Health Care		3,008	2,666	+12.8%	+9.9%
Generics		1,844	1,746	+5.6%	+5.0%
Total Pharmaceuticals		**28,871**	**27,890**	**+3.5%**	**-0.4%**

(1)

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

Diabetes

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

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

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

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

Oncology

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

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

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

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

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

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

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

Other pharmaceutical products

Lovenox® recorded a fall in net sales of 12.0% at constant exchange rates to €1,893 million in 2012, as a result of competition from generics in the United States, where sales slipped by 53.1% (at constant exchange rates) to €319 million. Sales generated outside the United States accounted for 83.1% of worldwide net sales and rose by 5.5% at constant exchange rates to €1,574 million, driven by Emerging Markets (up 11.6% at constant exchange rates at €615 million). Sanofi also launched its own generic version of Lovenox® in the United States, sales of which are recognized in the Generics business.

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

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

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

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

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

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

New Genzyme business

The **new Genzyme** business consists of products used to treat rare diseases, and products for the treatment of multiple sclerosis (Aubagio® and the experimental agent Lemtrada).

Because Genzyme's net sales have been consolidated from the acquisition date (i.e. the start of April 2011), the 2011 consolidated net sales of the new Genzyme business do not include sales for the first quarter of 2011. On a constant structure basis and at constant exchange rates, i.e. after including non-consolidated net sales for the first quarter of 2011, the net sales of the new Genzyme business rose by 16.9% in 2012 to €1,785 million.

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

(€ million)		**2012**	**2011**	**Change on a constant structure basis and at constant**
Product	**Indication**	**Reported**	**Reported**	**exchange rates (%)**
Aubagio®	Multiple sclerosis	7		
Sub-total Multiple sclerosis		7		
Cerezyme® [(1)]	Gaucher disease	633	441	+6.0%
Myozyme®/Lumizyme® [(1)]	Pompe disease	462	308	+11.4%
Fabrazyme® [(1)]	Fabry disease	292	109	+96.4%
Other rare disease products [(1)]		391	264	+7.5%
Sub-total Rare diseases [(1)]		*1,778*	*1,122*	*+16.4%*
Total: New Genzyme [(1)]		**1,785**	**1,122**	**+16.9%**

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

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

Net sales of **Myozyme®/Lumizyme®** were up 11.4% on a constant structure basis and at constant exchange rates at €462 million (+10,4% in Western Europe, at €257 million; +6.9% in the United States, at €117 million).

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

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

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

Consumer Health Care business

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

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

Generics business

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

Net sales of the **other prescription products** in the portfolio were down 9.1% at constant exchange rates, to €5,513 million. For a description of our other pharmaceutical products, see "Item 4. Information on the Company B. Business Overview Pharmaceutical Products."

The following table breaks down net sales of our Pharmaceutical segment products by geographical region in 2012:

(€ million) **Product**	**Western Europe** [1]	**Change at constant exchange rates**	**United States**	**Change at constant exchange rates**	**Emerging Markets** [2]	**Change at constant exchange rates**	**Other countries** [3]	**Change at constant exchange rates**
Lantus®	778	+5.3%	3,087	+22.0%	793	+25.4%	302	+20.6%
Apidra®	78	+14.7%	73	+3.1%	51	+37.8%	28	+30.0%
Amaryl®	28	-12.5%	3	-25.0%	263	+11.4%	127	-32.6%
Insuman®	98	-4.9%	1		37	+27.6%	(1)	
Other diabetes products	30	+190.0%	3				3	
Total: Diabetes	**1,012**	**+4.3%**	**3,167**	**+21.5%**	**1,144**	**+22.5%**	**459**	**+0.2%**
Eloxatine®	13	-65.8%	718	-18.0%	153	-10.5%	72	+3.1%
Taxotere®	53	-72.5%	53	-80.2%	270	-11.2%	187	-10.7%
Jevtana®	91	+104.5%	109	-23.7%	33	+153.8%	2	
Zaltrap®			24				1	
Mozobil® [4]	30		56		7		3	
Other oncology products [4]	104		281		95		39	
Total: Oncology	**291**	**-23.7%**	**1,241**	**-19.8%**	**558**	**0.0%**	**304**	**-1.7%**
Lovenox®	854	+1.9%	319	-53.1%	615	+11.6%	105	+2.1%
Plavix®	307	-25.8%	76*	-62.2%	799	+5.5%	884	+13.4%
Aprovel®/CoAprovel®	557	-26.4%	45*	-8.2%	395	+2.5%	154	+17.5%
Allegra®	11	-15.4%	(1)	-133.3%	120	+21.2%	423	-15.1%
Stilnox®/Ambien®/Myslee®	46	-13.2%	85	-4.9%	70	+7.7%	296	-5.5%
Copaxone®	19	-95.4%					5	-81.0%
Depakine®	143	-3.4%			251	+7.9%	16	-6.3%
Tritace®	150	-11.8%			180	-1.1%	15	-37.5%
Multaq®	46	-31.8%	200	+0.5%	8	0.0%	1	-25.0%
Xatral®	45	-24.1%	20	-74.7%	62	-6.3%	3	0.0%
Actonel®	33	-38.9%			66	-16.7%	35	-5.7%
Nasacort®	20	-20.0%	21	-63.0%	26	+8.7%	4	-25.0%
Renagel®/Renvela® [4]	128		451		53		21	
Synvisc®/Synvisc-One® [4]	20		302		24		17	
Aubagio®			7					
Sub-total Multiple sclerosis			*7*					
Cerezyme® [4]	215		166		190		62	
Myozyme®/Lumizyme® [4]	257		117		55		33	
Fabrazyme® [4]	52		152		41		47	
Other rare disease products [4]	92		122		83		94	
Sub-total Rare diseases [4]	*616*		*557*		*369*		*236*	
Total: New Genzyme [4]	**616**		**564**		**369**		**236**	
Other prescription products	2,105	-12.9%	567	-16.7%	2,062	-2.8%	779	-8.4%
Consumer Health Care	666	+2.2%	606	+2.2%	1,478	+19.9%	258	-2.1%
Generics	500	+11.5%	272	+42.4%	1,045	-2.7%	27	-29.4%
Total pharmaceuticals	**7,569**	**-9.9%**	**7,935**	**+0.9%**	**9,325**	**+7.8%**	**4,042**	**-0.3%**

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

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

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

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

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

Net Sales Human Vaccines (Vaccines) segment

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

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

(€ million)	2012 Reported	2011 Reported	Change on a reported basis (%)	Change at constant exchange rates (%)
Polio/Pertussis/Hib Vaccines (*including Pentacel® and Pentaxim®*)	1,184	1,075	+10.1%	+5.0%
Influenza Vaccines (*including Vaxigrip® and Fluzone®*)	884	826	+7.0%	-0.2%
of which seasonal influenza vaccines	*882*	*826*	*+6.8%*	*-0.6%*
of which pandemic influenza vaccines	*2*			
Meningitis/Pneumonia Vaccines (*including Menactra®*)	650	510	+27.5%	+18.0%
Adult Booster Vaccines (*including Adacel®*)	496	465	+6.7%	0.0%
Travel and Other Endemics Vaccines	364	370	-1.6%	-4.9%
Other Vaccines	319	223	+43.0%	+31.8%
Total Vaccines	**3,897**	**3,469**	**+12.3%**	**+5.7%**

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

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

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

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

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

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

(€ million)	Western Europe [1] Reported	Change at constant exchange rates	United States Reported	Change at constant exchange rates	Emerging Markets [2] Reported	Change at constant exchange rates	Other countries [3] Reported	Change at constant exchange rates
Polio/Pertussis/Hib Vaccines (*inc. Pentacel® and Pentaxim®*)	55	+52.8%	374	-25.1%	495	+5.7%	260	+105.0%
Influenza Vaccines [4] (*inc. Vaxigrip® and Fluzone®*)	79	+2.6%	466	-5.1%	317	+5.1%	22	+16.7%
Meningitis/Pneumonia Vaccines (*inc. Menactra®*)	4	+33.3%	473	+10.5%	165	+52.9%	8	-38.5%
Adult Booster Vaccines (*inc. Adacel®*)	59	-22.4%	372	+0.9%	45	+50.0%	20	-5.0%
Travel and Other Endemics Vaccines	21	-12.5%	96	-1.1%	201	-4.8%	46	-8.5%
Other Vaccines	9	-46.7%	277	+46.6%	18	0.0%	15	-25.0%
Total Vaccines	**227**	**-2.2%**	**2,058**	**-0.7%**	**1,241**	**+9.1%**	**371**	**+48.9%**

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

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

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

(4) *Seasonal and pandemic influenza vaccines.*

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

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

Net Sales Animal Health segment

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

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

(€ million)	2012 Reported	2011 Reported	Change on a reported basis	Change at constant exchange rates
Frontline® and other fipronil-based products	775	764	+1.4%	-3.4%
Vaccines	730	662	+10.3%	+7.6%
Avermectin	423	372	+13.7%	+7.8%
Other products	251	232	+8.2%	+3.9%

Total Animal Health	**2,179**	**2,030**	**+7.3%**	**+3.1%**

Net sales for the **companion animals** franchise rose by 1.8% at constant exchange rates to €1,372 million. Erosion in sales of the **Frontline®/fipronil** range of products was limited to 3.4% at constant exchange rates

(€775 million) despite competitive pressure in the United States (down 7.8% at constant exchange rates, at €411 million), thanks to good performances in Emerging Markets (up 10.5%, at €93 million).

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

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

(€ million) Product	Western Europe [1]	Change at constant exchange rates	United States	Change at constant exchange rates	Emerging Markets [2]	Change at constant exchange rates	Other countries [3]	Change at constant exchange rates
Frontline® and other fipronil-based products	208	-0.5%	411	-7.8%	93	+10.5%	63	-3.3%
Vaccines	181	-7.7%	152	+11.1%	375	+14.2%	22	+31.3%
Avermectin	62	-4.7%	223	+15.8%	65	+10.0%	73	-2.8%
Other products	88	-2.2%	94	+1.1%	46	+27.8%	23	0.0%
Total Animal Health	**539**	**-3.8%**	**880**	**+1.4%**	**579**	**+14.0%**	**181**	**+0.6%**

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

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

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

Net Sales by Geographical Region

We divide our sales geographically into four regions: Western Europe, the United States, Emerging Markets and other countries. The following table breaks down our 2012 and 2011 net sales by region:

(€ million)	2012 Reported	2011 Reported	Change on a reported basis	Change at constant exchange rates
Western Europe [1]	8,335	9,130	-8.7%	-9.3%
United States	10,873	9,957	+9.2%	+0.7%
Emerging Markets [2]	11,145	10,133	+10.0%	+8.3%
Of which Eastern Europe and Turkey	*2,721*	*2,666*	*+2.1%*	*+2.1%*
Of which Asia (excl. Pacific region [3])	*2,841*	*2,416*	*+17.6%*	*+10.1%*
Of which Latin America	*3,435*	*3,111*	*+10.4%*	*+11.3%*
Of which Africa	*1,018*	*949*	*+7.3%*	*+8.3%*
Of which Middle East	*1,001*	*872*	*+14.8%*	*+12.2%*
Other Countries [4]	4,594	4,169	+10.2%	+2.5%
Of which Japan	*3,274*	*2,865*	*+14.3%*	*+6.6%*
Total	**34,947**	**33,389**	**+4.7%**	**+0.5%**

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

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

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

(4)

Japan, Canada, Australia and New Zealand.

Net sales in Western Europe fell by 9.3% at constant exchange rates to €8,335 million, hampered by the transfer of the Copaxone® business to Teva; by competition from generics of Taxotere® (down 72.5% at constant exchange rates), Aprovel® (down 26.4% at constant exchange rates) and Plavix® (down 25.8% at constant exchange

rates); and by the impact of austerity measures implemented by European governments. After including Genzyme for the first quarter of 2011 and excluding Copaxone®, net sales fell by 7.5% at constant exchange rates.

In the United States, net sales were up 0.7% at constant exchange rates (but fell by 2.8% after including Genzyme in the first quarter of 2011) to €10,873 million. The year-on-year change reflected strong performances from Lantus® and from the new Genzyme and Generics businesses (including our own generic version of Lovenox®), but also the impact of generics of Taxotere®, Lovenox® and Eloxatine®.

In Emerging Markets, net sales reached €11,145 million, up 8.3% at constant exchange rates (or 7.2% after including Genzyme for the first quarter of 2011). In China, net sales were €1,249 million, up 15,0% at constant exchange rates, on a strong performance from Plavix® and Lantus®. In Brazil, net sales increased by 7.7% at constant exchange rates to €1,530 million, boosted by the Consumer Health Care business and the contribution from Genzyme, although growth was hampered by a slowdown in sales of generics. The Africa and Middle East zones topped the billion-euro mark for the first time (€1,018 million and €1,001 million, respectively). Sales in Russia reached €851 million, up 13.6% at constant exchange rates, driven by the Consumer Health Care and Generics businesses and also by Lantus®, Plavix® and Lovenox®.

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

Worldwide Presence of Plavix® and Aprovel®

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

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

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

On October 3, 2012, Sanofi and BMS announced the restructuring of their alliance with effect from January 1, 2013 (see " Financial Presentation of Alliances Alliance arrangements with Bristol-Myers Squibb" above).

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

(€ million)	2012	2011	Change on a reported basis	Change at constant exchange rates
	Sanofi			