Sanofi
Form 20-F
March 06, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

(Mark One)

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

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2011

OR

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

¨ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
Date of event requiring this shell company report . . . . . .

For the transition period from to

Commission File Number: 001-31368

Sanofi

(Exact name of registrant as specified in its charter)

N/A

(Translation of registrant s name into English)

France

(Jurisdiction of incorporation or organization)

54, Rue La Boétie, 75008 Paris, France

(Address of principal executive offices)

Karen Linehan, 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, 2011 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 x NO ¨.

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

YES ¨ NO x.

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 x No ¨

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

Yes x No ¨

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

Large accelerated filer x Accelerated filer ¨ Non-accelerated filer ¨

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

U.S. GAAP ¨ International Financial Reporting Standards as issued by the International Accounting Standards Board x Other ¨

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

Item 17 ¨ Item 18 ¨

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

YES ¨ NO x.

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PRESENTATION OF FINANCIAL AND OTHER INFORMATION

The consolidated financial statements contained in this annual report on Form 20-F have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and with IFRS as adopted by the European Union, as of December 31, 2011.

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

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.; epiCard (e-cue) a trademark of Intellijject; Gardasil® a trademark of Merck & Co.; Hyalgan® a trademark of Fidia Farmeceutici S.p.A, under license agreement in the United States; Leukine® a trademark of Alcafleu; 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; Pancréate a trademark of CureDM; Prevelle® a trademark of Mentor Worldwide LLC USA; RetinoStat® a trademark of Oxford Biomedica; and RotaTeq® a trademark of Merck & Co.;

- 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; DDAVP® a trademark of Ferring (except in the United States where it is a trademark of the Group); Lactacyd® a trademark of GSK in certain countries; Liberty®, LibertyLink® 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; ACT® a trademark of Johnson & Johnson on certain geographical areas (except the United States and other countries where it is a trademark of Signal Investment); Aspirine®, Cipro®, Advantage® and Advantix® trademarks of Bayer; Eprinex® a trademark of Merck & Co. in certain countries; Humaneered a trademark of KaloBios Pharmaceuticals; IC31® a trademark of Intercell; iPhone® a trademark of Apple Inc.; LentiVector® and RetinoStat® trademarks of Oxford BioMedica; Libertas a trademark of Apotex in the United States and of International Contraceptive & SRH Marketing Limited in the United Kingdom; Mediator® a trademark of Biofarma; PetArmor® a trademark of Velcera, Inc.; Rotarix® a trademark of GSK; Sklice® a trademark of Topaz Pharmaceuticals LLC; 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® and Aubagio trade names have not been approved by the FDA.

The data relative to market shares and ranking information for pharmaceutical products presented in particular 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 2011, in constant euros (unless otherwise indicated).

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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 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. The list below indicates some of the risk factors faced by the Company:

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 ;

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product liability claims could adversely affect our business, results of operations and financial condition ;

changes in the laws or regulations that apply to us could affect the Group s business, results of operations and financial condition ;

generic versions of some of our products may be approved for sale in one or more of their major markets ;

our long-term objectives may not be fully realized ;

we may fail to adequately renew our product portfolio whether through our own research and development or through acquisitions and strategic alliances ;

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

the diversification of the Group s business exposes us to additional risks ;

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 ;

we incurred substantial debt in connection with the acquisition of Genzyme which may limit our business flexibility compared to some of our peers ;

we face uncertainties over the pricing and reimbursement of pharmaceutical products ;

the ongoing slowdown of global economic growth and the financial crisis could have negative consequences for our business ;

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 ; and

risks related to financial markets.

We caution you that the foregoing list of risk factors is not exclusive and a number of important factors, discussed under Item 3. Key Information D. Risk Factors below, could affect the future results and cause actual results to differ materially from those contained in any forward-looking statements. Additional risks, not currently known or considered immaterial by the Group, may have the same unfavorable effect and investors may lose all or part of their investment.

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

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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, 2011, 2010 and 2009 are included in Item 18 of this annual report.

The consolidated financial statements of Sanofi for the years ended December 31, 2011, 2010 and 2009 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, 2011. 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, 2011.

Sanofi reports its financial results in euros.

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SELECTED CONDENSED FINANCIAL INFORMATION

	As of and for the year ended December 31,				
(million, except per share data)	**2011**	**2010**	**2009**	**2008**	**2007**
IFRS Income statement data[a]					
Net sales	33,389	32,367	29,785	27,568	28,052
Gross profit	24,156	24,638	23,125	21,480	21,636
Operating income	5,731	6,535	6,435	4,394	5,911
Net income attributable to equity holders of Sanofi	5,693	5,467	5,265	3,851	5,263
Basic earnings per share ( )[a]/[b] **:**					
Net income attributable to equity holders of Sanofi	4.31	4.19	4.03	2.94	3.91
Diluted earnings per share ( )[a]/[c] **:**					
Net income attributable to equity holders of Sanofi	4.29	4.18	4.03	2.94	3.89
IFRS Balance sheet data					
Goodwill and other intangible assets	61,718	44,411	43,480	43,423	46,381
Total assets	100,165	85,264	80,251	71,987	71,914
Outstanding share capital	2,647	2,610	2,618	2,611	2,657
Equity attributable to equity holders of Sanofi	56,219	53,097	48,322	44,866	44,542
Long term debt	12,499	6,695	5,961	4,173	3,734
Cash dividend paid per share ( )[d]	2.65 [e]	2.50	2.40	2.20	2.07
Cash dividend paid per share ($) [d]/[f]	3.43 [e]	3.34	3.46	3.06	3.02

[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 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 1,321.7 million shares in 2011, 1,305.3 million shares in 2010, 1,305.9 million shares in 2009, 1,309.3 million shares in 2008, and 1,346.9 million shares in 2007.*

[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., 1,326.7 million shares in 2011, 1,308.2 million shares in 2010, 1,307.4 million shares in 2009, 1,310.9 million shares in 2008, and 1,353.9 million shares in 2007.*

[d] *Each American Depositary Share, or ADS, represents one half of one share.*

[e] *Dividends for 2011 will be proposed for approval at the annual general meeting scheduled for May 4, 2012.*

[f] *Based on the relevant year-end exchange rate.*

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SELECTED EXCHANGE RATE INFORMATION

The following table sets forth, for the periods and dates indicated, certain information concerning the exchange rates for the euro from 2007 through March 2012 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)		
2007	1.46	1.38	1.49	1.29
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
Last 6 months				
2011				
September	1.34	1.37	1.43	1.34
October	1.39	1.37	1.42	1.33
November	1.35	1.36	1.38	1.32
December	1.30	1.32	1.35	1.29
2012				
January	1.31	1.29	1.32	1.27
February	1.34	1.32	1.35	1.31
March [2]	1.32	1.32	1.33	1.32

[1] *The average of the Noon Buying Rates on the last business day of each month during the relevant period for the full year average, and on each business day of the month for the monthly average. The latest available Noon Buying Rate being February 24, 2012, we have used European Central Bank Rates for the period from February 27, 2012 till February 29, 2012.*

[2] *In each case, measured through March 5, 2012.*

On March 5, 2012 the European Central Bank Rate was 1.3220 per euro.

B. Capitalization and Indebtedness

N/A

C. Reasons for Offer and Use of Proceeds

N/A

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D. Risk Factors

Important factors that could cause actual financial, business, research or operating results to differ materially from expectations are disclosed in this annual report, including without limitation the following risk factors and the factors described under Cautionary Statement Regarding Forward-Looking Statements . 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 certificate 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. 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, or our infringement claim may not result in a decision that our rights are valid, enforceable or infringed. Moreover, a number of countries are increasingly easing the introduction of generic drugs or biosimilar products through accelerated approval procedures.

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.

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 additional risks below). Substantial damage awards and/or settlements have been made 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

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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. Also our risk exposure also increased due to the fact that we are now commercializing some devices using new technologies which, in case of malfunction, could cause unexpected damages and trigger 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 and pricing could adversely affect our business, results of operations and financial condition.

The marketing of our products is heavily regulated, and alleged failures to comply fully with applicable regulations could subject us to substantial fines, penalties and injunctive or administrative remedies, potentially leading to the imposition of additional regulatory controls or exclusion from government reimbursement programs. 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. See Note D.22.c) to our consolidated financial statements included at Item 18 of this annual report.

Because many of these cases allege substantial unquantified damages, may be subject to treble damages and frequently seek significant punitive damages and penalties, it is possible that any final determination of liability or settlement of these claims or investigations could have a material adverse effect on our business, results of operations or financial condition.

There are other legal matters in which adverse outcomes could have a material adverse effect on our business, results of operations and financial condition.

The Group faces significant litigation and government investigations or audits, including allegations of securities law violations, claims related to employment matters, patent and intellectual property disputes, consumer law claims and tax audits.

Unfavorable outcomes in these matters, or in similar matters to be faced in the future, could preclude the commercialization of products, negatively affect the profitability of existing products and subject us to substantial fines, penalties and injunctive or administrative remedies, potentially leading to the imposition of additional regulatory controls or exclusion from government reimbursement programs. Any such result could materially and adversely affect our results of operations, financial condition, or business. 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.

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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 Regulation .

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

Generic versions of some of our products may be approved for sale in one or more of their major markets.

Many of our products are subject to aggressive generic competition, and additional products of the Group could become subject to generic competition in the future as product patents and/or exclusivities for several of our products have recently expired, or are about to expire. For example pediatric exclusivity for Aprovel® and Plavix® which contribute significantly to our net income will expire in the United States in March 2012 and May 2012, respectively, and the compound patent of Aprovel® will expire in most of the European Union in August 2012. Also, the U.S. market exclusivity of Eloxatin® will expire in August 2012, pursuant to settlement agreements. We expect this generic competition to continue and to implicate drug products with even relatively modest revenues.

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. Accordingly, 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. For instance in 2011, there was only one generic product of enoxaparin sodium (Lovenox®) marketed in the United States. The introduction of a second generic on the U.S. market in early 2012 is likely to decrease our sales and revenues on this product.

Our long-term objectives may not be fully realized.

We have established a strategy focused on three pillars: increased innovation in R&D, adaptation of our structure for future opportunities and challenges and pursuit of external growth opportunities. 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.

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As a further example, we are implementing a cost savings program across the Group and expect this new initiative, together with expected synergies from our recent acquisition of Genzyme, to generate additional incremental cost savings by 2015. We may fail to realize all the expected cost savings, which could materially and adversely affect our financial results.

We may fail to adequately renew our product portfolio whether through our own research and development or through acquisitions and strategic alliances.

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 2011, we spent 4,811 million on research and development, amounting to approximately 14.4% of our net sales.

Developing a product is a costly, lengthy and uncertain process. Also we may not be investing in the right technology platforms, leading 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 showing the same mechanism of action reaches earlier the market.

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). 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. Each regulatory authority may also impose its own requirements 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. Finally, 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.

Also our success depends on our ability to educate patients and healthcare providers and provide them with innovative data about our products and their 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.

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 approvals in sufficient time to meet product demand.

As a complement to our portfolio of products, we pursue a strategy of selective acquisitions, in-licensing and partnerships in order to develop new growth opportunities. The implementation of this strategy depends on our ability to identify business development opportunities at a reasonable cost and under acceptable conditions of

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financing. Moreover, entering into these 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.

Because of the active competition among pharmaceutical groups for such business development opportunities, there can be no assurance of our success in completing these transactions when such opportunities are identified.

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, 2011 compared with year ended December 31, 2010 Net Sales by Product Pharmaceuticals), which represented 37.6% of the Group s consolidated revenues in 2011. Among these products is Lantus®, which was the Group s leading product with revenues of 3,916 million in 2011, representing 11.7% 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.

Sales of Cerezyme®, our enzyme-replacement product for patients with Gaucher disease which is also amongst our flagship products, totaled 441 million for the year ended December 31, 2011, below the usual level of sales due to important production disruptions since 2009 (see 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. below). In addition the patient population with Gaucher disease is limited. Furthermore, changes in the methods for treating patients with such disease could limit growth, or result in a decline, in Cerezyme® sales.

In general, a reduction in sales of one or more of our flagship products or in their growth could affect our business, results of operations and 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.

For example, Cerezyme® and Fabrazyme® shortages due to manufacturing issues at our facility in Allston, Massachusetts (United-States) (see 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. below) created, and continue to create, opportunities for our competitors and have resulted in a decrease in the number of patients using these products and a loss of our overall market share of Gaucher and Fabry patients, respectively. Even if we are able again to provide a full, sustainable product supply, there is no guarantee these patients will return to using our products.

Additionally, 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.

The diversification of the Group s business exposes us to additional risks.

We are implementing a strategy that includes pursuing external growth opportunities to meet the challenges that we have identified for the future. The inability to quickly or efficiently integrate newly acquired activities or businesses, such as Genzyme, the loss of key employees or integration costs that are higher than anticipated, could delay our growth objectives and prevent us from achieving expected synergies. For instance, challenges that we may face in our efforts to integrate Genzyme include, among others:

addressing manufacturing problems and supply constraints that have negatively affected Genzyme s business in recent years;

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ensuring continued compliance with a consent decree that Genzyme entered into with the FDA in May 2010 relating to a manufacturing facility in Allston, Massachusetts (United-States) (see Item 4. Information on the Company B. Business Overview Production and Raw Materials.);

the outcome of ongoing legal and other proceedings to which Genzyme is a party, including shareholder litigation and patent litigation;

preserving and developing Genzyme s goodwill in the genetic disease community; and

realizing the potential of the research and development pipeline.

If we fail to effectively integrate Genzyme or the integration takes longer than expected, we may not achieve the expected benefits of the transaction.

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. It may take a considerable amount of time and be difficult to implement a risk analysis 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.

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:

we have increased exposure to the animal health business. 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 global 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, and 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. Any 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 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

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property protection, higher crime levels (particularly with respect to counterfeit products (see Counterfeit versions of our products harm our business, below)), corruption and fraud, as we operate in many parts of the world where corruption exists to some degree.

Our existing policies and procedures, which are designed to help ensure that we, our employees and our agents 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 taken by our employees, agents and intermediaries 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.

Health authorities, are increasingly focusing on product safety and on the risk/benefit profile of pharmaceuticals products. In particular, the FDA and the European Medicines Agency (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 unnecessary commercial harm, overly restrictive regulatory actions and erratic share price performance.

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. If we fail to adequately respond to a warning letter

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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.

For example, in May 2010, Genzyme entered into a consent decree with the FDA relating to its Allston facility (see Item 4. Information on the Company B. Business Overview Production and Raw Materials.). Pursuant to the consent decree, in November 2010, Genzyme paid $175.0 million to the U.S. Federal Governement disgorgement of past profits. The consent decree also requires 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. Remediation of the Allston facility in accordance with that plan is underway and is currently expected to continue for four more years, however, there is no guarantee that this timeframe will be respected.

We incurred substantial debt in connection with the acquisition of Genzyme which may limit our business flexibility compared to some of our peers

Our consolidated debt increased substantially in connection with our acquisition of Genzyme because we incurred debt to finance the acquisition price, and because our consolidated debt includes the debt incurred by Genzyme prior to the acquisition. Although we already achieved a partial deleverage by the end of 2011 (as of December 31, 2011, our debt, net of cash and cash equivalents amounted to 10.9 billion), we 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 uncertainties over the pricing and reimbursement of pharmaceutical products.

The commercial success of our existing products and our products candidates depends in part on the conditions under which our products are reimbursed. Pressure on pricing and reimbursement is strong due to:

- 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, health care reform law is increasing the government s role with respect to price, reimbursement and the coverage levels for healthcare-related expenses for the large government health care sector, imposed cost containment measures and imposed drug companies rebates to the government. 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 states are also considering legislation that would control the prices of and access to drugs and we believe that federal and state legislatures and health agencies will 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 example, in Spain, recent direct price-related measures include price discount to all products launched more than 10 years ago, all genericized products needing to be at a minor (lower) price, and no more gradualism in price reductions of originator post generics introduction. Additionally, measures such as INN prescriptions, have been implemented. Another example, in Turkey Government has accelerated enforcement of drugs costs containment measures which include increased institutional discount applied on reimbursement prices and lower reference prices for reimbursement of Generics and originals with Generics as well as 20-year old drugs without Generics.

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

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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. This effect may be expected to be particularly strong in markets having significant co-pays or lacking a developed third-party payer system, as individual patients may delay or decrease out-of-pocket healthcare expenditures. Such a slowdown could also reduce 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.

Additionally, to the extent the slowing economic environment, as well as ongoing sovereign debt crisis affecting several European countries, may lead to financial difficulties or even the default or failure of major players including wholesalers or public sector buyers financed by insolvent States, the Group could 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 manufacture and supply of a substantial portion of our raw materials, active ingredients and medical devices; supply disruptions and/or quality concerns could adversely affect our operating results and financial condition , We rely on third parties for the marketing of some of our products and Fluctuations in currency exchange rates could adversely affect our results of operations and financial condition below.

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 may lead some patients to switch to generic products, delay treatments, skip doses or use less effective treatments to reduce their costs. Moreover, current economic conditions in the United States have resulted in an increase in the number of patients in the Medicaid program, under which sales of pharmaceuticals are subject to substantial rebates and, in many U.S. states, to formulary restrictions limiting access to brand-name drugs, including ours.

Our animal health business may also be negatively affected by the current slowdown in global economic growth (for instance tight credit conditions may limit the borrowing power of livestock producers, causing some to switch to lower-priced products).

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. 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

[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.

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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). The investigation and remediation of any identified problems can cause production delays, substantial expense, lost sales and the delay of new product launches and can adversely affect our operating results and financial condition.

Like many of our competitors, we have faced, and to a certain extent continue to face, significant manufacturing issues, most notably in our Genzyme subsidiary for the production of Cerezyme® and Fabrazyme®. In June 2009, Genzyme announced it had detected a virus that impairs cell growth in one of the bioreactors used in the Allston, Massachusetts facility to produce Cerezyme®. This contamination has had a material adverse effect on Cerezyme® and Fabrazyme® revenues. We will continue to work with minimal levels of inventory for Cerezyme® and Fabrazyme® until we are able to build inventory. However, there can be no guarantee that we will be able to return to pre-contamination supply levels of such products, nor can there be any 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 manufacture and supply of a substantial portion of our raw materials, active ingredients and medical devices; supply disruptions and/or quality concerns could adversely affect our operating results and financial condition.

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.

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 may not have redundant manufacturing capacity for certain products particularly biologic products. For instance in summer 2011 a technical incident occurred in the filling line used for Apidra 3mL cartridges at our manufacturing site in Frankfurt and this has caused temporary shortages for Apidra 3mL cartridges. Also 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.

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.

We rely on third parties for the marketing of some of our products.

We market some of our products in collaboration with other pharmaceutical companies. For example, we currently have major collaborative arrangements with Bristol-Myers Squibb (BMS) for the marketing of Plavix® and Aprovel® in the United States and several other countries, with 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 major alliances. When we market our products through collaboration arrangements, we are subject to the risk that certain decisions, such as the establishment of budgets and promotion strategies, are subject to the control of our collaboration partners, and that deadlocks may adversely affect the activities conducted through the collaboration arrangements. For example, our alliances with BMS are subject to the operational management of BMS in some countries, including the United States. Any conflicts that

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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 62% of our consolidated U.S. pharmaceutical sales are accounted for by just three wholesalers. In addition, the Group s three main customers represent 17.4% 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 the beginning of 2010, financial difficulties in some countries of southern Europe have increased especially in Greece and Portugal. Part of our customers in these countries are public or subsidized health systems. The deteriorating economic and credit conditions in these countries has led to longer payment terms. This trend may continue and 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).

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.

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.

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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 Fluctuations in currency exchange rates could adversely affect our results of operations and financial condition below and The ongoing slowdown of global economic growth and the financial crisis could have negative consequences for our business above). For example, given the current level of investor confidence in the ability of the Greek State to avoid default, as a result of mark to market accounting standards, we recognized an impairment of 49 million on certain Greek bonds held by us in 2011.

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 some devices using new technologies which, in case of malfunctions could lead to a misuse causing a risk of damages to patients (see Product liability claims could adversely affect our business, results of operations and financial condition above). Our inability or the inability 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 could lead to data deterioration or loss in the event of a system malfunction, or allow data to be 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.

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 hazardous 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.

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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.

Environmental regulations are evolving (*i.e.*, in Europe, REACH, CLP/GHS, SEVESO, IPPC, 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 2011, 29.8% 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

[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.

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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 alleged or actual disruption in the use 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, 2011, the Group s net debt amounted approximately to 10.9 billion, an amount which increased substantially with the acquisition of Genzyme in 2011. 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.

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 offer new shares and they 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, to exercise their voting rights, as holders of ADSs, they must instruct the depositary how to vote their shares. Because of this extra procedural step involving the depositary, the process for exercising voting rights will take longer for holders of ADSs than for holders of shares. ADSs for which the depositary does not receive timely voting instructions will not be voted at any meeting.

Our largest shareholders own a significant percentage of the share capital and voting rights of Sanofi.

As of December 31, 2011, L Oréal and Total held approximately 8.82% and 3.22% of our issued share capital, respectively, accounting for approximately 15.69% and approximately 5.52%, respectively, of the voting rights (excluding treasury shares) of Sanofi. See Item 7. Major Shareholders and Related Party Transactions A. Major Shareholders. Affiliates of each of these shareholders are currently serving on our Board of Directors. To the extent these shareholders continue to hold a large percentage of our share capital and voting rights, L Oréal and Total will remain in a position to exert heightened influence in the election 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.

Neither L Oréal nor Total is, to our knowledge, subject to any contractual restrictions on the sale of the shares each holds in our Company. Both of these shareholders have announced that they do not consider their stakes in our Company as strategic to them, and Total makes regular sales of its holdings on the financial market. 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.

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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. 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;
- because a public market for the CVRs has a limited history, the market price and trading volume of the CVRs may be volatile;
- 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 are subordinated to the right of payment of certain of our indebtedness;
- we are not prohibited from acquiring the CVRs, whether in open market transactions, private transactions or otherwise, and on November 17, 2011, Sanofi publicly disclosed that it has obtained the necessary coporate authorizations to acquire any or all of the 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.

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Item 4. Information on the Company

Introduction

We are a global pharmaceutical group engaged in the research, development, manufacture and marketing of healthcare products. In 2011, our net sales amounted to 33,389 million. We are the fifth largest pharmaceutical group in the world and the third largest pharmaceutical group in Europe (source: IMS sales 2011). 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.

Our business includes three main activities: Pharmaceuticals, Human Vaccines through Sanofi Pasteur and Animal Health products through Merial Limited (Merial).

In our Pharmaceuticals activity, which generated net sales of 27,890 million in 2011, our major product categories are:

Diabetes: 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 first launched in Europe during the second quarter of 2011.

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

Oncology: our main products in the oncology market are Taxotere®, a taxane derivative representing a cornerstone therapy in several cancer types; Eloxatine®, a platinum agent, which is a key treatment for colorectal cancer; and Jevtana®, a new taxane derivative, indicated for patients with prostate cancer, launched in 2010 in the United States and in second quarter of 2011 in Europe.

Other flagship 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 launched in 2009; and Aprovel®/CoAprovel®, major 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.

The global pharmaceutical portfolio of Sanofi also comprises a wide range of other products in Consumer Health Care (CHC) and other prescription drugs including generics.

We are a world leader in the vaccines industry. Our net sales amounted to 3,469 million in 2011, with leading vaccines in five areas: pediatric combination 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 providing a comprehensive range of products to enhance the health, well-being and performance of a wide range of animals (production and companion animals). Our net sales amounted to 2,030 million in 2011.

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).

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For our pharmaceutical activity, except where otherwise stated, all market share percentages and rankings are based on full-year 2011 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

Sanofi 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. We operate under the commercial name Sanofi (formerly 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 113,719 employees at year end 2011. Our legacy companies, Sanofi-Synthélabo (formed by the 1999 merger of Sanofi and Synthélabo into the current holding company) and Aventis (formed by the combination of Rhône-Poulenc and Hoechst also in 1999), bring to the Group more than a century of experience in the pharmaceutical industry.

Sanofi was founded in 1973 by Elf Aquitaine, a French oil company, when it took control of the Labaz group, a pharmaceutical company. Its first significant venture into the U.S. market was the acquisition of the prescription pharmaceuticals business of Sterling Winthrop an affiliate of Eastman Kodak in 1994.

Synthélabo was founded in 1970 through the merger of two French pharmaceutical laboratories, Laboratoires Dausse (founded in 1834) and Laboratoires Robert & Carrière (founded in 1899). In 1973, the French cosmetics group L Oréal acquired the majority of its share capital.

Hoechst traces its origins to the second half of the 19th century, to the time of the German industrial revolution and the emergence of the chemical industry. Traditionally active in pharmaceuticals, Hoechst strengthened its position in that industry by taking a controlling interest in Roussel-Uclaf in 1974 and the U.S. pharmaceutical company Marion Merrell in 1995.

Rhône-Poulenc was formed in 1928 from the merger of two French companies: a chemical company created by the Poulenc brothers and the Société Chimique des Usines du Rhône, which was founded in 1895. The company s activities in the first half of the 20th century focused on producing chemicals, textiles and pharmaceuticals. Rhône-Poulenc began to focus its activities on life sciences in the 1990s, which led to the successive purchases of Rorer, a U.S. pharmaceutical company acquired in two stages in 1990 and 1997, the remaining 49% of shares of Pasteur Mérieux Serums & Vaccins S.A. in 1994, and the U.K.-based pharmaceuticals company Fisons in 1995.

Sanofi-Synthélabo took control of Aventis in August 2004 and changed its registered name to sanofi-aventis . On December 31, 2004, Aventis merged with and into sanofi-aventis, with sanofi-aventis as the surviving company.

In 1994, Pasteur Mérieux Serums & Vaccins, the Group s vaccines division, together with the vaccines division of Merck & Co., Inc. formed Sanofi Pasteur MSD, creating the only European firm entirely dedicated to vaccines.

Merial was founded in 1997 as a combination of the animal health activities of Rhône-Poulenc and Merck. Merial was a joint venture in which we and Merck each held 50%. On September 17, 2009, we acquired Merck s entire interest in Merial. 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. See Note D.2. to our consolidated financial statements included at Item 18 of this annual report.

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Starting in 2009, Sanofi made a series of acquisitions to create or strengthen our regional CHC and generics platforms including:

The Prague-based branded generics group Zentiva was acquired by Sanofi through a tender offer completed on March 11, 2009;

On April 27, 2009, Sanofi acquired a 100% equity interest in Medley, the third largest pharmaceutical company in Brazil and a leading generics company in that country;

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. Immediately following the tender offer, Sanofi held approximately 97% of Chattem s outstanding shares, and acquired the remaining shares in a short form merger on March 10, 2010; and

On February 24, 2011, we 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 of ours.

On April 4, 2011, we 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. Immediately following the tender offer, Sanofi held over 90% of Genzyme s outstanding shares, and acquired the remaining shares in a short form merger on April 8, 2011. The agreement is described at Item 10. Additional Information C. Material Contracts .

As of the May 2011 General Meeting of Shareholders, the Group changed its name to Sanofi .

B. Business Overview

Strategy

Sanofi is a diversified, global healthcare leader offering solutions across areas of core historical strength and multiple growth platforms. Like other pharmaceutical companies, 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. Starting in 2009, we have responded to these major challenges by implementing a new strategy with the objective of repositioning Sanofi for more stable and sustainable revenue and earnings growth. During that time we have transformed the Company 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 6 growth platforms (Emerging Markets[(1)], Diabetes Solutions, Human Vaccines, Consumer Health Care, Animal Health, and Innovative Products). Additionally, we became a global leader in rare genetic diseases through our acquisition of Genzyme in 2011.

We regularly review our strategy and are continuing to execute on this strategy along three prongs:

Increasing innovation in Research & Development (R&D)

We have conducted a complete review of our research and development portfolio since 2009, in order to improve the allocation of our resources. This review has led to a rationalization of our portfolio, focusing on high-value projects and reallocating part of our resources from internal infrastructure to partnerships and collaborations. We also redefined our decision-making processes so that commercial potential and the scope for value creation are better integrated into our development choices. We also redesigned our R&D footprint including increasing our presence in the Boston, MA area with its concentration of universities and innovative biotechnology companies. 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.

(1) We define Emerging Markets as the world excluding the United States, Canada, Western Europe (France, Germany, UK, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxemburg, Portugal, the Netherlands, Austria, Switzerland, Ireland, Finland, Norway, Iceland, Sweden and Denmark), Japan, Australia and New Zealand.

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In line with this policy, we signed new alliance and licensing agreements in 2011 designed to give us access to new technologies, and/or to broaden or strengthen our existing fields of research (including diabetes, oncology and vaccines). Finally, we have made progress on our objective of offering more products that add value for patients, with five New Molecular Entities (NMEs) submitted to regulatory agencies in 2011, and 18 potential new product launches possible before the end of 2015.

Adapting our structures to meet the opportunities and the challenges of the future

Since 2009, we have adapted our operating model, from being focused on the best-selling prescription drugs in our traditional markets, to a broader set of products and services reflecting the diversity of our activities and our geographical reach. In particular, we 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 Top 15 products to key growth platforms. In 2008, 61 % of our sales originated from our top 15 products while in 2011, 65 % of our sales originated from Genzyme and our growth platforms. Moreover, 30 % of our 2011 sales were in emerging markets where we have enhanced our offerings in high growth market segments such as Generics and Consumer Health Care by completing 17 transactions and investing a total of approximately 3.7 billion in acquisitions over the last three years.

We 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 keeping a tight control on SG&A expenses, this has helped enable us to successfully navigate through a period where multiple of our leading products faced the loss of patent exclusivity protection, despite an often tougher economic environment with new healthcare cost containment measures in many markets.

Exploring external 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 23 billion in external growth accounting for approximately 20% increase in 2011 consolidated sales. During 2011, we pursued this targeted policy actively, announcing 30 new transactions, including three acquisitions and 27 R&D alliances. We successfully completed our acquisition of Genzyme, a global leader in rare genetic diseases and an emerging leader in multiple sclerosis. We also strengthened our Emerging Markets growth platform with the acquisition of Universal Medicare, advancing our sustainable growth strategy in India and facilitating the creation of a Consumer Health Care platform in that country. Our U.S. vaccines operations were reinforced with the acquisition of Topaz Pharmaceuticals, which complements our pediatric offering.

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

Pharmaceutical Products

Main Pharmaceutical Products

Within our Pharmaceuticals business, we focus on the following categories: diabetes, rare diseases, oncology, and other flagship products in anti-thrombotics, cardiovascular, renal and biosurgery fields.

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.

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The following table sets forth the net sales of our best-selling pharmaceutical products for the year ended December 31, 2011. These products are major contributors to public health.

Therapeutic Area / Product Name	2011 Net Sales (million)	Drug Category / Main Areas of Use
Diabetes		
Lantus® (insulin glargine)	3,916	Long-acting analog of human insulin
		Type 1 and 2 diabetes mellitus
Apidra® (insulin glulisine)	190	Rapid-acting analog of human insulin
		Type 1 and 2 diabetes mellitus
Amaryl® (glimepiride)	436	Sulfonylurea
		Type 2 diabetes mellitus
Insuman® (insulin)	132	Human insulin (rapid and intermediate acting)
		Type 1 and 2 diabetes mellitus
Rare Disease		
Cerezyme® (imiglucerase for injection)	441(1)	Enzyme replacement therapy
		Gaucher disease
Fabrazyme® (agalsidase beta)	109(1)	Enzyme replacement therapy
		Fabry disease
Myozyme®/Lumizyme® (alglucidase alpha)	308(1)	Enzyme replacement therapy
		Pompe disease
Oncology		
Taxotere® (docetaxel)	922	Cytotoxic agent
		Breast cancer
		Non small cell lung cancer
		Prostate cancer
		Gastric cancer
		Head and neck cancer
Eloxatine® (oxaliplatin)	1,071	Cytotoxic agent
		Colorectal cancer
Jevtana® (cabazitaxel)	188	Cytotoxic agent
		Prostate cancer
Other Flagship products		
Lovenox® (enoxaparin sodium)	2,111	Low molecular weight heparin
		Treatment and prevention of deep vein thrombosis
		Treatment of acute coronary syndromes
Plavix® (clopidogrel bisulfate)	2,040	Platelet adenosine disphosphate receptor antagonist
		Atherothrombosis
		Acute coronary syndrome with and without ST segment elevation
Aprovel® (irbesartan) / CoAprovel® (irbesartan & hydrochlorothiazide)	1,291	Angiotensin II receptor antagonist
		Hypertension
Multaq® (dronedarone)	261	Anti-arrhythmic drug
		Atrial Fibrillation

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Therapeutic Area / Product Name	2011 Net Sales (million)	Drug Category / Main Areas of Use
Renagel® (sevelamer hydrochloride) / Renvala® (sevelamer carbonate)	415(1)	Oral phosphate binders High phosphorus levels in patients with chronic kidney disease, or CKD, on dialysis
Synvisc® / Synvisc-One® (hylan G-F 20)	256(1)	Viscosupplements Pain associated with osteoarthritis of the knee
Others		
Stilnox® /Ambien®/Myslee® (zolpidem tartrate)	490	Hypnotic Sleep disorders
Allegra® (fexofenadine hydrochloride)	580(2)	Anti-histamine Allergic rhinitis Urticaria
Copaxone® (glatiramer acetate)	436	Non-interferon immunomodulating agent Multiple sclerosis
Tritace® (ramipril)	375	Angiotensin Converting Enzyme inhibitor Hypertension Congestive heart failure Nephropathy
Depakine® (sodium valproate)	388	Anti-epileptic Epilepsy
Xatral® (alfuzosin hydrochloride)	200	Uroselective alpha1-blocker Benign prostatic hypertrophy
Actonel® (risedronate sodium)	167	Biphosphonate Osteoporosis Paget s disease
Nasacort® (triamcinolone acetonide)	106	Local corticosteroid Allergic rhinitis

(1) Since date of acquisition
(2) Excluding Allegra® OTC sales.

Diabetes

The prevalence of diabetes is expected to increase significantly over the next 20 years, 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® solution range of blood glucose meters for patients with diabetes, whether they are treated with insulin or not.

Lantus®

Lantus® (insulin glargine) is a long-acting analog of human insulin, offering improved pharmacokinetic and pharmacodynamic profiles compared to other basal insulins. 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 six years and above with type 1 diabetes mellitus.

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Lantus® is a well-established treatment with over 38 million patient-years exposure since 2000. The clinical trial experience with Lantus® covers over 100,000 patients.

Lantus® can be administered subcutaneously using syringes or specific pens including:

- Lantus® SoloSTAR® is a pre-filled disposable pen available in over 50 countries worldwide. It is the only disposable pen that combines a low injection force, up to 80 units per injection, and ease-of-use; and

- ClikSTAR® is a reusable insulin pen first approved in 2009 in the European Union and Canada. It is now available in more than 35 countries worldwide.

In September 2009, following four highly publicized but methodologically limited registry analyses, some of which created concern over a potential link between the use of Lantus® and an increased risk of cancer, we announced an action plan to provide methodologically robust research that will contribute to the scientific resolution of the debate over insulin safety, including insulin analogs and Lantus®. The research program encompasses both preclinical and clinical programs involving human insulin and insulin analogues, including insulin glargine; it is designed to generate more information on whether there is any association between cancer and insulin use, and to assess whether there is any difference in risk between different types of insulins. The plan is structured to yield short-term and longer-term results. Three epidemiological studies (two retrospective cohort studies and one case-control study) have been launched:

- the Northern European Study will compare the risk of cancer in adults prescribed insulin glargine versus those prescribed human insulin, and other types of insulin, and in all users of insulin combined. The results of the Northern European Database Study of Insulin and Cancer Risk are under review by health authorities and will be presented to scientific conferences in 2012. These results confirm Sanofi s confidence in the safety of Lantus®;

- the U.S. Study will compare the risk of breast, prostate and colon cancer (each considered separately) in glargine users versus human NPH insulin users. Study completion is for the end of the first half of 2012; and

- the International Study of Insulin and Cancer, being carried out in the United Kingdom, France and Canada, will assess the association of breast cancer with the use of insulins. The study results are expected by end 2012.

The ADA/ACS (American Diabetes Association / American Cancer Society) Consensus Report published on June 16, 2010 reasserted the inconclusiveness of any link between insulin and cancer.

In January 2011, the FDA updated its ongoing safety review of Lantus®. In addition to the analysis of the four registry analyses published in 2009, the FDA also reviewed results from a five-year diabetic retinopathy clinical trial in patients with type 2 Diabetes. Based on these data, the FDA has not concluded at this time that Lantus® increases the risk of cancer. FDA review remains ongoing.

In December 2011, results of new meta-analysis were presented at the World Diabetes Congress. This new meta-analysis of all published studies observational studies derived from databases as well as randomized controlled clinical trials and one case-control study has demonstrated no increased risk in people using Lantus® when compared to the users of human insulin.

The ADA and European Association for the Study of Diabetes (EASD) have maintained their 2008 treatment recommendations for type 2 diabetes. These guidelines 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, 2011 sales) and is available in over 70 countries worldwide. The three leading countries for sales of Lantus® in 2011 were the United States, France and Japan.

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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 associated 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 60 countries worldwide.

Due to a technical incident on a manufacturing line, Apidra® faced a temporary shortage of Apidra® 3mL cartridges (including Apidra® SoloSTAR®) which impacted supplies in some markets. The production of Apidra® 3mL cartridges is expected to return to full capacity in the first half of 2012. Apidra® vials were not impacted.

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 mostly 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.

Our leading market for Amaryl® is Japan, where it is the best-selling oral anti-diabetes product by volume (source: IMS 2011 sales). A number of generics have received marketing authorization and have been launched in Europe and the United States. Generic became available in Japan in November 2010 but the impact on Amaryl® sales compared to the impact of generic sales generally observed in the U.S. or the EU has been more moderate.

BGStar® / iBGStar

Sanofi and its partner AgaMatrix are co-developing innovative solutions in diabetes care with the aim of simplifying the diabetes management experience for patients and healthcare providers. The blood glucose monitoring solutions will be exclusive to Sanofi and are designed to be synergistic with our Diabetes portfolio, with a positive effect on sales of Lantus® and other products expected.

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BGStar® and iBGStar are blood glucose meters that feature Dynamic Electrochemistry®, an innovative technology that extracts a spectrum of information from blood that is inaccessible to traditional electrochemical methods and compensates for many interfering factors that often distort blood glucose results.

These monitoring devices are an important step towards our vision of becoming the global leader in diabetes care by integrating innovative monitoring technology, therapeutic innovations, personalized services and support solutions. During 2011, the BGStar® and iBGStar were made commercially available in Germany, France, Switzerland, Spain, the Netherlands and Italy.

In December 2011, the FDA approved the iBGStar the first blood glucose meter that connects to the iPhone® allowing patients to view and analyze accurate, reliable information in real time .

The main compounds currently in Phase II or III clinical development in the Diabetes/Other Metabolic Disorders field are:

Lixisenatide (AVE0010 GLP-1: Glucagon-like peptide-1 agonist, type 2 diabetes mellitus; Phase IIIb; lixisenatide is in-licensed from Zealand Pharma A/S). The GETGOAL Phase III studies were finalized and demonstrated that lixisenatide was effective in lowering blood sugar and decreasing body weight with good safety and tolerability. These results were presented at international conferences (e.g. ADA, EASD, IDF). Lixisenatide was submitted in the fourth quarter of 2011 to EMA, Switzerland, Mexico, Brazil, Canada, Ukraine, South Africa and Australia. Additional Phase IIIb studies have been initiated.

Phase I studies on combination of lixisenatide and Lantus® have been successfully finalized. A proof-of-concept study to compare insulin glargine/ lixisenatide fixed ratio combination versus insulin glargine on glycemic control over 24 weeks has begun.

Preliminary Phase II results of **SAR236553**, co-developed with Regeneron (REGN727: anti-PCSK9 mAb), have been obtained. Treatment with SAR236553 leads to mean relative LDL-Cholesterol reduction of greater than 65% after 8-12 weeks of treatment in patients with high LDL-C at baseline.

The partnership with Metabolex on the GPR119 receptor agonist **SAR260093** has been terminated.

Oncology

Sanofi is present in the oncology field, primarily in chemotherapy, with three major products: Taxotere®, Eloxatine®, and Jevtana®, which was launched commercially in the United States in 2010 and in the second quarter of 2011 in Europe.

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 100 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 gained approval 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 2011 were the United States, Japan, France, and China. Generics of docetaxel were launched at the end of 2010 in Europe and in April 2011 in the U.S. Exclusivity for Taxotere® in Japan will be maintained through November 2013 (see Patents, Intellectual Property and Other Rights below).

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Eloxatin®

Eloxatin® (oxaliplatin) is a platinum-based cytotoxic agent. Eloxatin® combined 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.

Eloxatin® is in-licensed from Debiopharm and is marketed in more than 70 countries worldwide.

Following the end of the Eloxatin® European regulatory data exclusivity in April 2006, a number of oxaliplatin generics have been launched throughout Europe. With regard to the U.S. market, a number of oxaliplatin generics received final marketing authorization from the FDA and were marketed until June 30, 2010, when their manufacturers were ordered by the U.S. District Court for the District of New Jersey to cease selling their unauthorized Eloxatin® generic in the United States. Eloxatin U.S. market exclusivity is expected to be maintained through August 9, 2012. See Item 8. Financial Information A. Consolidated Financial Statements and other Financial Information Patents .

Jevtana®

Jevtana® (cabazitaxel) is a new 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.

The results of the TROPIC Phase III study demonstrated that cabazitaxel plus prednisone/prednisolone significantly improved overall survival versus the standard regimen of mitoxantrone plus prednisone/prednisolone in patients with metastatic hormone-refractory prostate cancer whose disease progressed following treatment with docetaxel-based chemotherapy. A combination of cabazitaxel and prednisone/prednisolone significantly reduced the risk of death by 28% with an improvement in median overall survival of 15.1 months vs. 12.7 months in the mitoxantrone combination arm.

Jevtana® was launched in the United States in July 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 and was launched during the second quarter of 2011 in Germany and France. Jevtana® is now approved in 53 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 patients with advanced gastric cancer.

The top four countries contributing to sales of Jevtana® in 2011 were the United States, Germany, Brazil and France.

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

Zaltrap®, also known as aflibercept, is an investigational angiogenesis inhibitor with a unique mechanism of action. This fusion protein binds all forms of Vascular Endothelial Growth Factor-A (VEGF-A), as well as VEGF-B and placental growth factor (PIGF), additional angiogenic growth factors that appear to play a role in tumor angiogenesis and inflammation. Zaltrap has been shown to bind VEGF-A, VEGF-B, and PlGF with higher affinity than their native receptors. Sanofi Oncology and Regeneron are collaborating on a broad oncology development program for Zaltrap. The Phase III clinical program was designed to evaluate Zaltrap in combination with common chemotherapy regimens

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in the treatment of patients with advanced cancers, including cancers where bevacizumab has not demonstrated efficacy. Patients who had previously received bevacizumab were also included in the clinical trials for certain second-line treatment settings. In June 2011, Sanofi announced the positive results from VELOUR, a multinational, randomized, double-blind trial comparing the FOLFIRI (irinotecan-5-fluorouracil-leucovorin) chemotherapy regimen in combination with either Zaltrap or placebo in the treatment of patients with mCRC. The study randomized 1,226 patients with mCRC who previously had been treated with an oxaliplatin-based regimen. About one-third of the participants received bevacizumab as part of their first-line therapy. The primary endpoint was an improvement in overall survival. Secondary endpoints included progression-free survival, response to treatment and safety. Results were first presented at the ESMO World Congress on Gastrointestinal Cancer on June 25, 2011. The abstract (#0-0024) was published in the June 2011 supplement to Annals of Oncology. The current development program also explores Zaltrap for the treatment of metastatic prostate cancer with VENICE: First-line treatment for androgen-independent (hormone-refractory) metastatic prostate cancer in combination with docetaxel and prednisone (Phase III). Final results are anticipated in 2012. The aflibercept dossier was accepted for review by the EMA at the end of 2011. A NDA was filed in February 2012.

Semuloparin is a novel ultra-low-molecular-weight heparin (ULMWH) characterized by a high anti-Xa and a residual anti-IIa activity. Semuloparin s binding feature is directly responsible for the prolonged half-life (16-20 hours). In the Phase III placebo-controlled SAVE-ONCO trial, whose results were presented at ASCO 2011, Semuloparin has been investigated for its use in the prophylaxis of venous thromboembolism (VTE) in 3,212 cancer patients receiving chemotherapy for locally advanced or metastatic solid tumors (lung, pancreas, stomach, colon/rectum, bladder or ovary). Overall, Semuloparin 20mg once daily administered subcutaneously over a mean treatment duration of 3.2 months, significantly reduced VTE or VTE related death by 64% and PE by 59% vs placebo. The treatment effect was consistent across the components of primary endpoint, DVT and PE, cancer type, stage and various levels of VTE risk. The incidence of major bleeding was similar in the two groups: 1.2% and 1.1% in the Semuloparin and placebo groups, respectively. Further study analyses by sub-groups have been presented in oral presentations at ESMO and ASH 2011. A new drug application (NDA) has been accepted for review by the FDA and the EMA end of October 2011. Semuloparin is expected to be the first anti-coagulant approved for the indication of VTE prophylaxis in cancer patients receiving chemotherapy.

BSI-201 (iniparib SAR240550) is an agent with novel mechanism of activity that is currently being studied in advanced squamous non-small cell lung cancer (Phase III) 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.

Ombrabulin (AVE8062; combretastatin derivative, a new anti-vascular agent in-licensed from Ajinomoto; sarcoma; Phase III). Single agent and combination studies with platinums and taxanes alone or in combination have been conducted with ombrabulin. A Phase III study in soft tissue sarcoma in combination with cisplatin was initiated in 2008 and will terminate enrollment in 2012. Ombrabulin is also investigated in a Phase II trial in Non-Small-Cell Lung Cancer in combination with taxanes and platinum salts, which is over 90% enrolled and will report results in 2012, as well as in an ongoing Phase II trial in ovarian cancer.

SAR302503 (TG101348) was purchased from Targegen in 2009 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, a global Phase III trial of SAR302503 in primary and secondary myelofibrosis. The unique ability of SAR302503 to decrease allele burden will be further explored in the JAKARTA trial. In addition, a Phase II study in MF has recently completed accrual. Also ongoing is a Phase II trial in hydroxyurea-resistant PV and ET.

SAR245408 (XL147) was in-licensed from Exelixis, Inc. and is being developed by Sanofi. This phosphoinositide-3-kinase (PI3K) inhibitor is under evaluation in a Phase II study of monotherapy for

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the treatment of advanced or recurrent endometrial cancer. Combinations with paclitaxel/carboplatin, letrozole and trastuzumab are also being evaluated. Phase I trials of novel combinations with MSC1936369B (under a collaboration with Merck Serono, a division of Merck KGaA, Darmstadt, Germany) and MM121 (see below) have been initiated.

SAR245409 (XL765) was also in-licensed from Exelixis, Inc. and is being developed under an alliance 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 I/II study in combination with letrozole for the treatment of metastatic hormone-receptor-positive breast cancer is ongoing and a Phase II trial in mantle cell lymphoma, follicular lymphoma and chronic lymphocytic leukemia has been initiated. Combinations with temozolomide, bendamustine and rituximab are also being evaluated.

SAR256212 (MM-121). Under an exclusive global collaboration and licensing agreement, Merrimack 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 (Breast, Lung and Ovarian cancers), while a number of combinations with chemotherapy and targeted agents are being explored in the Phase I program. A companion diagnostic tool is being developed in parallel with the clinical program.

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 entering Phase II stage in Diffuse Large B Cell Lymphoma (DLBCL, aggressive lymphoma type) with the aim of confirming the clinical benefit observed in patients during Phase I trials. Ongoing/Planned trials in unmet medical need subsets of patients are: one Phase II study as single agent and one study in combination with Rituximab (rituxan, anti CD20 mAb) in Relapsed/Refractory (R/R) DLBCL patients. A biomarker exploratory sub-study is associated to the clinical NHL program in order to evaluate drivers for anti tumor response. In parallel, preclinical experiments to identify potential synergistic combinations (hypothesis driven combinations and unbiased in vitro screens) are being performed. A second indication is developed in a setting of large medical need, with the start of one exploratory Phase II study in adult patients with R/R ALL.

Clorafabine (Clolar® / Evoltra®) (Genzyme) (Purine-nucleosid analog). A Phase III program is on going in the treatment of acute myeloid leukemia.

In 2011, we conducted several additional collaborations with other companies, universities and institutes to investigate novel oncology agents (see Pharmaceutical Research & Development Portfolio below).

Collaborations with Regeneron

We and Regeneron globally collaborate on the development and commercialization of Zaltrap®. Under the terms of our September 2003 collaboration agreement, as amended, we and Regeneron will share co-promotion rights and profits on sales, if any, of Zaltrap® outside of Japan for disease indications included in our collaboration. In Japan, Sanofi will develop and commercialize Zaltrap®, with Regeneron entitled to a royalty payment. Under the terms of the agreement, Sanofi is responsible for funding 100% of the development costs of Zaltrap®. Once Zaltrap® starts to be marketed, Regeneron will repay 50% of the development costs (originally paid by Sanofi) in accordance with a formula based on Regeneron s share of the profits. Sanofi may also be responsible for making milestone payments upon receipt of specified marketing approvals for Zaltrap® in the United States or the European Union and in Japan.

In November 2007, Sanofi signed additional agreements with Regeneron to discover, develop and commercialize fully-human therapeutic antibodies. These agreements were broadened, and their term extended, on November 10, 2009. Under the terms of the discovery agreement, Sanofi committed to fund the costs of Regeneron s antibody research program until 2017. Sanofi has an option to license for further development

those antibodies discovered by Regeneron which advance to IND. Upon exercise of the option, Sanofi is primarily responsible for funding the development and co-developing the antibody with Regeneron. Sanofi and Regeneron would also share co-promotion rights and profits on sales. Once a product begins to be marketed, Regeneron will repay out of its profits (provided they are sufficient) 50% of the development costs borne by Sanofi for all antibodies licensed by Sanofi. Sanofi may also be responsible for making milestone payments based upon aggregate sales of antibodies under the collaboration.

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Rare Diseases

The acquisition of Genzyme in April 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 principle 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 alfa) to treat Pompe disease.

Cerezyme®

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

Cerezyme® is the only therapy with a 17-year history of reducing, relieving and reversing many of the symptoms and risks of Type 1 Gaucher disease. Cerezyme® is administered by intravenous infusion over 1-2 hours.

In June 2009, Genzyme interrupted production of Cerezyme® and Fabrazyme® at its Allston facility after identifying a virus in a bioreactor used for Cerezyme® production. Genzyme resumed Cerezyme® shipments in the fourth quarter of 2009. This interruption was followed by a second one in March 2010 resulting from a municipal electrical power failure that compounded issues with the facility s water system.

Genzyme communicated at the end of 2011 that, given current productivity and progress in the manufacturing recovery, we expect an improving supply outlook as the year progresses. We have begun communicating with the U.S. Gaucher community to inform them that, beginning in February 2012, current patients in the U.S. can be returned to normal dosing. Genzyme will also begin the process of returning additional regions globally back to normal supply. This process will begin in the second quarter of 2012 and continue gradually through the remainder of the year, to ensure that a ramp-up can be sustained. Regions outside of the U.S. will be maintained at their current allocation of Cerezyme®, as Genzyme assesses the timing of the return of additional regions to full supply. No regional allocation will be decreased to accommodate the U.S. ramp-up. We continue to make Cerezyme® available to patients as it is produced. However, since we have minimal inventory, any change to our manufacturing plans can have an immediate impact on our ability to provide product.

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

Fabrazyme®

Fabrazyme® (agalsidase beta) is an enzyme replacement therapy that is 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, and has been used in hundreds of patients.

Due to the June 2009 production interruption and low manufacturing productivity upon re-start of production, Fabrazyme® shipments decreased in the fourth quarter of 2009 and Genzyme began shipping Fabrazyme® at a rate equal to 30% of estimated product demand. Throughout 2011, Genzyme has maintained consistent supply of Fabrazyme® to current patients at a reduced dose. To return to normal supply levels of Fabrazyme® for existing and new patients, it will be necessary to utilize the additional capacity from Genzyme s new manufacturing facility in Framingham, Massachusetts, that was approved in January 2012 by the FDA and the EMA. Genzyme will begin the process of moving the most severely affected patients in Europe to full dose of Fabrazyme® during the first quarter of 2012. Beginning in March 2012 in the U.S., all patients currently on therapy are expected to be able to return to full dosing (1mg/kg). In addition, Genzyme will begin to transition

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new patients in the U.S. onto Fabrazyme® at full dosing (1mg/kg) levels. Beginning of March, Genzyme started shipping Fabrazyme® from Framingham. Globally, the return to normal supply levels of Fabrazyme® is expected to begin in the second quarter of 2012 and continue throughout the year as planned, as Genzyme works to obtain all global regulatory approvals throughout the year and to build inventory.

The principal markets for Fabrazyme® are the United States and Europe.

Myozyme® / Lumizyme®

Myozyme® / Lumizyme® (alglucosidase alfa) 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 8 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.

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 a treatment alternative to bi-weekly infusions. The first three years of data from the Phase II trial of eliglustat tartrate showed clinically significant improvements in hematological, visceral and bone disease parameters in the range expected for enzyme replacement therapy. During 2011, the two pivotal Phase III registration studies completed enrollment and the third Phase III study closed screening. Its recruitment should be completed in 2012.

Other Flagship 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.

In 2008, new oral anticoagulants were launched for the prevention of VTE in orthopedic surgery and were approved in 2011 for stroke prevention in patients with atrial fibrillation, with the objective to replace vitamin K antagonists (e.g. warfarin). However, the impact has been limited on Lovenox® usage as prevention of VTE in orthopedic surgery is a small segment of Lovenox® usage and as stroke prevention in atrial fibrillation is not a Lovenox® approved indication.

In VTE prophylaxis in acutely ill medical patients, a major market segment for Lovenox®, two large clinical trials have compared new oral anti-coagulants to Lovenox®: extended prophylaxis using new oral anti-coagulants has not shown added benefit compared to short term prophylaxis using Lovenox®.

Competing generics of enoxaparin were launched respectively in July 2010 and in February 2012 in the U.S. An authorized generic is available in the U.S.. See Item 5. Operating and Financial Review and Prospects Impacts from generic competition .

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In 2011, Lovenox® was the leading anti-thrombotic in Germany, France, Italy, Spain, and the United Kingdom (source: IMS 2011 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). This indication is supported by the results of the landmark CAPRIE trial, including almost 20,000 patients. CAPRIE demonstrated the superior efficacy of Plavix® over acetylsalicylic acid (ASA, the active ingredient of Aspirin®), with a comparable safety profile.

Following the significant results of several clinical trials, involving a total of almost 62,000 patients, 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 January 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.

A Phase III mortality and shunt-related morbidity study in infants palliated with a systemic to pulmonary artery shunt was completed in 2010. Even though results did not support an indication in such infants, the FDA granted Sanofi an additional six month period of exclusivity to market Plavix® (clopidogrel bisulfate). Exclusivity for Plavix® in the U.S. is now scheduled to expire on May 17, 2012.

To further characterize patient responsiveness to Plavix® and provide the best guidance to healthcare professionals, a clinical program designed in close collaboration with the FDA has been completed by Sanofi and Bristol-Myers Squibb (BMS). Based on this program the label was updated worldwide in 2010, including new results on the pharmacological interaction of omeprazole with Plavix® and recent pharmaco-genomics data which have shown genomic variability of the response to Plavix® treatment (diminished effectiveness in poor metabolizers). This has been highlighted in the U.S. label with a boxed warning.

The extensive clinical development program for Plavix®, including all completed, ongoing and planned studies, is among the largest of its kind, involving more than 130,000 patients overall. Plavix® indications are incorporated into major scientific guidelines in North America, Europe and Japan. Over 115 million patients are estimated to have been treated with Plavix® since its launch in 1998, providing significant evidence of real-life efficacy and safety experience with this product.

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 combination has already been launched in several countries (including Australia, Germany, the Netherlands, Ireland, Spain, and Mexico).

The marketing of Plavix® / CoPlavix® / DuoPlavin® is organized through our alliance with BMS (see Alliance with BMS below). Sales of Plavix® in Japan are consolidated by Sanofi and are outside the scope of our alliance with BMS.

Plavix® is the leading anti-platelet in the U.S., Chinese and Japanese markets (source: IMS 2011 sales). In Europe, a number of generics have received marketing authorization and have been launched. Plavix® market

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share [(1)] by value was 29.1% in Western Europe and 27.2% in Germany (source: IMS 2011 sales). In Canada, generics were launched in December 2011. Plavix® U.S. market exclusivity is expected to be maintained through May 2012.

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 (see Alliance with BMS 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 is expected to be maintained through March 2012.

Alliance with Bristol-Myers Squibb (BMS)

Plavix® and Aprovel® are marketed through a series of alliances with BMS. The alliance agreements include marketing and financial arrangements that vary depending on the country in which the products are marketed.

Three principal marketing arrangements are used in the BMS alliance:

co-marketing: each company markets the products independently under its own brand names;

exclusive marketing: one company has the exclusive right to market the products; and

co-promotion: the products are marketed through the alliance arrangements (either by contractual arrangements or by separate entities) under a single brand name.

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

In the territory under our operational management, the marketing arrangements are as follows:

we use the co-promotion system for most of the countries of Western Europe for Aprovel® and Plavix® and for certain Asian countries for Plavix®;

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

(1) *Plavix® market = oral platelet aggregants inhibitors.*

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we have the exclusive right to market Aprovel® and Plavix® in Eastern Europe, Africa and the Middle East, and we have the exclusive right to market Aprovel® in Asia, Scandinavia and Ireland.

In the territory under BMS operational management, the marketing arrangements are as follows:

we use the co-promotion system in the United States and Canada, where the products are sold through the alliances under the operational management of BMS;

we use the co-marketing system in Brazil, Mexico, Argentina and Australia for Plavix® and Aprovel® and in Colombia only for Plavix®; 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 often sell the active ingredients for the products to BMS or associated entities.

The financial impact of our principal alliances on our financial position and income is significant, and is described under Item 5. Operating and Financial Review and Prospects Financial Presentation of Alliances ; see also Item 3. Key Information D. Risk Factors Risks Relating to Our Business We rely on third parties for the marketing of some of our products for more information relating to risks in connection with our alliance agreements.

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 as seen in the ATHENA study.

The landmark ATHENA trial is the only double-blind anti-arrhythmic study in patients with AF to have assessed morbidity-mortality. The study enrolled a total of 4,628 patients. In this trial, the efficacy and safety of Multaq® was evaluated in patients with AF/AFL or a recent history of these conditions. Multaq® 400mg twice a day, in addition to standard therapy, was shown to significantly reduce the risk of first cardiovascular hospitalization or death by 24% ($p<0.001$) when compared to placebo, meeting the study s primary endpoint. In a secondary analysis of the ATHENA trial, Multaq® significantly reduced the total number of hospital days versus placebo.

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. In Europe, EMA has then coordinated a review of all available data concerning the possible risks of liver injury associated with the use of Multaq® and their impact on its benefit-risk balance. The review was extended to include cardiovascular safety of Multaq® following premature termination of the PALLAS study (Permanent Atrial fibriLLAtion outcome Study) in July 2011.

The PALLAS study, using dronedarone on top of standard therapy, was a randomized, double-blind, parallel-group, placebo-controlled study comparing the efficacy of dronedarone 400 mg twice-daily to placebo in patients with permanent AF, a population different from the population with non-permanent AF for which Multaq® is currently approved. The study was discontinued in July 2011 following recommendation from the study s Operations Committee and the Data Monitoring Committee which observed a significant increase in cardiovascular events in the dronedarone arm. The decision to terminate the study was not related to any hepatic adverse event.

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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 of paroxysmal and persistent Atrial Fibrillation patients. 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 reinforcing warnings and precautions for use.

Multaq® has a convenient fixed dose regimen of twice daily 400 mg tablets to be taken with morning and evening meals. Treatment with Multaq® does not require a loading dose and it can be initiated in an outpatient setting.

Multaq® has been launched in 39 countries. The three leading countries for sales of Multaq® in 2011 were the United States, Germany and Spain.

Renagel® and Renvela®

Renagel® (sevelamer hydrochloride) and Renvela® (sevelamer carbonate) are oral phosphate binders used by chronic kidney disease (CKD) patients on dialysis 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 but who have very high blood phosphorus levels.

The principal markets for Renagel® are the United States, the EU and Brazil. The principal markets for Renvela®, which was first marketed in 2008, are the United States and the EU (launched in 2010). In 2011, new launches took place in Singapore, Malaysia, Thailand, Israel, Columbia, Panama and Switzerland.

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

The top five countries contributing to the sales of our Renal portfolio in 2011 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 a triple-injection product and Synvisc-One® is our next-generation, single-injection product. The principal viscosupplementation market is treatment of pain associated with osteoarthritis of the knee.

The principal markets for Synvisc® are the U.S., the EU, and Japan (where launch took place in December 2010). The principal markets for Synvisc-One® are the United States and the EU, markets in which Synvisc-One® was first approved in 2009 and 2007, respectively.

We market Synvisc® and Synvisc-One® through Genzyme s employee sales force directly to physicians, hospitals, and pharmacies. We distribute these products directly and through independent distributors. In Japan, Synvisc® is marketed and distributed by Teijin Pharma Limited.

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The top five countries contributing to Synvisc® and Synvisc-One® sales in 2011 were the U.S., Japan, Canada, France, and Germany.

Other pharmaceutical products

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.

We have developed a controlled release formulation of zolpidem tartrate, marketed only in the United States under the brand name Ambien® CR.

Stilnox® is marketed in over 100 countries. It was launched in Japan under the brand name Myslee® in December 2000. Myslee® has been co-promoted jointly with Astellas since 2006. Myslee® is the leading hypnotic in Japan (source: IMS 2011).

Generic zolpidem tartrate has been available in Europe since 2004. In the United States, generics of the immediate release formulation of Ambien® have been available since 2007. Ambien® CR generics entered the U.S. market in October 2010. In Japan, competing generics of Myslee® are likely to enter the market in 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, with the notable exception of Japan.

In March 2011, in the U.S., Allegra® family moved to over-the-counter (OTC) use in adults and children two years of age and older (see Consumer Health Care below).

Allegra®/Telfast® is marketed in approximately 80 countries. The largest market for prescriptions of Allegra® is Japan. In Japan, competing generics of Allegra® may possibly enter the market in the second half of 2012 if the generic manufacturers get marketing approvals. Sanofi appealed at the IP High Court to defend two Allegra® use patents following their invalidation by the patent office (for more information see Item 8 Financial Information A. Consolidated Financial Statements and Other Financial Information Information on Legal or Arbitration Proceedings).

Copaxone®

Copaxone® (glatiramer acetate) is a non-interferon immunomodulating agent indicated for reducing the frequency of relapses in patients with relapsing-remitting multiple sclerosis. Copaxone® is available as a self-injectable pre-filled syringe storable at room temperature for up to one month.

This disease-modifying drug is characterized by an original and specific mode of action on multiple sclerosis. Clinical studies have shown that Copaxone® is more effective than placebo at two years, but also that it has a clinical efficacy over 15 years both in reducing relapses and progression of disability. A significant effect on lesions has also been confirmed by nuclear magnetic resonance imaging.

In 2009, the U.K. Medicine and Healthcare Regulatory Agency (MHRA) approved an expanded label for Copaxone® to include the treatment of patients with clinically isolated syndrome suggestive of multiple sclerosis.

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We have marketed Copaxone® outside the United States and Canada through our alliance with Teva. As of February 29, 2012 we no longer market or sell Copaxone®: on a country-by-country basis, we instead receive a payment of 6% on sales from Teva for a period of two years from the date of transfer (see Alliance with Teva below).

Alliance with Teva

We in-licensed Copaxone® from Teva and marketed it until 2012 through an agreement with Teva, which was originally entered into in 1995, and has been amended several times, most recently in 2005.

Under the agreement with Teva, marketing and financial arrangements vary depending on the country in which the products are marketed.

Sales and distribution rights were returned to Teva in 2008 for the United States and Canada.

Outside the United States and Canada, there were two principal marketing arrangements:

Exclusive marketing: we had the exclusive right to market the product. This system was used in a number of European countries (Portugal, Italy, Greece, Finland, Denmark, Sweden, Norway, Iceland, Ireland, Luxembourg, Poland, Lichtenstein, Switzerland), as well as in Australia and New Zealand.

Co-promotion: the product was marketed under a single brand name. We used the co-promotion system in Germany, the United Kingdom, France, the Netherlands, Austria, Belgium, the Czech Republic and Spain.

Under the terms of our agreement, the Copaxone® business has been transferred to Teva over a period running from the third quarter of 2009 to February 29, 2012 depending on the country. Following the transfer, Sanofi will receive from Teva a royalty of 6% for a period of two years, on a country-by-country basis. In September 2009, the Copaxone® business was transferred to Teva in Switzerland and Lichtenstein. In 2010, the Copaxone® business was transferred to Teva in Poland, in the Czech Republic and in the United Kingdom. In 2011, the Copaxone® business was transferred to Teva in Norway, Germany, Austria, Portugal, and Sweden. In January and February 2012 the Copaxone® business was transferred to Teva in Denmark, the Netherlands, Belgium, France, Greece, Cyprus, Ireland, Italy, Spain, Australia, and New Zealand.

Tritace ®/Triatec® /Delix®/Altace®

Tritace® (ramipril) is an angiotensin converting enzyme (ACE) inhibitor indicated for the treatment of hypertension, congestive heart failure following or in the absence of acute myocardial infarction, and nephropathy. Tritace® is the only ACE inhibitor approved for the prevention of stroke, myocardial infarction and death in high-risk patients and has the broadest spectrum of indications among ACE inhibitors for the treatment of cardiovascular diseases.

The combinations with diuretics (ramipril + hydrochlorothiazide) and calcium channel blockers (ramipril + felodipine) are available in Europe.

Tritace® is marketed in over 70 countries. A number of generics have received marketing authorization and have been launched since December 2001 in Europe.

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. Depakine® is recommended as a first

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line treatment in these indications by international guidelines such as the guidelines of the World Federation of Societies of Biological Psychiatry Guidelines 2009, the Canadian Network for Mood and Anxiety Treatments 2009, and the British Association for Psychopharmacology 2009.

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.

Xatral®/Uroxatral®

Xatral® (alfuzosin hydrochloride) belongs to the class of alpha1-blockers. Capable of acting selectively on the lower urinary tract, it was the first alpha1-blocker indicated and marketed exclusively for the treatment of symptoms of benign prostatic hyperplasia (BPH). It is also the only alpha1-blocker indicated as an adjunctive therapy with catheterization for acute urinary retention, a painful and distressing complication of BPH.

Xatral® OD (extended release formulation) is active from the first dose, provides rapid and lasting symptom relief, and improves patient quality of life. Xatral® is the only alpha1-blocker showing no deleterious effect on ejaculation, as shown by the final results of the international ALF-LIFE trial. The once-daily formulation of Xatral® (branded Uroxatral® in the United States) has been registered in over 90 countries and is marketed worldwide, with the exception of Australia and Japan.

Generic alfuzosin became available in most European countries in 2009. Generics of the extended release formulation of alfuzosin became available in the U.S. in July 2011.

Actonel®/Optinate® /Acrel®

Actonel® (risedronate sodium) belongs to the bisphosphonate class that helps prevent osteoporotic fractures.

Actonel® is the only osteoporosis treatment that reduces the risk of both vertebral and non-vertebral fractures in as little as six months. Actonel® also provides reduced risk of fracture at all key osteoporotic sites: vertebral, hip and non-vertebral sites, studied as a composite endpoint (hip, wrist, humerus, clavicle, leg and pelvis).

Actonel® is available in various dosage strengths and combination forms to better suit patient needs. Depending on dosage form, Actonel® is indicated for the treatment of post-menopausal osteoporosis, osteoporosis in men, or Paget s disease.

Actonel® is marketed in more than 75 countries through an alliance with Warner Chilcott see Note C.2 to our consolidated financial statements included at Item 18 of this annual report .

The contribution of this alliance on our financial position and income is described under Item 5. Operating and Financial Review and Prospects Financial Presentation of Alliances . See Item 3. Key Information D. Risk Factors Risks Relating to Our Business We rely on third parties for the marketing of some of our products for more information relating to risk in connection with our alliance agreements.

Nasacort®

Nasacort®AQ Spray (NAQ) (triamcinolone acetonide) is an unscented, water-based metered-dose pump spray formulation unit containing a microcrystalline suspension of triamcinolone acetonide in an aqueous medium. Previously indicated for the treatment of the nasal symptoms of seasonal and perennial allergic rhinitis in adults and children six years of age and older, Nasacort® AQ received an additional approval for the seasonal and annual treatment of pediatric patients between the ages of two and five years from the FDA in September 2008. NAQ is an intranasal corticosteroid, which is recommended in treatment guidelines as first-line treatment for moderate to severe allergic rhinitis patients.

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Following a settlement of patent litigation, a competing generic triamcinolone acetonide has been sold in the United States since June 2011.

Main compounds currently in Phase II or III clinical development:

In the Multiple Sclerosis field:

Teriflunomide Aubagio (orally active dihydroorotate dehydrogenase inhibitor, multiple sclerosis; Phase III). The dossier has been submitted in August 2011 in the U.S. and in January 2012 in Europe for the treatment of relapsing forms of multiple sclerosis as a monotherapy agent. Results of the first pivotal study, 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 NEJM in October 2011. In addition, a Phase III adjunctive therapy study (TERACLES) has been launched to define the additional efficacy and safety profile of teriflunomide, when added to background stable therapy with interferon (IFN-beta). This study follows on from the successful Phase II study which showed teriflunomide had an acceptable tolerability in adjunct to IFN-beta and demonstrated significant improvements of the disease as measured by magnetic resonance imaging (MRI).

Alemtuzumab (Lemtrada) Humanized monoclonal antibody targeting CD52 antigen abundant on the surface of B and T lymphocytes leading to changes in the circulating lymphocyte pool. Alemtuzumab targets patients with relapsing forms of Multiple Sclerosis (MS). The two Phase III studies demonstrating the safety and efficacy of alemtuzumab were completed in 2011. The first study, CARE-MS I, demonstrated strong and robust treatment effect on the relapse rate co-primary endpoint vs Rebif. 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 both cases, safety results were consistent with previous alemtuzumab use in MS and adverse events continued to be manageable. The dossier is scheduled to be submitted to FDA review in the second quarter of 2012.

In the context of a business combination prior to the Sanofi takeover, Genzyme acquired in May 2009, from Bayer Schering Pharma A.G (Bayer), development rights and world marketing rights for alemtuzumab. Genzyme also acquired the rights for the products Fludara® and Leukine®. Alemtuzumab is already approved in oncology as the product Campath® (also acquired from Bayer). In exchange, Bayer was granted the right to co-promote Lemtrada on a global basis, as well as the right to receive contingent payments (for more information See Note D.1.1. to our consolidated financial statements included in this annual report at Item 18). In connection with the acquisition of Genzyme, Sanofi issued contingent value rights (CVR) entitling holders to cash payments upon the achievement of certain milestones, including regulatory approval of alemtuzumab for treatment of multiple sclerosis and on achievements of certain aggregate sales thresholds (see Item 10. Additional Information C. Material contracts The Contingent Value Rights Agreement.)

In the Ophthalmology field:

Sanofi acquired the French ophthalmology specialist Fovea in October 2009. Products in the pipeline include:

A Phase II eye-drop fixed dose combination of prednisolone acetate and cyclosporine A for the treatment of allergic conjunctivitis (**FOV1101**);

A Phase II eye-drop formulation of a bradykinin B1 receptor antagonist for the treatment of diabetic macular edema (**FOV2304**);

FOV2302 was halted in December 2011 for toxicity reasons.

Oxford BioMedica entered into collaboration with Sanofi in April 2009 to develop novel gene-based medicines, utilizing LentiVector® gene delivery technology, for the treatment of ocular disease. The agreement covers four LentiVector®-based product candidates for different ophthalmologic indications such as wet age-related macular degeneration, Stargardt disease, Usher syndrome, and corneal graft rejection.

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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 for 2013.

Celivarone (anti-arrhythmic; Phase IIb): project terminated because of lack of efficacy (prevention of shocks and major clinical outcomes) in the Phase II study in patients fitted with an implantable cardioverter/defibrillator.

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, entered in Phase III in adult patient with moderate to severe rheumatoid arthritis.

SAR231893, a monoclonal antibody against the Interleukin-4 Receptor (anti IL-4R mAb) derived from our alliance with Regeneron, has entered Phase IIa in asthma and continued development in Phase I in atopic dermatitis.

Mipomersen (Genzyme) Antisense oligonucleotide (ASO) that inhibits the synthesis of apoB, a primary protein constituent of atherogenic lipoproteins. In collaboration with Isis Pharmaceuticals Inc. mipomersen is being developed 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. The marketing authorization application (MAA) for mipomersen was submitted in the third quarter of 2011 in Europe.

Consumer Health Care (CHC)

Consumer Health Care is a core growth platform identified in our broader strategy for achieving sustainable growth. In 2011, we recorded CHC sales of 2,666 million; nearly half of our CHC sales were in emerging markets, 24% 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. This switch constitutes a key step in our CHC growth strategy in the U.S. The Allegra® family of OTC products is the number one OTC brand for Sanofi globally.

2011 CHC sales were also supported by our legacy CHC brands, which provides 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 the 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

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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, well-known brands are:

Chattem s products in the United States, other than the Allegra® family of OTC products, are mainly 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®.

Oenobiol s products in France are dietetary supplements for beauty (sun care, weight, hair care, skin care); well-being (digestive comfort, anti-stress) and menopausal problems.

BMP Sunstone products in China include leading pediatric cough and cold brand, Haowawa® (which means Goodbaby in Chinese). BMP Sunstone also brings Sanofi a very well-established national distribution network providing unique access to the fast-growing prefecture level and rural level cities.

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

In August 2011, we entered into a definitive agreement to acquire the Indian domestic branded formulations business of Universal Medicare, one of the leading providers in the country of nutraceuticals and lifestyle management products including vitamins, antioxidants, mineral supplements, and anti-arthritics.

The top three countries contributing to our CHC sales in 2011 were the United States, France, and Russia.

Generics

In 2011, sales of the generics business grew by 16.2% to 1,746 million led by sales in Emerging Markets and in the United States. U.S. generic business growth was driven by sales of recent launches of authorized generics of Taxotere®, Ambien® CR and Lovenox®. Authorized generic of

Taxotere® launched in March 2011 has captured more than 10% of docetaxel generics (source: IMS December 2011). Sales in Emerging Markets were supported by the roll out of Medley products in additional countries in Latin America. In 2011, 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, 2011 Compared with Year Ended December 31, 2010 Net Sales by Product Pharmaceuticals .

In March 2009 we created our European Generics Platform, covering generics activities across Western and Eastern Europe, Russia and Turkey. In 2010, we decided to rebrand all our European generics businesses under the Zentiva name. This means that the generics businesses of Winthrop and Helvepharm in France, Germany, Italy, Switzerland, Portugal and the United Kingdom now operate under the Zentiva brand. The roll out will continue in 2012 in the EU countries where Zentiva operates.

In Japan in 2011 we established a new joint venture, Sanofi Nichi-Iko K.K., to develop a strong presence in the fast-growing Japanese generics market: we started co-promotion for two molecules (edaravone in August 2011 and donepezil in October 2011). Scope of products to be co-promoted should be expanded in the future.

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Vaccine Products

Sanofi Pasteur is a fully integrated vaccines division offering a broad range of vaccines. In 2011, 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 3,469 million. Sales were favorably impacted by strong growth in markets outside North America and Europe, 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, 2011 Compared with Year Ended December 31, 2010 Net Sales Human Vaccines (Vaccines).

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® in the joint venture s geographic scope. In 2011, Sanofi Pasteur MSD net sales, which are accounted for using the equity method, amounted to 791 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).

The table below shows net sales of vaccines by product range:

(million)	**2011 Net Sales**
Influenza Vaccines *	826
Polio/Pertussis/Hib Vaccines	1,075
Meningitis/Pneumonia Vaccines	510
Adult Booster Vaccines	465
Travel and Other Endemics Vaccines	370
Other Vaccines	223
Total Human Vaccines	**3,469**

* *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 five 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 acellular pertussis-based pentavalent vaccine, is the standard of care in the United Kingdom since 2004 for protecting against diphtheria, tetanus, pertussis, polio and *Haemophilus influenzae* type b disease. 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 100 million doses of Pentaxim® have been distributed in over 100 countries, and the vaccine has been included in the national immunization programs in 23 countries.

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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 a hexavalent pediatric vaccine providing protection against diphtheria, tetanus, pertussis, poliomyelitis (polio), *Haemophilus influenzae* type b infections and hepatitis B. The vaccine is currently under the registration process (Article 58) at EMA, with an opinion expected in 2012.

PR5I is a combination vaccine designed to help protect against six potentially serious diseases: diphtheria, tetanus, whooping cough (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, 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.

In September of 2011, Sanofi Pasteur donated to the WHO a vaccine strain used for polio eradication. The biological material given by Sanofi Pasteur is the original viral seed used to produce large quantities of OPV against type 3 poliovirus. With this donation from Sanofi Pasteur, the WHO will be in full control of the storage of the vaccine strain and its distribution to vaccine producers worldwide.

Sanofi Pasteur is also supporting the introduction of eIPV in the international region. With recent progress towards polio eradication, 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.

On February 23, 2011, Sanofi Pasteur applied for approval of manufacturing and marketing of standalone inactivated vaccine against polio (acute poliomyelitis) in Japan.

Shantha Biotechnics 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 2011 to better meet increasing demand. In recent years, influenza vaccine demand has experienced strong growth in many countries, particularly in the U.S., South

Korea, 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 May 2011, Sanofi Pasteur received regulatory approval by the U.S. FDA for Fluzone® ID in adults from 18 to 64 years of age. The advantages of this vaccine are particularly its convenience and ease of administration. Fluzone ID®, Intanza®/IDflu® vaccine is now approved in the United States, European Union, Canada, Australia and other countries for the prevention of seasonal influenza in both adults (age 18 and over) and the elderly (age 60 and over).

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In December 2009, the FDA approved Sanofi Pasteur s supplemental Biologics License Application (sBLA) for licensing of Fluzone® High-Dose influenza virus vaccine. The Fluzone® High-Dose vaccine was specifically designed to generate a more robust immune response 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. This new vaccine was launched in the United States in 2010 and continued strong growth in 2011.

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. The targeted population is the same as standard-dose Fluzone® TIV (trivalent vaccine): children 6 months through 17 years, and adults and elderly 18 years and above. A Phase III clinical trial was completed in 2011 for Fluzone QIV IM and regulatory submission is planned for the first half 2012. Vaxigrip QIV IM, targeting the European market, entered Phase III clinical trials in October 2011.

Adult and Adolescent Boosters

Pertussis (whooping cough) affects children, adolescents and adults. Resurgence, in particular in the State of California in the U.S. and other parts of the world in 2010, 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. Since 2004, Adacel® has been the standard of care in Canada, where most provinces provide routine adolescent immunization. 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. A Phase III clinical trial began in April 2011.

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, arguably the deadliest form of meningitis in the world. In October 2007, the FDA granted Sanofi Pasteur a license to expand the indication of Menactra® to children two years through 10 years of age. Menactra® is now indicated for people aged 2-55 years in the United States and in Canada. In 2011, sales of Menactra® continued to grow in the United States following the CDC s Advisory Committee on Immunization Practices recommendation that a single dose at 11 or 12 years of age be followed-up with a booster dose several years later for protecting adolescents at the time of their highest risk. An Infant/Toddler (age 9/12 months) biological license application for Menactra® was approved by the U.S. FDA in March 2011. Sanofi Pasteur also launched Menactra® in the Middle East and Latin America in 2010 and in Asia in 2011.

Meningitis A, C, Y, W-135 conj. Second Generation is a project that targets 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.

For over 30 years, Sanofi Pasteur has supplied vaccines for meningococcal meningitis serogroups A and C used to combat annual epidemics in Sub-Saharan countries (African meningitis belt).

Travel and Endemics Vaccines

Sanofi Pasteur provides a wide range of travelers and endemic vaccines with hepatitis A, typhoid, rabies, yellow fever, cholera measles, mumps, rubella (MMR) vaccines and anti-venoms. These vaccines are used in

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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.

A Japanese encephalitis vaccine is also in preparation. Japanese encephalitis is endemic in Southeast Asia. Sanofi Pasteur will offer a new vaccine in the market: IMOJEV™. The Australian healthcare authorities granted approval of IMOJEV™ on August 16, 2010 for individuals aged 12 months and over. On October 29, 2010, the Thai Food and Drug Administration granted licensure in the same age indication.

The new generation Vero serum-free vaccine (VRVg) will provide a worldwide, single rabies vaccine as a replacement to our current rabies vaccine offerings. Results from the 2009 Phase I clinical trial demonstrated non-inferiority of VRVg versus Verorab®. AFSSAPS in France approved VRVg as a line extension of VeroRab in January 2011. Clinical development is continuing in China and India.

In December 2009, Shantha launched ShanChol™, India s first oral vaccine to protect against cholera in children and adults. In September 2011, Shanchol™ was approved for procurement to United Nations Agencies (i.e. WHO Pre-qualified).

Other Products

In October 2011, Sanofi Pasteur acquired Topaz Pharmaceuticals, Inc., a small privately-held U.S. specialty pharmaceutical company focused on developing and commercializing treatments primarily for pediatric and dermatology markets. Established in June 2005 and based in Horsham PA, Topaz Pharmaceuticals offers a late-stage prescription product for the treatment of head lice. This investigational product, known as Sklice , Topical Lotion, is a formulation of Ivermectin. It is the sole pipeline product of the company. The regulatory submission for Sklice, topical Lotion, for treatment of head lice in children and adults, was filed with the U.S. FDA in April 2011. In February 2012, the FDA approved Sklice® (ivermectin) lotion, 0.5% for the topical treatment of head lice, in patients 6 months of age and older.

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 animals (production and companion animals). Its net sales for 2011 amounted to 2,030 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 2011); 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 2011).

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

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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.

Regarding companion animals and specially the fipronil franchise, on June 21, 2011 the U.S. District Court for the Middle District of Georgia ruled in favor of Merial holding that sales of PetArmor Plus products infringed Merial s patent, and it barred Cipla and Velcera from making or selling those products in the United States. A court-ordered seizure of the inventory in the United States still in possession of the generic manufacturers went into effect on August 21, 2011. However, the generic products already sold to retailers were not recalled (see Item 8. Financial Information A. Consolidated Financial Statements and Other Financial Information). In July 2011, Merial launched Certifect®, a new fipronil combination parasiticide for tick and flea control for dogs.

Regarding production animals, in the ruminant segment, performance was driven by the launch in the U.S. of the antibiotic Zactran® against bovine respiratory disease.

Merial s major stand-alone markets are the United States, France, Brazil, Italy, the United Kingdom, Australia, Germany, Japan, Spain, China, and Canada. The group of Emerging Markets countries, with double digit sales growth in 2011, accounts now for 25.0% of total Merial sales.

Merial operates through a network of 16 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 5,600 employees worldwide.

Pharmaceutical Research & Development

The pharmaceutical industry as a whole has been facing significant challenges in the recent years.

These include:

- Patent cliff for several products considered as blockbusters, putting revenues under pressure and increasing competition of me-too drugs,

Decrease in New Molecular Entities approvals by Health Authorities (a 50% drop when compared to the 1990 s),

Increasing regulatory requirements and payers demands for demonstrated medical and economic value impacting the costs of development

Increased complexity of science leading to a decrease in the success rate for research projects.

To overcome this new situation, Sanofi has revised its overall infrastructure and operations footprint and opened up to external innovation and new fields of opportunity, so as to feed and strengthen its pipeline. We have adopted a network-based organization, open to external opportunities, to enable our R&D to be more creative and make the most of both in-house and external innovation. In December 2011, out of 48 products in clinical development or registration, 34 (or 71%) originate from external R&D. Employee year-end headcount in the research and development functions generally reflects this trend to greater externalization, and amounted to 18,823 for 2011 compared to 16,983 for 2010 and 19,132 for 2009 (in each case excluding Merial but including Genzyme in 2011 - 2,006 employees).

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We intend to have the most effective R&D organization in the pharmaceutical industry in place by 2013. The new R&D approach aims to foster greater creativity and innovation. Streamlined organizational structures are designed to make R&D more flexible and entrepreneurial and hence better adapted to overcome future challenges.

Organization

During the first phase of transformation (2009-2011) we carried out a rigorous and deep re-evaluation of all current development programs. As a result, we have refocused our efforts on 48 clinical programs (see table below).

In parallel we undertook a profound transformation of our operating model reinforcing our patient centric approach and setting an open innovation strategy.

Decentralization with the creation of Oncology, Diabetes and Ophthalmology divisions, five Therapeutic strategic units (TSUs), several Distinct Project Units (DPUs) and five Scientific platforms.

A renewed effort at business development to fill the pipeline by acquiring or in-licensing products which has led to a series of acquisitions.

In line with the Group s diversification strategy, acquisition of Genzyme in April 2011 leading to a push in biotechnology and bringing the Group s goal of building a globally integrated R&D organization a step closer.

With Sanofi Pasteur, Genzyme and Merial, targeted initiatives launched internally to best leverage each other s knowledge and experience and establish a governance model to foster effective collaboration and innovation between all organizations.

Creation of alliances with premier academic programs in the U.S., Europe and a major effort in France with the Aviesan program.

Portfolio

During 2011, R&D followed up the rigorous and comprehensive portfolio review already initiated in 2009. Projects were assessed using seven key criteria which allow management to rapidly understand how the portfolio performs in terms of innovation, unmet medical needs, risk and value. They can be summarized as follows:

science: level of innovation, level of safety, quality and reliability of the scientific data;

pharmacovigilance: assessment of the benefit/risk ratio for products (i.e., the clinical benefit versus the potential side effects).

execution: likelihood of development and manufacturing success;

market: existence of a market, positioning within this market, and our place in the market;

reimbursement: likelihood of achieving the desired price and reimbursement based on the health authorities positioning and Sanofi competencies;

regulatory/legal: dealing with the environment around the project, patent status, regulatory guidelines; and

financial: predicted return on investment for the project.

At the end of 2011, the current clinical portfolio is the result of decisions taken during these reviews, plus compounds entering the portfolio from the discovery phase or from third parties through 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.

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

	Phase I	Phase II	Phase III /registration
Diabetes	SAR164653	SAR236553	Lixisenatide
	SAR407899		
Oncology	SAR125844	SAR245408 (XL147)	aflibercept (AVE005)
	SAR153192	SAR245409 (XL765)	ombrabulin (AVE8062)
	SAR307746	SAR256212 (MM-121)	SAR240550 (BSI-201)
	SAR566658	SAR3419	SAR302503
	SAR650984		semuloparin (AVE5026)
	Genz-644282		
	GC1008		
Ophthalmology	RetinoStat®	FOV1101	
	StarGen	FOV2304	
	sFLT-01 AAV		
Genzyme	AAV-AADC		alemtuzumab
	rhASM		mipomersen
	Fresolumimab		eliglustat tartrate
TSU Aging	SAR114137	SAR110894	
	SAR292833	SAR113945	
		SAR164877	
TSU Fibrosis & Wound Repair	SAR100842		
	SAR156597		
TSU Infectious Diseases		Ferroquine	
		SAR97276	
		SAR279356	
TSU Immuno-Inflammation	SAR339658	SAR231893	
DPUs	SAR126119		otamixaban
	SSR411298		teriflunomide
			sarilumab (SAR153191)

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. (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.

The 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 Phase I compounds entries, and lists projects that were terminated in 2011.

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 acute coronary syndromes.

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A new formulation of insulin glargine has been tested in Phase I. This new product shows an improved pharmacodynamic profile. Phase III investigating the efficacy and safety in a broad patients population has been initiated end of 2011.

Lantus: the Lantus Pediatric Investigational plan was finalized as scheduled and results have been submitted in Europe in time.

The development of **SAR101099**, an Urotensin II Receptor Antagonist, has been discontinued.

Oncology portfolio

With the acquisition of Genzyme in April 2011, the following compounds have reinforced Sanofi Phase I pipeline. Thus, in addition to the marketed intravenous formulation of clofarabine, a potent DNA synthesis inhibitor already registered for pediatric ALL, an oral formulation of the same active ingredient is being developed in new hematological malignancies indications. Also, GENZ-644282, a non-camptothecin topo1 inhibitor, and GC 1008, an anti-TGFß monoclonal antibody, are being developed in solid tumors.

Furthermore, SAR307746 (REGN910), a monoclonal antibody directed against Ang2 issued from the partnership with Regeneron, entered Phase I in oncology in the first quarter of 2011.

Finally, the global development of SAR103168, a Phase I multikinase inhibitor being developed in AML, **was halted** due to pharmacokinetic considerations

Genzyme portfolio

rhASM Enzyme replacement therapy targeting the treatment of Niemann-Pick B disease. A Phase II study is under preparation.

Fresolumimab TGF-ß antagonist targeting the treatment of Focal Segmental Glomerulosclerosis (FSGS). Preparations for Phase II took place in 2011.

AAV-AADC Gene therapy based on AAV vector targeting the treatment of moderate to severe Parkinson s disease. The low-dose cohort of the Phase I study is completed and follow-up is ongoing.

Ophthalmology portfolio

A number of compounds for the treatment of eye disease were added to the portfolio via the acquisition of Fovea, the collaboration agreement with Oxford BioMedica and the acquisition of Genzyme (see Pharmaceutical Products Main Pharmaceutical Products Other Pharmaceutical Products above).

In gene therapy, three compounds targeting the treatment of Age-related Macular Degeneration (AMD) and Stargardt Disease entered into Phase I in 2011

- RetinoStat® (AMD) gene therapy based on Lentivector
- sFlt01 (AMD) gene therapy based on AAV vector
- Stargen (Stargardt disease) gene therapy based on Lentivector

TSU Aging portfolio

Two compounds have progressed into Phase II clinical development:

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)

1 compound has completed a Phase I program and should enter Phase II in 2012

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

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1 compound recently completed a Phase I program results analysis on-going:

SAR114137 (Cathepsin S/K inhibitor for the oral treatment of chronic pain)

1 compound will enter Phase I clinical development in the first quarter of 2012:

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

1 compound has been terminated:

SAR152954 (H3 receptor antagonist)

In 2011, two key research agreements were signed with Audion Therapeutics and Aviesan to develop potential treatments in hearing loss and hearing disorders.

For Discovery/development partnerships:

In-license agreement signed in December 2011 with SCIL Technology GMBH, a German biopharmaceutical company to develop CD-RAP products in osteoarthritis indication.

Opt-in agreement signed with Regeneron in December 2011 to develop an anti-GDF8 mAb in the sarcopenia indication

TSU Infectious Diseases portfolio

Ferroquine (4-aminoquinoline; malaria; Phase IIb). 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.

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 and worldwide license from Alopexx Pharmaceuticals LLC for the development and commercialization of SAR279356 was exercised in October 2010. Phase I was successfully completed in early 2011 and a Phase II PK/PD study started in the third quarter of 2011 is ongoing.

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. A Phase IIa study started in the third quarter of 2011.

TSU Immuno-Inflammation portfolio

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 is on track to enter Phase II in 2012.

Other Projects portfolio

The Phase I program for **SAR126119**, an injectable synthetic inhibitor of TAFI (thrombin-activable fibrinolysis inhibitor) has been conducted successfully. The Phase II study in the treatment of acute ischemic stroke (AIS), is expected to start in 2012.

The development of **SSR411298** an oral fatty acid amide hydrolase (FAAH) inhibitor as treatment of chronic pain in cancer patients has been initiated. The results of the on going Proof-of-Concept (POC) study are expected by the end of 2012 and should confirm the potential interest of the molecule in pain indication.

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R&D expenditures for late stage development

Expenditures on research and development amounted to 4,811 million in 2011, of which 4,101 million in the pharmaceutical segment, 564 million in Human Vaccines and 146 million in Animal Health. Research and development expenditures were the equivalent of about 14.4% of net sales in 2011, compared to about 14.1% in 2010 and 15.5% in 2009. The discontinuation of a number of projects contributed to the decrease in such expenditure in 2009 and 2010 and going forward the level of expenditure can be expected to continue to vary as a reflection of the number of products in late stage development among other factors. Preclinical research in the pharmaceutical segment amounted to 1,113 million in 2011, compared to 1,037 million in 2010 and 1,047 million in 2009. Of the remaining 2,988 million relating to clinical development in the pharmaceutical sector (2,848 million in 2010 and 3,043 million in 2009), the largest portion was generated by Phase III or post-marketing studies reflecting the cost of monitoring large scale clinical trials.

For each of our current late stage (Phase III) compounds in the Pharmaceutical segment, we set out below the date at which this compound entered into Phase III development, information concerning any compound patent in the principal markets for innovative pharmaceutical products (the United States, European Union and Japan) as well as comments regarding significant future milestones that are reasonably determinable at this date. Because the timing of such milestones typically depends on a number of factors outside of our control (such as the time to validate study protocols, recruit subjects, the speed with which endpoints are realized, as well as the substantial time taken by regulatory review) it is frequently not possible to provide such estimates, and any such estimates as are given should be understood to be indicative only. See also Item 3. Key Information D. Risk Factors Risks Relating to Our Business .

Phase III	**Entry into Phase III [1]**	**Compound Patent Term [2]**			**Comments**
(month/year)		**U.S.**	**E.U.**	**Japan**	
Lyxumia® (lixisenatide) [4]	May 2008 [3]	2020	2020	2020	Dossier submitted in Europe in October 2011; to be submitted in the U.S. in 2012.
Zaltrap® (aflibercept)	July 2006	2020	2020	2020 [4]	2nd line colorectal cancer, dossier submitted in Europe in November 2011 and in the U.S. in February 2012.
ombrabulin (AVE8062)	June 2008	2016	2016	2016	1st line prostate cancer Phase III (VENICE) results expected in the second quarter 2012 Sarcoma Phase III results expected in the third quarter 2012
iniparib (BSI-201)	June 2009	2013	2014	N/A	Phase III program on going in 1st line squamous Non Small Cell Lung Cancer Phase II program in 2nd line ovarian cancer to be launched in 2012

	Complementary Phase II studies in breast cancer on going

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Phase III (month/year)	Entry into Phase III [1]	Compound Patent Term [2] U.S.	E.U.	Japan	Comments
Visamerin®/Mulsevo® (semuloparin) [4]	May 2008	2024	2023	2023	Dossier submitted in Europe and U.S. in September 2011
otamixaban	April 2010	2016	2016	2016	Phase III results in Acute Coronay Syndrome (ACS) expected in the fourth quarter 2012
Aubagio (teriflunomide) [4]	September 2004	2014	expired	expired	In the monotherapy treatment of multiple sclerosis, dossier submitted in August 2011 in U.S. and in February 2012 in Europe
					Adjunct therapy treatment of multiple sclerosis, Phase III program on going
					Treatment of Clinically Isolated Syndrome, Phase III program on going.
Clolar® / Evoltra®	Life Cycle Management	expired	expired	expired	Phase III program on going in the 1st line treatment of Acute Myeloid Leukemia
SAR302503 (TG101348)	January 2012	2026	2026 [4]	2026 [4]	Phase III program on going in the treatment of myelofibrosis
Lemtrada (alemtuzumab)	September 2007 (MS)	2015	2014	expired	Dossier to be submitted in Europe and U.S. for the treatment of Relapsing forms of Multiple Sclerosis during the 1st semester of 2012
New formulation Insulin glargine	December 2011	2015 [5]	2014	2014	Phase III program on going
Kynamro (mipomersen) [4]	August 2007	2025	pending	pending	Dossier submitted in Europe in July 2011 in the treatment of homozygous familial hypercholesterolemia (HoFH) and severe heterozygous familial hypercholesterolemia (HeFH)
					Phase III program in severe HeFH on going for a U.S. submission

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Phase III	Entry into Phase III [1]	Compound Patent Term [2]			Comments
(month/year)		U.S.	E.U.	Japan	
eliglustat tartrate	September 2009	2022	pending	pending	Phase III program on going in the treatment of Gaucher Disease type 1 results expected the 1st quarter of 2013
sarilumab	August 2011	2028	2027	2027	Phase III program in the treatment of Rheumatoid Arthritis on going

[1] *First entry into Phase III in any indication.*
[2] *Subject to any future supplementary protection certificates and patent term extensions.*
[3] *Development of lixisenatide as stand alone entity. A program evaluating the benefit of a combination of lixisenatide / Lantus® is currently in Phase I.*
[4] *Application pending.*
[5] *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, 12 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.

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Portfolio

The Sanofi Pasteur R&D portfolio includes 13 vaccines currently in advanced development as shown in the table below. The portfolio includes five vaccines/antibody products for novel targets and eight vaccines which are enhancements of existing vaccine products.

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

(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 (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.

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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. The last Phase II clinical trial in India was initiated in November 2011. In 2011, Sanofi Pasteur reviewed the rabies mAb project, developed in partnership with Crucell. Crucell, acquired by Johnson & Johnson, will take 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). Results of a Phase II clinical trial in adults in the United States demonstrated proof of concept of the lead quadrivalent vaccine candidate. Sanofi Pasteur s dengue vaccine research program includes ongoing clinical studies (adults and children) in several countries in endemic regions. The first Phase III study was initiated in October 2010 in Australia. This final stage of clinical development aims at demonstrating that production of the vaccine on an industrial scale will meet the consistency criteria required for market authorizations. The study in Australia is the first to use our dengue vaccine doses produced on an industrial scale. Two Phase III studies to evaluate efficacy (Latin America and Asia Pacific) began in June 2011. In February 2011, Sanofi Pasteur announced that it was partnering with the International Vaccine Institute (IVI) to support the recently launched Dengue Vaccine Initiative (DVI) in collaboration with the Sabin Vaccine Institute, the Johns Hopkins University, and the WHO to support development of vaccines to control dengue fever.

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, with full enrollment completed in June 2011.

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. Last year, 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 by participating in the Pox-T-cell consortium and the IPPOX Foundation in 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 an alarming rate since 2003, driven

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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. The ongoing stage 2 of the study is evaluating the dosing schedule.

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.

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.

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

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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 2011, 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 an active ingredient 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 Generic versions of some of our products may be approved for sale in one or more of their major markets ; and We may lose market share to competing remedies or generic brands if they are perceived to be equivalent or superior products . In some cases, it is possible to continue to obtain commercial benefits from product manufacturing trade secrets or from other types of patents, such as patents on processes, intermediates, structure, formulations, methods of treatment, indications or delivery systems. Certain categories of products, such as traditional vaccines and insulin, have been historically relatively less reliant on patent protection and may in many cases have no patent coverage, although it is increasingly frequent for novel vaccines and insulins to be patent protected. See Focus on Biologics below. Patent protection is also an important factor in our animal health business, but is of comparatively lesser importance to our Consumer Health Care and generics businesses, which rely principally on trademark protection.

Regulatory Exclusivity

In some markets, including the European Union and the United States, many of our pharmaceutical products may also benefit from multi-year regulatory exclusivity periods, during which a generic competitor may not rely on our clinical trial and safety data in its drug application. Exclusivity is meant to encourage investment in research and development by providing innovators the exclusive use for a limited time of the innovation represented by a newly approved drug product. This exclusivity operates independently of patent protection and may protect the product from generic competition even if there is no patent covering the product.

In the United States, the FDA will not grant final marketing approval to a generic competitor for a New Chemical Entity (NCE) until the expiration of the regulatory exclusivity period (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

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(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 twelve 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. 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).

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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 improvement 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 therefore do not reflect six-month pediatric extensions to the FDA s Orange Book dates for the products concerned (Aprovel®, Lantus®, Plavix®, and Actonel®).

We do not provide later filed improvement 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 EU regulatory exclusivity is intended to be applied throughout the European Union, in some cases member states have taken positions prejudicial to our exclusivity rights. See Regulatory Exclusivity above.

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	Compound: November 2014

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Apidra® (insulin glulisine)

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

Taxotere® (docetaxel)

U.S.	**E.U.**	**Japan**
Compound: expired	Compound: expired in most of the EU	Compound: June 2012
Generics on the market	Generics on the market	Later filed improvement patents: coverage ranging through November 2013

Eloxatin® (oxaliplatin)[1]

U.S.	**E.U.**	**Japan**
Compound: expired	Compound: expired	N/A[3]
Later filed improvement patents: coverage ranging through August 2016[2]	Generics on the market	

[1] *We do not own most Eloxatin® patents but license them from Debiopharm for marketing.*
[2] *Generics removed from the market by court order. Return anticipated in August 2012. See Item 8 - A. Consolidated Financial Statements and Other Financial Information Patents Eloxatin® (oxaliplatin) Patent Litigation .*
[3] *No rights to compound in Japan.*

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 improvement patents: coverage ranging through December 2025	Later filed improvement patents: coverage ranging through September 2024	Later filed improvement 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

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Plavix® (clopidogrel bisulfate)

U.S.	**E.U.**	**Japan**
Compound: November 2011 Extended to May 2012, by Pediatric exclusivity	Generics on the market	Compound: February 2013 Regulatory exclusivity: January 2014

Aprovel® (irbesartan)

U.S.	**E.U.**	**Japan**
Compound: September 2011 Extended to March 2012 by Pediatric exclusivity	Compound: August 2012 in most of the EU; exceptions: February 2013 in Latvia and May 2013 in Lithuania. No compound patent in force in Spain, Portugal, Finland, Norway and much of Eastern Europe and expired in 2011 in the Czech Republic, Hungary, Romania and Slovakia	Compound: March 2016
Later filed improvement patents: coverage ranging through December 2015 with Pediatric exclusivity	Later filed improvement patents: coverage ranging through June 2016 Generics on the market in some EU countries	Later filed improvement patent: coverage ranging through June 2016 (June 2021 if PTE granted) Regulatory exclusivity: April 2016

Tritace® (ramipril)

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

[1] *No rights to compound in the U.S.*

Multaq® (dronedarone hydrochloride)

U.S.	**E.U.**	**Japan**
Compound: July 2012 (July 2016 if PTE petition is granted) Later filed improvement patent: formulation (June 2018) Regulatory exclusivity: July 2014	Compound: expired Later filed improvement patent: formulation June 2018 (June 2023 if SPC granted) Regulatory exclusivity: November 2019	Compound: expired

Stilnox® (zolpidem tartrate)

U.S.	**E.U.**	**Japan**

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

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Copaxone® (glatiramer acetate)[1]

U.S.	**E.U.**	**Japan**
N/A[2]	Compound: May 2015	N/A[2]

1 *As of February 29, 2012 Sanofi no longer markets or sells Copaxone®. See Item 4 B. Business Overview Other Pharmaceutical Products Alliance with Teva .*

2 *No rights to compounds in the U.S. and Japan.*

Depakine® (sodium valproate)

U.S.	**E.U.**	**Japan**
N/A[3]	Compound: expired	Compound: expired
	Later filed improvement patent: Depakine® Chronosphere	Later filed improvement patent: Depakine® Chronosphere
	formulation (October 2017)	formulation (October 2017)

3 *No rights to compounds in the U.S.*

Allegra® (fexofenadine hydrochloride)

U.S.	**E.U.**	**Japan[4]**
Compound: expired	Compound: expired	Compound: expired
Generics on the market		
Converted to Over-the-Counter	Generics on the market	Later filed improvement patents: coverage ranging through January 2016

4 *In December 2011, the Japan patent office found two patents covering Allegra® to be invalid. This decision in under appeal by Sanofi (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)[5]

U.S.	**E.U.**	**Japan**
Compound: expired	Compound: expired	Compound: expired
Later filed improvement patents: formulation and method of use July 2016	Later filed improvement patent: formulation July 2017	
Generics on the market		

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

Xatral® (alfuzosin hydrochloride)

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

Generics on the market	Generics on the market	Generics on the market
	Actonel® (risedronate sodium)[6]	
U.S. Compound: December 2013, Extended to June 2014 by Pediatric extension	**E.U.** Compound: expired	**Japan** Expired

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Actonel® (risedronate sodium)[6]

Later filed improvement patents: coverage ranging through June 2018	Later filed improvement patents: coverage ranging through June 2018	

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

Amaryl® (glimepiride)

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

Insuman® (human insulin)

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

Fabrazyme® (agalsidase beta)

U.S.	**E.U.**	**Japan**
Compound: N/A	Compound: N/A	Compound: N/A
Later filed improvement patents: coverage ranging through September 2015		Later filed improvement patents: November 2013
Biologics Regulatory Exclusivity: April 2015		Orphan regulatory exclusivity: January 2014

Cerezyme® (imiglucerase)

U.S.	**E.U.**	**Japan**
Compound: August 2013	Compound: N/A	Compound: N/A
Later filed improvement patents: coverage ranging through September 2019		

Lumizyme® / Myozyme® (alglucosidase alfa)

U.S.	**E.U.**	**Japan**
Compound: August 2018	Compound: July 2021	Compound: N/A
		Orphan Regulatory Exclusivity: April 2017
Later filed improvement patents: coverage ranging through February 2023	Later filed improvement patents: coverage ranging through February 2023	
Orphan Drug Exclusivity: April 2013	Orphan Regulatory Exclusivity: March 2016	
Biologics Regulatory Exclusivity: April 2018	Biologics Regulatory Exclusivity: March 2016	

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	Renagel® (sevelamer hydrochloride)	
U.S.	**E.U.**	**Japan**
Compound: N/A	Compound: N/A	Compound: N/A
Later filed improvement patent: coverage ranging through August 2013 and September 2014	Later filed improvement patent: August 2014	Later filed improvement patent: August 2014
	SPC coverage to January 2015 in certain EU countries	PTE protection to December 2016
	Renvela® (sevelamer carbonate)	
U.S.	**E.U.**	**Japan**
Compound: N/A	Compound: N/A	Compound: N/A
Later filed improvement patent: coverage ranging through August 2013 and September 2014	Later filed improvement patent: August 2014	Later filed improvement patent: August 2014
New dosage form regulatory exclusivity: August 2012		
	Synvisc® (hyaline G-F 20)	
U.S.	**E.U.**	**Japan**
Compound: expired	Compound: N/A	Compound: N/A
Later filed improvement patent: March 2012		
	Synvisc One® (hyaline G-F 20)	
U.S.	**E.U.**	**Japan**
Compound: expired	Compound: N/A	Compound: N/A
Later filed improvement patent: January 2028		

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.

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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.

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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 integrate the manufacture of our products in order to have better control of quality and distribution. Our manufacturing process consists of three principal stages: the manufacture of active pharmaceutical ingredients, the transformation of these ingredients into products, and packaging.

We have a general policy of producing our main active ingredients and principal products at our own plants in order to minimize our dependence on external manufacturers and ensure the strict and precise control of the product throughout the production cycle. In some cases however, we rely on third parties for the manufacture and supply of some active ingredients and medical devices. We also have outsourced certain production elements, particularly as part of supply framework agreements entered into within the context of plant divestitures, or in order to adapt locally to market growth in emerging markets. In particular, we outsource a 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 section 3.D. Risk factors Risks Relating to Our Business .

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

Our pharmaceutical production sites are divided into three categories:

- global sites, which serve all the markets. Situated principally in Europe, these are plants dedicated to the manufacture of our active ingredients, injectables and a number of our principal products in solid form;

- regional sites, which serve the markets at a continent level, in Europe and particularly the BRIC-M countries (Brazil, Russia, India, China and Mexico), marking our strong industrial presence in the emerging markets;

local sites, which wholly serve the domestic market.

Sanofi Pasteur produces vaccines at sites located in North America, France, China, Thailand, Argentina and India. Le Trait (France) and Anagni (Italy) pharmaceutical sites form part of Sanofi Pasteur s industrial operations and carry out aseptic filling and freeze-drying activities. A new antigen production unit in Mexico for seasonal and pandemic influenza vaccines is scheduled to commence commercial production in 2012, once the necessary production and marketing approvals have been obtained from the Mexican authorities.

In 2011, our industrial operations diversified into rare diseases with the acquisition of Genzyme and the integration of Merial, Sanofi s dedicated animal health division.

Genzyme s activities throughout the world cover all biomedicine development stages, from initial research to clinical trials, regulatory matters, manufacture and marketing.

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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 industrial operations dedicated to animal health cover all activities, from the purchase of raw materials through to the delivery of the finished products, ensuring its customers needs can be met through a reliable and flexible offer that meets quality expectations. There are sixteen production sites spread across nine countries.

All of our pharmaceutical and vaccine facilities are Good Manufacturing Practices (GMP) compliant with international guidelines. Our principal sites are approved by the U.S. Food & Drug Administration (FDA): this includes our pharmaceutical facilities in Ambarès, Tours, Le Trait, Maisons-Alfort and Compiègne in France, Dagenham and Holmes Chapel in the United Kingdom, Frankfurt in Germany, Veresegyhaz in Hungary and Saint Louis in the United States, as well as our vaccine facilities in Marcy l Etoile and Val de Reuil (our worldwide distribution site) in France, Swiftwater in the United States and Toronto in Canada. The Genzyme facilities in the United States (Allston, Framingham, Ridgefield, Cambridge) and in Europe (Geel, Lyon, Haverhill and Waterford) are all FDA approved. Our animal health facilities in Athens, Gainesville, Berlin and Raleigh in the United States are managed by the U.S. Department of Agriculture (USDA). 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 of Lovenox®, for example.

In February 2011, we had 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 improvement action plan. In October 2011, we notified the FDA of the end of this program. We expect the FDA inspection to take place during the second quarter of 2012.

On May 24, 2010, Genzyme entered into a consent decree with the FDA relating to the Allston facility following FDA inspections at the Allston facility that resulted in 483 observations and a warning letter raising 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 paid an upfront disgorgement of past profits of $175.0 million. Conditioned upon Genzyme s compliance with the terms of the consent decree, Genzyme is permitted to continue manufacturing at the site during the remediation process.

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 previously reported to Genzyme or identified as part of a comprehensive inspection that was completed by a third-party expert in February 2011. This third party expert has been retained by Genzyme and will monitor and oversee the implementation of the remediation workplan. The required comprehensive remediation workplan was submitted to the FDA in April 2011 and accepted by the FDA in January 2012. The workplan is expected to take approximately four more years to complete. The workplan includes a timetable of specified remediation compliance 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.

Genzyme will be meeting with the FDA to propose modifications to the workplan as a result of planned changes in manufacturing operations regarding Cerezyme® and Fabrazyme® for the Allston Landing Facility.

The new Genzyme Framingham (U.S.) facility was approved by the FDA and the EMA in January 2012 for the production of Fabrazyme® (agalsidase beta).

The Merial animal health facilities are regulated by different authorities depending on the product and the country (EPA, FDA, USDA, EU GMP, local authorities).

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

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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 105 million in 2011.

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 2011, Sanofi spent 41 million on rehabilitating sites previously contaminated by soil or groundwater pollution. During the year ended December 31, 2011, 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 763 million as at December 31, 2011; 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

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(24 in 2011) 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 17 specialized audits covering contractors or biosafety were done by our teams. Moreover, 172 loss prevention technical visits were carried out in 2011.

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

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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 the relevance of the risk assessments.

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, 55 sites are currently ISO 14001 certified. We believe that this strategy clearly expresses the commitment of both management and individuals to health, safety and the environment. In 2011, 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 2011, we reduced carbon dioxide emissions caused by our sales representation car fleet by 10% versus 2010, due to the policy of using energy efficient cars as well as a reduction in the number of cars. Since 2005, in terms of our activity level per unit produced, our direct and indirect carbon dioxide emissions have decreased by 9.5% and 15.6% respectively[(1)].

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 2009, 2010 and 2011 can be found at Note D.35. to our consolidated financial statements included at Item 18 of this annual report.

The following market shares and ranking information is based on sales data from IMS Health MIDAS, retail and hospital for full year 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 date of acquisition.

(1) The CO_2 emissions variations per produced unit are calculated for each business and added proportionally to their respective contribution to the total direct and indirect CO_2 emissions. Each business defines a specific indicator of its activity (e.g., hours worked for vaccines, number of boxes produced for pharmaceuticals, etc.).

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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 B. Business Overview Strategy , above) represent 30.3% of our net sales, the largest contribution to net sales of any region. We are the leading healthcare company in emerging markets. In 2011, sales in emerging markets grew by 10.1% at constant exchange rates. This performance was due to robust organic growth (10.4% excluding Genzyme and A/H1N1 vaccines sales). Brazil sales were up 16.9% (excluding Genzyme and A/H1N1 vaccines sales), China sales were up 38.5% (excluding Genzyme), and Russia sales were up 7.4% (excluding Genzyme). In 2011, Asia and Latin America continued to deliver strong double digit sales growth of 15.7% and 18.1% respectively (excluding Genzyme and A/H1N1 vaccines sales). Sales in Eastern Europe and Turkey were slightly down (-0.4% excluding Genzyme and A/H1N1 vaccines sales), which were particularly impacted by price cuts and generic competition for Taxotere® in Turkey.

The United States represent 29.8% of our net sales; we rank thirteenth with a market share of 3.1% (3.1% in 2010). Sales in the U.S. were up 6.8% at constant exchange rates in 2011 (down 5.7% excluding Genzyme and A/H1N1 vaccines sales) reflecting the impact of generics of Lovenox®, Taxotere®, Ambien® CR, Allegra® and Xyzal®; partially off-set by Lantus® growth, Eloxatin® return to market exclusivity and the launch of Allegra® OTC.

Western Europe represents 27.3% of our net sales; we are the leading pharmaceutical company in France where our market share is 9.9% (10.1% in 2010), and we rank fifth in Germany with a 4.6% market share (after Copaxone® transfer and without taking into account parallel trade). In 2011, sales in Western Europe were down 4.0% at constant exchange rate (down 10.5% excluding Genzyme and A/H1N1 vaccines sales) due to the impact of generic competition for Plavix® and Taxotere® as well as the impact of austerity measures.

Japan represents 8.6% of our net sales; our market share is 3.4% (3.1% in 2010). Full-year 2011 sales in Japan were up 20.2% at constant exchange rate, or up 12.0% excluding Genzyme and were supported by Plavix® (up 22.9%), Allegra® (up 22.2%) and Hib vaccine sales.

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, 2011 Compared with Year Ended December 31, 2010.

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. With regard to rare disease, renal, and biosurgery products, we sell these products directly to physicians as well. 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, 2011, 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 Pharmaceutical Products Main pharmaceutical products above. See also Item 3. Key Information D. Risk Factors We rely on third parties for the marketing of some of our products.

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Our vaccines are sold and distributed through multiple channels, including physicians, pharmacies, hospitals 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 the countries legislation for veterinary products. Merial takes into account each country s specific characteristics and sells either to veterinaries, chemists, or via wholesalers. In 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; AstraZeneca in cardiovascular disease, hypertension and oncology; Bayer-Schering in thrombosis prevention; Boehringer-Ingelheim in atherothrombosis; Bristol-Myers Squibb in oncology; Lilly in diabetes and oncology; GlaxoSmithKline in oncology, allergies, diabetes and thrombosis; Merck in hypertension, osteoporosis, diabetes and benign prostatic hyperplasia; Novartis in hypertension and oncology; Novo Nordisk in diabetes; Pfizer in oncology, thrombosis and allergies; Shire plc in rare diseases and in renal; Fresenius Medical Care in renal and Roche in oncology and osteoporosis.

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 also in international donor markets. Multinational players are increasingly seeking alliances with manufacturers from emerging economies to secure positions in their markets of origin.

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; with Virbac, Ceva and Vetoquinol, French companies with global presence, for pharmaceuticals and vaccines except for Vetoquinol operating 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

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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 is committed to being part of any efforts made to overcome drug counterfeiting and has implemented the following actions:

- Intensification of close collaboration with international organizations and with customs and police to reinforce regulatory frameworks and to investigate suspected counterfeiters; and

- Development of technologies to make drugs more difficult to copy through packaging protection programs and to ensure no direct traceability.

Regulation

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.

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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, emergent 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 identified as clusters (i.e. pediatrics, oncology, advanced therapy medicinal products, vaccines, pharmacogenomics, orphans, biosimilars, blood products) between the United States and the European Union, as well as creating permanent representatives from the FDA and Japanese Pharmaceutical and Medical Devices Agency (PMDA) now based 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 meaningfully extend the time for market entry beyond the initial marketing approval. While marketing authorizations for new pharmaceutical products in the European Union have been substantially 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 a EU marketing authorization. Such a marketing authorization is valid throughout the EU and the drug may be marketed within all European Union 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 EU 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 an approved reference product in the European Union. 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 from the date of approval of the originator product has elapsed.

Another relevant aspect in the EU regulatory framework is the sunset clause : a provision leading to the cessation of the validity of any marketing authorization which is not followed by marketing within three years or not remaining on the market for a consecutive three year period.

Post-authorization safety monitoring of pharmaceutical products is carefully regulated in Europe. The EU 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.

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It is possible for the regulatory authorities to withdraw products from the market for safety reasons. The responsibilities for pharmacovigilance rest with the regulatory authorities of all the EU member states in which the marketing authorizations are held. In accordance with applicable legislation, each EU 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 authorisation 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 assume their obligations and responsibilities.

In 2010 new legislation aimed at strengthening and rationalizing the EU Pharmacovigilance System was approved, which will be enforced in July 2012. Changes include a strengthened legal basis for regulators to require post-authorization safety and efficacy studies throughout the life cycle of the medicinal product. An additional scientific committee called the Pharmacovigilance Risk Assessment Committee, with a key role in pharmacovigilance assessments (scope: all marketed drugs in the EU), is being established at the level of the EMA. This committee, which includes a patient representative, can hold public hearings. As a result, the Periodic Safety Update Report work-sharing procedure, as well as the new Urgent Union procedure should improve the harmonization of regulatory outcomes of safety evaluation for nationally authorized products.

Implementation of this pharmacovigilance legislation will be a particular priority in light of the highly-publicized Mediator affair in France. Given AFSSAPS stature as a leading regulatory agency, as well as the way the European regulatory network is organized, (with national agencies that are closely entwined with the EMA through their experts membership of EMA s scientific committees and groups), it is possible the affair will have EU repercussions. Indeed member states may bring additional tighter national requirements. For example, the recently French law of December 29, 2011 that aims at reinforcing the oversight of safety of medical products allows the French regulator to ask for clinical trials to be conducted against both an active comparator and placebo for marketing authorisation purposes.

In addition the EU regulatory framework for medical devices will undergo to an in-depth revision in 2012, that will aim to improve coordination, evaluation and certification of medical devices, as well as reinforcing efficient vigilance and post-market surveillance systems with greater harmonization of EU member states market surveillance activities.

In the United States, applications for drug and biological approval are submitted to the FDA for review which has broad regulatory powers over all pharmaceutical products that are intended for U.S. sale and marketing. 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. An application for a generic drug product does not currently require a user fee payment; however this will likely change under GDUFA (Generic Drug User Fee Act) which is expected to be

introduced as an Omnibus Bill in 2012. User fees for generic drug applications are

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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 copies of drugs approved under the FD&C Act and not for BLA approved biological products under the PHS Act.

In Japan, regulatory authorities can require local development 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 United States. In order to solve this drug-lag problem, the MHLW (Ministry of Health, Labour 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 is compensated by a Premium for a maximum of 15 years. Premium are 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 6 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 generic products, the data necessary for filing is similar to that which is required in EU and U.S. 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. In March 2009, the CHMP adopted a guideline on preclinical and clinical development of biosimilars of low molecular weight heparins (LMWH). Currently in Europe a potential product candidate claiming to be biologically similar to Lovenox® must show therapeutic equivalence in terms of efficacy and safety in at least one adequately powered, randomized, double-blind, parallel group clinical trial. However in 2011, the EMA initiated the revision of several of the existing biosimilar guidelines (general guidelines, as well as product-related guidelines for recombinant insulins and LMWH).

While the EMA has adopted so far a balanced approach for all biosimilars, which allows evaluation on a case-by-case, 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 only combined with an extensive quality package. With respect to vaccines, the CHMP position is that, at present, it is 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. Different from the CHMP guidelines, the main scope of the guideline includes recombinant proteins and polypeptides, but not polysaccharides such as LMWH.

In the United States, several complex protein-based drugs have been approved as NDAs under the Federal Food Drug and Cosmetic Act (FD&C Act). It is currently possible to submit an abbreviated application (ANDA) with respect to those particular products (e.g., Lovenox®, Lantus®). Since an ANDA is not required to contain

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clinical trial data other than from bioequivalence studies, the appropriateness of an ANDA with respect to these NDA approved biological products raises significant scientific issues for the FDA. Lovenox® (enoxaparin) was approved as a drug by the FDA on March 29, 1993 under Section 505(b)(1) of the FD&C Act and not as a biologic under Section 351 of the Public Health Service Act; therefore it was not possible to submit a biosimilar of the product. An abbreviated NDA (ANDA/generic) application was submitted to FDA August 2005 by Momenta/Sandoz under section 505(j) of the FD&C Act. This application was approved in July 2010; the generic product was approved as therapeutically equivalent to Lovenox®. The FDA approved a second enoxaparin ANDA on September 19, 2011. The sponsor, Amphastar, had submitted the application in 2003. A third ANDA from TEVA, also submitted in 2003, is still pending.

U.S. law now provides for a pathway for biosimilar versions of a reference product licensed as a biological under the PHS Act. Healthcare reform legislation entitled the Patient Protection and Affordable Care Act, was signed into law by the President on March 2010. Title VII, Subtitle A Biologics Price Competition and Innovation , allows for the creation of a regulatory approval pathway for biosimilars and a litigation procedure for patent infringement lawsuits brought against biosimilar applicants.

Under the new law, the definition of biological product in section 351(i) is revised to include proteins, except any chemically synthesized polypeptide. In addition, the law describes how a biosimilar product may be highly similar to the reference product notwithstanding minor differences in clinically inactive components , and for which there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency of the product .

This law also stated that approval of an application under section 351(k) may not be made effective until 12 years after the date on which the reference product was first licensed under section 351(a). The date on which the reference product was first licensed does not include the date of approval of: (1) a supplement for the biological product that is the reference product; (2) a subsequent application by the reference product sponsor or manufacturer for a change (other than a structural modification) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength for the previously licensed reference product; or (3) a subsequent application by the reference product sponsor or manufacturer for a modification to the structure of the reference product that does not result in a change in safety, purity, or potency.

Other provisions of this new U.S. law state that ten years after enactment, certain biological products approved under section 505 of the FD&C Act will be deemed licensed under section 351 of the PHS Act. Prior to that time, the current legal interpretation is that they cannot be reference products for applications submitted under section 351(k) of the PHS Act. The new law also describes how a biological product that is shown to meet the new interchangeability standards, may be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product .

On February 15, 2012, the FDA published for consultation three draft guidances 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. The Agency has stated at publicly attended meetings that they are conducting resource-intensive pre-IND meetings with sponsors on a range of biosimilar products.

Focus on transparency and public access to documents

Over the last two to three years the pharmaceutical industry is subject to growing pressure for greater transparency about clinical trials (conduct and results). Regulatory authorities are also being pushed for more openness and transparency to make more comprehensive the rationale and

basis of regulatory decisions on medicinal products, for enhanced credibility of the regulatory process. This is a meaningful 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.

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

EU pharmaceutical legislation for medicinal products requires national regulatory authorities and the EMA to actively publish information concerning authorisation 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 EU pharmacovigilance legislation, there will be an increased level of 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 a considerably 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 should be redacted before disclosure in order to protect information contained therein that cannot be disclosed (commercial confidential information or personal data), the identification of commercially confidential information (CCI) and protection of personal data (PPD) within the structure of the marketing-authorization dossier has been restricted according to the draft document released in June 2011 for public consultation by the EMA and the Head of Medicines Agencies (HMA). Therefore, the scope of the information accessible to the public is considerably widened (e.g., clinical study reports in a marketing authorization dossier, but also major parts of non-clinical test data).

In the highly competitive field of medicinal products, there is the need to reinforce the principle that non-innovators cannot obtain marketing authorization solely based on the originator s data released in the EU and while the data protection period runs.

In the U.S., the FDA has initiated a transparency initiative 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); 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.

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, 2011 was marked by continued implementation of the health insurance and market reforms that are expected to lead to a large number of uninsured being covered by 2014, either through

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state aid or mandatory coverage, with a system of fines for non-compliance. These reforms are the subject of litigation. These reforms will also lead to the establishment of health insurance exchanges which is expected to expand health care coverage.

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 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 industry. France has implemented, in 2011, 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 is 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 Asia, while the Chinese market continues to grow, the National Development and Reform Commission continues to bring controls on drug prices through severe price cuts. As with China, in India, there is a strong move towards a universal minimum health coverage, with the National Pharmaceutical Pricing Authority also pushing for price control of an essential drug list (EDL).

In Russia, healthcare provision guarantees were signed into law with as yet undefined treatment standards to control usage. However, the 2012 EDL has been established but prices have not been changed considerably.

In Japan, 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. In South Korea, after many announcements on pricing and reimbursement revisions the government is looking into premium measures for innovative products.

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.

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 Liability, Stock and Transit, and Directors & Officers Liability.

Our captive insurance company, Carraig, participates in our coverage for various lines of insurance including, but not only, excess property, stock and transit and product liability. Carraig is run under the supervision of the Irish regulatory authorities, is wholly-owned by Sanofi, and has sufficient resources to meet those portions of our risks that it has agreed to cover. It sets premiums for Group entities at market rates. Claims are assessed using the traditional models applied by insurance and reinsurance companies, and the company s reserves are regularly verified and confirmed by independent actuaries.

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Our Property & Business Interruption program covers all Group entities worldwide, wherever it is possible to use a centralized program operated by our captive insurance company. This approach shares risk between Group entities, enabling us to set deductibles and guarantees that are appropriate to the needs of local entities. It also incorporates a prevention program, including a comprehensive site visit program covering our production, storage, research and distribution facilities and standardized repair and maintenance procedures across all sites. Specialist site visits are conducted every year to address specific needs, such as testing of sprinkler systems or emergency plans to deal with flooding risks.

The Stock and Transit program protects goods of all kind 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 our insurers, 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 Liability & 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 emerging from healthcare products which are not subject to market 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.

In respect of all lines of business of Carraig, outstanding claims are covered by provisions for the estimated cost of settling all claims incurred up to, but not paid at the balance sheet date, whether reported or not, together with all related claims handling expenses. Where there is sufficient history from the company or from the market of claims made and settlements, an incurred but not reported (IBNR) actuarial technique is developed by management with the assistance of expert external actuaries to determine a reasonable estimate of the captive s exposure to unasserted claims for those risks. The actuaries perform an actuarial valuation of the IBNR loss and ALAE (allocated loss adjustment expense) liabilities of the Company as of year end. Two ultimate loss projections (based upon reported losses and paid losses respectively) using the Bornhuetter-Ferguson method are computed each year. Provisions are recorded on that basis.

The Directors & Officers Liability program protects all our legal entities and their directors and officers. Our captive insurance company is not involved in this program.

These 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. This is now also the case for Genzyme and Merial which are integrated in the Group cover at each inception date. By centralizing our major programs, not only do we reduce costs, but we also provide world-class coverage for the entire Group.

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C. Organizational Structure

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, 2011. For a complete list of our main consolidated subsidiaries, see Note F. to our consolidated financial statements, included in this annual report at Item 18.

Significant Subsidiary or Affiliate	Country of Organization	Ownership and Voting Interest
Aventis Inc.	United States	100%
Aventis Pharma S.A.	France	100%
Genzyme Corporation	United States	100%
Hoechst GmbH	Germany	100%
Merial Ltd	United Kingdom	100%
Merial S.A.S.	France	100%
Sanofi-Aventis Amérique du Nord S.A.S.	France	100%
Sanofi-Aventis Deutschland GmbH	Germany	100%
Sanofi-Aventis Europe S.A.S.	France	100%
Sanofi-Aventis France	France	100%
Sanofi-Aventis K.K.	Japan	100%
Sanofi-Aventis Participations S.A.S.	France	100%
Sanofi-Aventis U.S. LLC	United States	100%
Sanofi Pasteur Inc.	United States	100%
Sanofi-Synthelabo Inc.	United States	100%
Sanofi-Synthelabo UK Ltd	United Kingdom	100%
Sanofi Winthrop Industrie	France	100%

Sanofi and its subsidiaries form a group, organized around three activities: Pharmaceutical products, Human Vaccines and Animal Health products.

The patents and trademarks of the pharmaceutical activity are primarily owned by the Sanofi parent company, Aventis Pharma S.A. (France), Hoechst GmbH (Germany), Sanofi-Aventis Deutschland GmbH (Germany) and Genzyme Corporation (United States). The main patents and trademarks of the Human Vaccines and Animal Health activities are owned by Sanofi Pasteur S.A. and Merial Ltd, respectively.

Within the Group, the holding company oversees research and development activities by defining strategic priorities, coordinating work, and taking out industrial property rights under its own name and at its own expense. In order to fulfill this role, Sanofi subcontracts research and development to its specialized French and foreign subsidiaries, in many cases licensing its patents, manufacturing know-how and trademarks. In these cases, the licensee subsidiaries manufacture and distribute the Group s products, either directly or via local distribution entities.

In certain countries, Sanofi carries out part of its business operations through ventures with local partners. In addition, the Group has signed worldwide alliances by which two of its products (Plavix® and Aprovel®) are marketed through an alliance with BMS and Actonel® is marketed through an alliance with Warner Chilcott. See Pharmaceutical Products Main Pharmaceutical Products above.

For most Group subsidiaries, Sanofi provides financing and centrally manages their cash surpluses. Under the alliance arrangement with BMS, cash surpluses and cash needs arising within alliance entities give rise to symmetrical monthly transfers between the two groups. The holding company also operates a centralized foreign exchange risk management system, which enters into positions to manage the operational risks of its main subsidiaries.

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D. Property, Plant and Equipment

Our headquarters are located in Paris, France. See Office Space below.

We operate our business through offices and research, production and logistics facilities in approximately 100 countries. All our support functions operate out of our office premises. A breakdown of these sites by use and by ownership/leasehold status is provided below. Breakdowns are based on surface area. All surface area figures are unaudited.

Breakdown of sites by use*

Industrial	59%
Research	18%
Offices	13%
Logistics	6%
Other	4%

* *The Group s Human Vaccines and Animal Health businesses include offices and research, production and warehouse facilities. They are allocated between the four uses for premises shown at the top of the table above.*

Breakdown of the Group s sites between owned and leased

Leased	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.

Research and Development Sites: Pharmaceuticals segment

Research and Development activities are housed at 21 sites:

- seven operational sites in France, in Vitry/Alfortville, Montpellier, Chilly-Longjumeau, Toulouse, Strasbourg and Lyon;
- outside France, six sites are located in other European countries (Germany, UK, Holland and Italy), the largest being in Frankfurt, Germany;

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

one site in China, a Clinical Research Unit in Beijing.

Sanofi s Industrial Sites

The Group has 116 production sites for pharmaceuticals (including rare diseases), vaccines and animal health located in 40 countries.

Sanofi believes its production plants and research centers are in compliance with all regulatory requirements, are properly maintained and are generally suitable for future needs. Nonetheless, the Group regularly inspects and evaluates its production facilities with regard to environmental, health, safety and security matters, quality compliance and capacity utilization. For more information about the Group s property, plant and equipment, see Note D.3 to the consolidated financial statements.

Industrial Sites: Pharmaceuticals Segment

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).

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

France: Ambarès (Aprovel®, Depakine®, Multaq®), Le Trait (Lovenox®), Maisons-Alfort (Lovenox®), Neuville (dronedarone), Quetigny (Stilnox®, Plavix®), Sisteron (clopidogrel bisulfate, dronedarone, zolpidem tartrate), Tours (Stilnox®, Aprovel®, Xatral®), Vitry-sur Seine / Alfortville (docetaxel);

Germany: Frankfurt (insulins, ramipril, Lantus®, Tritace®, pens, Apidra®);

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

United Kingdom: Dagenham (Taxotere®, Elaxotine®), specialties currently being transferred to Frankfurt, Fawdon (Plavix®, Aprovel®); Holmes Chapel (Nasacort®);

Hungary: Ujpest (irbesartan), Csanyikvölgy (Lovenox®);

Japan: Kawagoe (Plavix®);

United States: Kansas City (Allegra®), speciality currently being transferred to Tours and Compiègne, and Chattanooga (Consumer Health Care products).

In the field of rare diseases, Genzyme became a Sanofi subsidiary in April 2011. This acquisition expands the Group s presence in biotechnologies, especially rare diseases. Genzyme manages 11 production sites and collaborates with over 20 subcontractors to manufacture 22 commercial products over an entire range of technological platforms

Genzyme sites are as follows:

United States, Massachusetts: Allston (Cerezyme®), Framingham (Fabrazyme®, Myozyme®, Thyrogen®, Seprafilm®, Hyaluronic Acid); Cambridge (Carticel®, Epicel®, MACI® (Matrix-induced Autologous Chondrocyte Implantation)) ;

United States, New Jersey: Ridgefield (Synvisc®, Hectorol®, Mozobil®, Jonexa®, Prevelle®);

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

United Kingdom, Suffolk: Haverhill (sevelamer hydrochloride API (Renagel®), sevelamer carbonate API (Renvela®), Cerezyme®, Fabrazyme®, Thyrogen®, Myozyme®, etc).

Belgium: Geel (alglucosidase alfa: Myozyme®/Lumizyme®);

France: Lyon (Thymoglobuline®, Celsior® (Immunosuppression in transplantation: preventing and treating graft rejection));

Denmark: Copenhagen (MACI®);

Australia: Perth (MACI®);

Sanofi Pasteur Industrial Sites

The headquarters of the Group s Vaccines division, Sanofi Pasteur, are located in Lyon, France. Sanofi Pasteur s production and/or Research and Development sites are located in Swiftwater, Cambridge, Rockville Canton and Orlando, United States, Toronto, Canada, Marcy l Etoile, Neuville and Val de Reuil, France, Shenzhen, China, Pilar, Argentina, Chachoengsao, Thailand, Hyderabad, India, and Ocoyoacac, Mexico.

In May 2009, Sanofi launched the construction of a new vaccine manufacturing center in Neuville-sur-Saône, France. This 300 million site investment is the largest ever made by Sanofi. The objective is to progressively transition the existing chemical activity to vaccine production beginning in 2013.

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, reduced time to market and increased probability of success rates in pre-clinical and clinical stages.

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

Animal Health Industrial Sites (Merial)

Since the announcement of Merck and Sanofi in March 2011 that they will maintain separate activities in the field of animal health, Merial has become a dedicated Sanofi division. Merial has 16 industrial sites, distributed throughout nine countries; nine research and development sites and numerous administrative offices with its principal headquarters located at Lyon, France.

Merial industrial sites are as follows:

Brazil: Paulinia (avermectin-based pharmaceutical products and vaccines to prevent 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: Berlin, Maryland, Gainesville, Georgia, and Raleigh, North Carolina, three Merial sites dedicated to Merial s avian business; and Athens, Georgia dedicated to viral and bacterial vaccines for mammals;

New Zealand: Auckland, Ankara (pharmaceutical products mainly for ruminants).

Acquisitions, Capital Expenditures and Divestitures

The carrying amount of our property, plant and equipment at December 31, 2011 was 10,750 million. In 2011, we invested 1,440 million (see Note D.3. to the consolidated financial statements) in increasing capacity and improving productivity at our various production and R&D sites.

The Group s principal capital expenditures and divestments for, 2009, 2010, and 2011 are set out in this annual report at Item 5. Operating and Financial Review and Prospects Divestments , Acquisitions and Liquidity and Capital Resources and in Note D.1., Note D.2., Note D.3. and Note D.4. to our consolidated financial statements included at Item 18 of this annual report.

Our principal investments in progress are described below:

Pharmaceuticals Segment

In Europe, we continued to optimize our industrial facilities, in particular by investing in two new Lantus® production lines at the Frankfurt site and acquiring the Diabel manufacturing site from Pfizer to strengthen our insulin production capacity. We invested in the Brindisi (Italy) site to expand its production of spiramycin, the active ingredient of the antibiotic Rovamycin®. In the United States, we are investing ahead of the launch of epiCard, a gas powered single dose, single use auto-injector with audible user instructions for the injection of epinephrine, indicated for the emergency treatment of severe allergic reactions.

We have also begun the Biolaunch project, designed to convert our chemical facilities to biotechnologies, with a project to create a monoclonal antibody production facility at our Vitry-sur-Seine site in France from 2012, plus investments in the creation of a new innovative biosynthetic process at the Saint-Aubin-Lès-Elbeuf and Vertolaye industrial sites, in order to improve our corticosteroid production competitiveness at a global level.

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In Emerging Markets, we currently rely on industrial sites dedicated to serving regional markets, a situation reinforced by our 2009 acquisitions (Zentiva in Eastern Europe and Medley in Brazil). In China, the project to extend our current manufacturing facility located at the Beijing Economic and Technological Development Area enables us to install assembly and packaging lines for SoloSTAR®, the pre-filled injection pen used to administer Lantus® (insulin glargine). In Hangzhou (China), we are building a new manufacturing site to replace the current manufacturing facility in downtown Hangzhou. The new site is scheduled to be completed in 2012. In Russia, the Orel insulin factory, acquired following the deal with Bioton Vostok, is a key element of our strategy to improve and accelerate our access to the fast-growing Russian market. In the Middle East, Sanofi entered into an agreement with the King Abdullah Economic City to build a manufacturing facility for solid-dose form pharmaceuticals in Saudi Arabia. In Latin America, where Sanofi already has a broad industrial platform, the Group is building a plant in Brazilia to be dedicated to hormonal products.

Genzyme s industrial investments include the expansion of Myozyme® production capacity in Geel (Belgium), Fabrazyme® in Framingham (United States), Thymoglobulin® in Lyon (France) and for filling operations in Waterford (Ireland). Also, in the United States, a new laboratory and office spaces have been built in Framingham and the distribution center in Northborough has been expanded.

Vaccines Segment (Sanofi Pasteur)

Our Vaccines business has invested significantly in recent years, with the construction of a state-of-the-art research facility in Toronto (Canada); the creation of a new vaccines campus in Neuville (France); the construction of bulk and filling facilities in Val de Reuil (France) and a bacteriological bulk facility in Marcy l Étoile (France); the creation of two new influenza vaccine facilities in Shenzhen (China) and Ocoyoacac (Mexico); and the completion of bulk and filling facilities in Swiftwater (United States), mainly dedicated to influenza and meningitis vaccines.

Animal Health Segment (Merial)

A significant proportion of the investment in Europe over the last several years has been allocated to transferring Lyon Gerland s vaccine production operations to the new Saint Priest site. In Toulouse, Merial adapted its production capacity to the arrival of new products. Merial invested in a packaging line for Certifect® production (managed according to the Good Manufacturing Practices applicable in the European Union, and approved by the Environmental Protection Agency in the United States) and an injectible facility for Zactran® production. In 2009, Merial acquired a site to produce vaccines against foot-and-mouth disease in Lelystad, Netherlands, which thereby granted Merial two foot-and-mouth vaccine production licenses of the three in existence in Europe.

In the United States, Merial has invested significantly in Athens, Georgia in a pharmaceutical form unit in an effort to increase its capacity to meet the growing number of products.

In Emerging Markets, Merial invested in China to transfer an existing site to a new production site located in Nanchang s high-tech development zone, in order to support future growth of avian and other species vaccines. In addition, Merial invested in a R&D laboratory in Shanghai in order to facilitate local vaccine development in China.

As of December 31, 2011, our firm orders related to future capital expenditure amounted to 292 million. They were mainly related to the following industrial sites: Frankfurt (Germany) and Elbeuf (France) for the Pharmaceuticals segment, Swiftwater (United States) and Neuville (France) for the Vaccines segment, and the La Boétie site (the Group s corporate headquarters in France).

In the medium term and on a constant structure basis, we expect our yearly average capital expenditure to be in the range of 1.7 billion. We believe that our existing cash resources and unused credit facilities will be sufficient to finance these investments.

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Office Space

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

This review is expected to result in all our Group support functions and operating divisions being housed on a smaller number of sites (five in 2012, when phase 1 is implemented). All of these sites will meet environmental certification standards, and offer cost-effective space solutions.

Closing of the property located in Gentilly, Val de Bièvre marked the 2011 step in this Master Plan.

Preparing our new global corporate headquarters in first quarter 2012 on the Rue La Boétie, in the 8th *arrondissement* of Paris, at the heart of the city s business district will bring all our Group support functions together within a single site, symbolizing the transformation of the Group.

Finally, our former corporate headquarters at 174 avenue de France in the 13th *arrondissement* of Paris will be closed in 2012, along with the adjacent site at 182 avenue de France.

The second phase of the Greater Paris office space master plan is currently under consideration, the aim being to reduce the overall area in use and the overall cost of operation.

A second Master Plan was initiated in late 2011 to outline the Group s medium-term office space needs for the greater Lyon area.

A project was launched to integrate office sites from the property portfolio of Genzyme and Merial, and represents a presence in 50 countries and 540,000 m^2.

Item 4A. Unresolved Staff Comments

N/A

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Item 5. Operating and Financial Review and Prospects

You should read the following discussion in conjunction with our consolidated financial statements and the notes thereto included in this annual report at Item 18.

Our consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and with IFRS adopted by the European Union as of December 31, 2011.

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.

2011 Overview

In 2011, the Group, which changed its name to Sanofi following the May 2011 General Meeting of Shareholders, continued to implement its transforming and sustainable growth strategy through the year. Sanofi acquired Genzyme Corporation (Genzyme), a leading American biotechnology company specializing in rare diseases with operations in the areas of renal diseases, endocrinology, oncology, biosurgery, and multiple sclerosis. Despite competition from generics and their impact on the sales of some of our flagship products, as well as the absence of sales of pandemic Influenza A/H1N1 vaccines in 2011, our continuing efforts to establish growth platforms have helped the Group to improve its position in Emerging Markets, Diabetes, Vaccines, Consumer Health Care, and Animal Health. Sanofi has shown resilience in terms of net sales and profitability.

The Group s net sales for the year totaled 33,389 million, up 3.2% compared to 2010 (5.3% at constant exchange rates (see definition at Presentation of Net Sales below), buoyed by the solid performance of its growth platforms, Emerging Markets, Diabetes, Vaccines, Consumer Health Care, and Animal Health, as well as the consolidation of Genzyme (2,395 million in net sales from early April 2011), and this is despite significant competition from generics, which based on 2010 sales at constant exchange rates represented a 2.2 billion loss in net sales (see Impacts from generic competition below). In terms of organic growth developments, 2011 was especially marked by the launch of the cancer drug Jevtana® in the European Union, the approval of Allegra® for over-the-counter use in the United States, FDA approval of the influenza vaccine Fluzone® ID in the United States, and launch of Certifect® for animal health in the United States.

By continuing to adapt its resources, the Group has managed to reduce its R&D costs and its selling and general expenses by 2.4% and 2.6%, respectively (at constant exchange rates, excluding Genzyme). Business net income totaled 8,795 million, down 4.6% compared to 2010 on a reported basis, caused by the competition from generics and the absence of pandemic influenza A/H1N1 vaccine sales. Business earnings per share was 6.65, down 5.8% compared with 2010. 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 totaled 5,693 million, 4.1% higher than in 2010. Basic earnings per share for 2011 were 4.31, 2.9% higher than in 2010; diluted earnings per share for 2011 were 4.29 (2.6% higher).

Sanofi continued to pursue its strategy of targeted acquisitions and R&D partnerships. The acquisition of Genzyme in April 2011 has been described above. In Consumer Health Care, the Group successfully completed its acquisition of BMP Sunstone in China. In Animal Health, 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 activities. In addition, partnership and licensing agreements have enabled the Group to expand and to further develop its existing areas of research.

In September 2011, the Group announced new objectives for the 2012-2015 period based on three initiatives: improvement of growth platforms, maintenance of tight cost-control, and advances in transforming R&D. While we remain focused on these objectives, we expect erosion from generic competition to continue, with a negative impact on net income in 2012 (see Impacts from generic competition below).

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Our operations generate significant cash flow. We recorded 9,319 million of net cash provided by operating activities in 2011 compared to 9,859 million in 2010. During the course of 2011, we paid out 1.4 billion in dividends and contracted new debt of $18.0 billion to finance the Genzyme acquisition. With respect to our financial position, we ended 2011 with our debt, net of cash and cash equivalents (meaning the sum of short-term and long-term debt plus related interest rate and currency derivatives, minus cash and cash equivalents) at 10,859 million (2010: 1,577 million). Debt, net of cash and cash equivalents, is a non-GAAP financial measure that is used by management and investors to measure the Company s overall net indebtedness and to assess the Company s financing risk as measured by its gearing ratio (debt, net of cash and cash equivalents, to total equity). Our gearing ratio was 19.3% at the end of 2011 versus 3.0% at the end of 2010. See Liquidity and Capital Resources Consolidated Balance Sheet and Debt below and Note D.17. to our consolidated financial statements included at Item 18 of this annual report.

Impacts from generic competition

Our flagship products experienced sales erosion in 2011 due to generic competition. While it is not possible to state with certainty what sales levels would have been achieved in the absence of generic competition, it is possible to estimate the sales impact of generic competition for each product.

By comparing 2011 and 2010 net sales figures included at Results of Operations Year Ended December 31, 2011 Compared with Year Ended December 31, 2010 , competition from generics represented a 2.2 billion loss in net sales in 2011 (at constant exchange rates), or 2.3 billion on a reported basis. The table below presents the detailed impact by product.

(million)	**2011**	**2010**	**Change on a**	**Change on a reported basis**
Product	**Reported**	**Reported**	**reported basis**	**(%)**
Plavix® Western Europe	414	641	(227)	-35.4%
Aprovel® Western Europe	753	825	(72)	-8.7%
Taxotere® Western Europe	189	709	(520)	-73.3%
Allegra® U.S.	3	147	(144)	-98.0%
Eloxatin® U.S.	806	172	+634	+368.6%
Lovenox® U.S.	633	1,439	(806)	-56.0%
Xyzal® U.S.	13	127	(114)	-89.8%
Ambien® U.S.	82	443	(361)	-81.5%
Xatral® U.S.	75	155	(80)	-51.6%
Nasacort® U.S.	54	130	(76)	-58.5%
Taxotere® U.S.	243	786	(543)	-69.1%
Total	**3,265**	**5,574**	**(2,309)**	**-41.4%**

We expect erosion from generic competition to continue in 2012, with a negative impact on net income. The following products are expected to be impacted by generics in 2012:

products for which new generic competition can reasonably be expected in 2012 based on the expiration dates or patent or other regulatory exclusivity: Plavix® and Avapro® in the U.S (sales not consolidated by Sanofi), Myslee® in Japan, and possibly Allegra® in Japan in the second half of the year provided that the generic manufacturers get marketing approval;

products for which generics competition started during 2011, and for which generic competition should continue in 2012: Taxotere®, Xatral® and Nasacort® in the U.S.; and Aprovel® in Western Europe;

products which already faced generic competition as of January 1, 2011, but for which 2012 sales can reasonably be expected to be further eroded: Plavix®, Eloxatin® and Taxotere® in Europe; and Lovenox®, Ambien®, Xyzal® and Eloxatin® in the U.S;

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A special case is Eloxatin® in the U.S., which was subject to generic competition for part of 2010 until a court ruling prevented further sales of unauthorized generics from June 2010 till August 9, 2012. Wholesalers worked down their inventories of generic products in the second half of 2010 and in the first half of 2011.

Aggregate 2011 consolidated net sales generated by all the products in the specific countries where generic competition exists or is expected in 2012, excluding Plavix® and Avapro® in the U.S., totaled 4,014 million, including 1,909 million in the U.S., 1,356 million in Europe and 749 million (Allegra® and Myslee®) in Japan. The negative impact on our 2012 net sales could be estimated to potentially represent a substantial part of these sales but will depend on a number of factors, such as actual launch dates of generics products in 2012, selling prices of such products, and potential litigation outcomes.

In addition, the loss of Plavix® and Avapro® exclusivity in the U.S. in 2012 is anticipated to impact our 2012 net income by around 1.4 billion compared to 2011. Net sales for Plavix® and Avapro® in the U.S. are not consolidated by Sanofi, however they impact Sanofi s net income (see Financial Presentation of Alliances Alliance Arrangements with Bristol-Myers Squibb below).

Purchase Accounting Effects

Our results of operations and financial condition for the years ended December 31, 2011, December 31, 2010 and December 31, 2009 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 (1,788 million in 2011, 3,070 million in 2010, and 3,175 million in 2009) and impairment of intangible assets (reversal of 34 million in 2011 and charges of 127 million in 2010 and 344 million in 2009). The Genzyme acquisition has given rise to new amortization of intangible assets in 2011 (709 million).

In order to isolate the impact of these and certain other items, we use as an evaluation tool 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. For consistency of application of this principle, business net income also takes into account the impact of our subsequent acquisitions.

Business net income for the years ended December 31, 2011, 2010 and 2009 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.

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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 activities relating to pharmaceutical products, 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 with pharmaceutical business activities, 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 includes 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), and 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 accordance 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 Restructuring costs, Fair value remeasurement of contingent consideration liabilities and Other gains and losses, and litigation are eliminated;
- amortization and impairment losses charged against intangible assets (other than software) are eliminated;
- the share of profits/losses from 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.

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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 [1]	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**

[1] *The results of operations of Merial, which was previously reported as a business held for exchange, have been reclassified and included in net results of continuing operations in accordance with paragraph 36 of IFRS 5, following the announcement that Merial and Intervet/Schering-Plough are to be maintained as two separated businesses operating independently (see Note D.2. to our consolidated financial statements included at Item 18 of this annual report).*

The following table presents our Business Operating Income for the year ended December 31, 2009.

(million)	Pharmaceuticals	Vaccines	Animal Health [1]	Other	Total
Net sales	**25,823**	**3,483**	**479**		**29,785**
Other revenues	1,412	31	4		1,447
Cost of sales	(6,527)	(1,326)	(176)		(8,029)
Research and development expenses	(4,091)	(491)	(46)		(4,628)
Selling and general expenses	(6,762)	(561)	(146)	(2)	(7,471)
Other operating income and expenses	387	(3)	(5)	1	380
Share of profit/(loss) of associates and joint ventures	792	41	178 [2]	8	1,019
Net income attributable to non-controlling interests	(426)	(1)			(427)
Business operating income	**10,608**	**1,173**	**288**	**7**	**12,076**

(1) *The results of operations of Merial, previously reported as a business held for exchange, have been reclassified and included in net results of continuing operations in accordance with paragraph 36 of IFRS 5, following the announcement that Merial and Intervet/Schering-Plough are to be maintained as two separated businesses operating independently (see Note D.2. to our consolidated financial statements included at Item 18 of this annual report).*

(2) *Including Merial until September 17, 2009.*

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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 charges. 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 in 2010 and starting September 18, 2009 (in accordance with IFRS 5); (viii) the tax effect related to the items listed in (i) through (vii); as well as (ix) the 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 (iii), (v) and (vi) correspond to those reported in the income statement line items Restructuring costs , Fair value remeasurement of contingent consideration liabilities , and Other gains and losses, and litigation , as defined in Notes B.19. and B.20. to our consolidated financial statements.

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The following table reconciles our business net income to Net income attributable to equity holders of Sanofi for the years ended December 31, 2011, 2010 and 2009:

(million)		2011	2010 [1]	2009 [1]
Business net income		**8,795**	**9,215**	**8,629**
(i)	Amortization of intangible assets	(3,314)	(3,529)	(3,528)
(ii)	Impairment of intangible assets	(142)	(433)	(372)
(iii)	Fair value remeasurement of contingent consideration liabilities	15		
(iv)	Expenses arising from the impact of acquisitions on inventories [2]	(476)	(142)	(90)
(v)	Restructuring costs	(1,314)	(1,384)	(1,080)
(vi)	Other gains and losses, and litigation [3]	(327)	(138)	
(vii)	Impact of the non-depreciation of the property, plant and equipment of Merial (IFRS 5)		77	21
(viii)	Tax effects on the items listed above, comprising:	1,905	1,856	1,644
	amortization of intangible assets	*1,178*	*1,183*	*1,130*
	impairment of intangible assets	*37*	*143*	*136*
	fair value remeasurement of contingent consideration liabilities	*34*		
	expenses arising from the impact of acquisitions on inventories	*143*	*44*	*24*
	restructuring costs	*399*	*466*	*360*
	other gains and losses, and litigation	*114*	*46*	
	non-depreciation of property, plant and equipment of Merial (IFRS 5)		*(26)*	*(6)*
(iv)/(ix)	Other tax items [4]	577		106
(x)	Share of items listed above attributable to non-controlling interests	6	3	1
(iv)/(v)	Restructuring costs and expenses arising from the impact of acquisitions on associates and joint ventures [5]	(32)	(58)	(66)
Net income attributable to equity holders of Sanofi		**5,693**	**5,467**	**5,265**

[1] *The results of operations of Merial, previously reported as a business held for exchange, have been reclassified and included in net results of continuing operations in accordance with paragraph 36 of IFRS 5, following the announcement that Merial and Intervet/Schering-Plough are to be maintained as two separate businesses operating independently (see Notes D.2. and D.8.1. to our consolidated financial statements included at Item 18 of this annual report).*

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

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

[4] *In 2011, related to Advance Pricing Agreement impact for 349 million and 228 million reflecting a decrease in deferred tax liabilities related to the remeasurement of intangible assets following changes in tax laws. In 2009: reversal of deferred taxes following ratification of the Franco-American Treaty.*

[5] *This line shows the portion of major restructuring costs incurred by associates and joint ventures, and expenses arising from the impact of acquisitions on associates and joint ventures (workdown of acquired inventories, amortization and impairment of intangible assets, and impairment of goodwill).*

The 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 that was written up to 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.

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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, which represented 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 years and a half) 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.

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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 2011, 2010 and 2009. 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, 2011 Compared with Year Ended December 31, 2010 Net Sales and at Results of Operations Year Ended December 31, 2010 Compared with Year Ended December 31, 2009 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, 2011 Compared with Year Ended December 31, 2010 and Year Ended December 31, 2010 Compared with Year Ended December 31, 2009 , in particular in Net sales , Other Revenues , Share of Profit/Loss of Associates and Joint Ventures and Net Income Attributable to Non-Controlling Interests .

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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.

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 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, 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.

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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 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

S*anofi 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.

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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 2011, we earned 29.8% 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

On December 19, 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 or 2009.

Acquisitions

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. In 2011, Genzyme generated full-year net sales of 3.1 billion, out of which 2.4 billion were consolidated by Sanofi as from the acquisition date. 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. Total purchase price amounted to 14.8 billion. The provisional purchase price allocation is disclosed in Note D.1.1. 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 neutraceuticals 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

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innovative biotechnology company, focusing on proprietary genomic technology to discover drugs of natural origin. Under the terms of the agreement, Sanofi and TRV / Greylock will invest 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. 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. 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.

The principal acquisitions during 2009 are described below:

On September 17, 2009, and further to the agreement signed on July 29, 2009, Sanofi completed the acquisition of the interest held by Merck & Co., Inc. (Merck) in Merial Limited (Merial) for consideration of $4 billion in cash. Founded in 1997, Merial was previously held jointly (50/50) by Merck and Sanofi. Merial is one of the world s leading animal health companies, with annual sales of $2.6 billion in 2009 and 2010. With effect from September 17, 2009, Sanofi has held 100% of the shares of Merial and has exercised exclusive control over the company.

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In connection with the agreement signed on July 29, 2009, Sanofi had also signed an option contract giving it the possibility, once the Merck/Schering-Plough merger would be complete, to combine the Merck-owned Intervet/Schering-Plough Animal Health business with Merial in a joint venture to be held 50/50 by Merck and Sanofi. Because of the high probability of the option being exercised as of year-end 2009 and 2010, Merial was treated as an asset held for sale or exchange pursuant to IFRS 5 as of December 31, 2009 and December 31, 2010. On March 8, 2010, Sanofi exercised its contractual right to combine the Intervet/Schering-Plough Animal Health business with Merial. However, on March 22, 2011, Merck and Sanofi announced that they had mutually terminated their agreement to form a new animal health joint venture and decided to maintain Merial and Intervet/Schering-Plough as two separate entities, operating independently. This decision was mainly due to the increasing complexity of implementing the proposed transaction. Starting from January 1, 2011, Merial is no longer accounted for separately on the consolidated balance sheet and income statements of Sanofi. Detailed information about the impact of Merial on the consolidated financial statements of Sanofi as of December 31, 2011 is provided in Note D.2. and Note D.8.1. to our consolidated financial statements included at Item 18 of this annual report.

In March 2009, Sanofi successfully closed its offer for Zentiva N.V. (Zentiva). As of December 31, 2009, Sanofi held about 99.1% of Zentiva s share capital. Following the buyout of the remaining non-controlling interests, Sanofi held 100% of Zentiva s share capital as of December 31, 2010. The purchase price was 1,200 million, including acquisition-related costs.

In March 2009, Sanofi acquired Laboratorios Kendrick, one of Mexico s leading manufacturers of generics, with sales of approximately 26 million in 2008.

In April 2009, Sanofi acquired a 100% equity interest in Medley, the third largest pharmaceutical company in Brazil and a leading generics company in that country. The purchase price was 348 million inclusive of acquisition-related costs.

In April 2009 Sanofi acquired 100% of BiPar Sciences, Inc. (BiPar), a U.S. biopharmaceutical company developing novel tumor-selective approaches for the treatment of different types of cancers. The purchase price was in large part contingent on the achievement (regarded as probable) of milestones related to the development of BSI-201, and could reach $500 million. See Note D.18. to our consolidated financial statements included at Item 18 of this annual report.

In July 2009, Sanofi completed the acquisition of 100% of the share capital of Helvepharm, a Swiss generics company.

In August 2009, Sanofi took control of Shantha Biotechnics (Shantha), a vaccines company based in Hyderabad (India). As of December 31, 2010, Sanofi held approximately 96.4% of Shantha. The purchase price allocation led to the recognition of intangible assets (excluding goodwill) worth 374 million. This amount includes the acquisitions-date value of the Shan5 pentavalent vaccine, which was partially written down in 2010 (see Note D.5. to our consolidated financial statements included at Item 18 of this annual report).

In October 2009, Sanofi acquired 100% of the share capital of Fovea Pharmaceuticals SA, a privately-held French biopharmaceutical research and development company specializing in ophthalmology. The purchase consideration included contingent milestone payments of up to 280 million linked to the development of three products. See Notes D.1. and D.18. to our consolidated financial statements included at Item 18 of this annual report.

In November 2009, Sanofi completed the acquisition of 100% of the share capital of Laboratoire Oenobiol, one of France s leading players in health and beauty dietary supplements.

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Results of Operations

Year Ended December 31, 2011 Compared with Year Ended December 31, 2010

The consolidated income statements for the years ended December 31, 2011 and December 31, 2010 break down as follows:

(under IFRS)		**as % of**		**as % of**
(million)	**2011**	**net sales**	**2010 [1]**	**net sales**
Net sales	**33,389**	**100.0%**	**32,367**	**100.0%**
Other revenues	1,669	5.0%	1,669	5.2%
Cost of sales	(10,902)	(32.7%)	(9,398)	(29.0%)
Gross profit	**24,156**	**72.3%**	**24,638**	**76.1%**
Research & development expenses	(4,811)	(14.4%)	(4,547)	(14.0%)
Selling & general expenses	(8,536)	(25.6%)	(8,149)	(25.2%)
Other operating income	319		369	
Other operating expenses	(315)		(292)	
Amortization of intangible assets	(3,314)		(3,529)	
Impairment of intangible assets	(142)		(433)	
Fair value remeasurement of contingent consideration liabilities	15			
Restructuring costs	(1,314)		(1,384)	
Other gains and losses, and litigation [2]	(327)		(138)	
Operating income	**5,731**	**17.2%**	**6,535**	**20.2%**
Financial expenses	(552)		(468)	
Financial income	140		106	
Income before tax and associates and joint ventures	**5,319**	**15.9%**	**6,173**	**19.1%**
Income tax expense	(455)		(1,430)	
Share of profit/(loss) of associates and joint ventures	1 070		978	
Net income	**5,934**	**17.8%**	**5,721**	**17.7%**
Net income attributable to non-controlling interests	241		254	
Net income attributable to equity holders of Sanofi	**5,693**	**17.1%**	**5,467**	**16.9%**
Average number of shares outstanding (million)	1,321.7		1,305.3	
Average number of shares outstanding after dilution (million)	1,326.7		1,308.2	
Basic earnings per share (in euros)	4.31		4.19	
Diluted earnings per share (in euros)	4.29		4.18	

[1] *The results of operations of Merial, previously reported as a business held for exchange, have been reclassified and included in net results of continuing operations in accordance with IFRS 5.36., following the announcement that Merial and Intervet/Schering-Plough will be maintained as separate businesses operating independently (see Note D.2. to our consolidated financial statements included at Item 18 of this annual report).*

[2] *See Note B.20.2. to our consolidated financial statements included at Item 18 of this annual report.*

Net Sales

Net sales for the year ended December 31, 2011 totaled 33,389 million, up 3.2% on 2010. The unfavorable currency fluctuation of 2.1 points was primarily the result of the U.S. dollar s depreciation against the euro. At constant exchange rates, and after taking account of changes in structure (mainly the consolidation of Genzyme from April 2011), net sales were up 5.3% year-on-year.

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Excluding Genzyme, the Group s net sales were down 2.6% in 2011 at constant exchange rates, a reflection of the loss in sales associated with competition from generics and the impacts of austerity measures in the European Union. Excluding both Genzyme and sales of A/H1N1 vaccines, the Group s net sales were down 1.2% at constant exchange rates.

The following table sets forth a reconciliation of our reported net sales for the years ended December 31, 2011 and December 31, 2010 to our net sales at constant exchange rates:

			Change
(*million)*	**2011**	**2010** [(1)]	**(%)**
Net sales	**33,389**	**32,367**	**+3.2%**
Effect of exchange rates	704		
Net sales at constant exchange rates	**34,093**	**32,367**	**+5.3%**

[(1)] *Net sales of Merial are included. See Note D.2. to our consolidated financial statements included at Item 18 of this annual report.*

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

The following table breaks down our 2011 and 2010 net sales by business segment:

				Change at constant
	2011	**2010**	**Change on a reported basis**	**exchange rates**
(*million)*	**Reported**	**Reported**	**(%)**	**(%)**
Pharmaceuticals	27,890	26,576	+4.9%	+6.7%
Vaccines	3,469	3,808	-8.9%	-5.5%
Animal Health	2,030	1,983	+2.4%	+4.3%
Total	**33,389**	**32,367**	**+3.2%**	**+5.3%**

Net Sales by Product Pharmaceuticals

Net sales generated by our Pharmaceuticals segment were 27,890 million in 2011, up 4.9% on a reported basis and 6.7% at constant exchange rates. This change reflects the positive impact from the Genzyme consolidation, the negative impact from the competition of generics on sales of Lovenox®, Ambien® CR and Taxotere® in the United States, Plavix® and Taxotere® in the European Union, as well as the effects of healthcare reform in the U.S. and austerity measures in Europe. Excluding Genzyme, our Pharmaceuticals segment posted net sales of 25,495 million, a drop of 4.1% on a reported basis and 2.7% at constant exchange rates.

Flagship Products

Our flagship products (Lantus® and other products in the Diabetes business, Lovenox®, Plavix®, Taxotere®, Aprovel®/CoAprovel®, Eloxatin®, Multaq® and Jevtana®) are discussed below. Sales of Plavix® and Aprovel® are discussed further below under Worldwide Presence of Plavix® and Aprovel® .

Net sales in the Diabetes business were 4,684 million, up 12.0% at constant exchange rates, bolstered by the growth of Lantus®.

Lantus®, the world s leading diabetes brand (source: IMS 2011 sales), posted a 15.0% increase in net sales at constant exchange rates in 2011 to 3,916 million. This change is a result of the sharp growth in Emerging Markets (26.0% at constant exchange rates), especially in China (61.7%) and Brazil (29%), as well as solid performance in the United States (14.6%) and Japan (19.5%). In Western Europe, growth was more moderate (6.4%), which reflected the pricing pressures specifically in Germany.

Net sales of the rapid-acting insulin analog **Apidra®** advanced by 9.6% at constant exchange rates in 2011 to 190 million, led by solid performances in Japan (87.9% growth) and the United States (11.3% growth). At year-end, sales were impacted negatively by a temporary shortage of Apidra® 3ml cartridges.

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Amaryl® saw net sales decrease by 7.9% at constant exchange rates in 2011 to 436 million, due principally to competition from generics in Japan, and despite an 8.6% increase (at constant exchange rates) in Emerging Markets.

Lovenox® saw net sales decrease by 23.4% at constant exchange rates in 2011 to 2,111 million, a result of competition from generics in the United States where net sales declined by 54.3% to 633 million. Outside the United States, net sales were up 9.0% at constant exchange rates, to 1,478 million (representing 70.0% of worldwide 2011 sales of Lovenox®), posting good performances in Western Europe (up 6.4%) and Emerging Markets (up 14.0%).

Taxotere® reported net sales of 922 million, down 57.0% at constant exchange rates. This product has faced competition from generics in Western Europe (down 73.6%) and the United States (down 69.2%), although the decline was much less pronounced in Emerging Markets (down 24.6%).

Eloxatin® net sales rebounded sharply in 2011 by 160.9% at constant exchange rates to 1,071 million, which reflects recovering sales in the United States (806 million in 2011, versus 172 million in 2010), following a court ruling barring manufacturers of generics in the U.S. from selling their unapproved generic versions of oxaliplatin from June 30, 2010.

Multaq® posted a 56.4% growth in net sales to 261 million at constant exchange rates, achieved primarily in the United States (184 million) and Western Europe (66 million).

Jevtana®, which has been available in the U.S. market since July 2010, and has become gradually available throughout most of the countries of Western Europe since April 2011, registered 188 million in sales in 2011, 131 million of which was in the United Sates.

Our other major products are described below.

Net sales of the hypnotic **Stilnox®/Ambien®/Myslee®** fell by 41.4% at constant exchange rates to 490 million, reflecting competition from Ambien® CR generics in the United States. In Japan, Myslee® continued to post a solid performance with net sales up 9.2% at constant exchange rates at 284 million.

Allegra® prescription sales were down 8.6% (at constant exchange rates) to 580 million. In Japan, which represents 80.2% of Allegra® s worldwide sales, net sales totaled 465 million (up 22.1% at constant exchange rates) with the sharp increase in seasonal allergies. A generic has been approved but not yet distributed in Japan. The drop in prescription sales in the United States (98.6% at constant exchange rates) is related to the approval of Allegra® as an over-the-counter (OTC) product starting in March 2011 on the U.S. market. Following this approval, we account for U.S. sales of Allegra® under CHC and not prescription sales.

Copaxone® net sales, achieved primarily in Western Europe, fell by 15.4% at constant exchange rates to 436 million, a reflection of the end of the co-promotion agreement with Teva for certain countries, specifically since the end of 2010 in the UK and the end of 2011 in Germany.

The **Consumer Health Care** business posted year-on-year growth of 22.8% at constant exchange rates to 2,666 million, supported by the successful launch of Allegra® as an over-the-counter product in the U.S. in the first quarter of 2011, generating 211 million in net sales for the year (out of a worldwide total of 245 million), and by the performance of Emerging Markets in which net sales have increased by 20.8% at constant exchange rates to 1,225 million. These figures consolidated the consumer health products of Chattem in the United States as of February 2010, and of BMP Sunstone in China as of February 2011.

The **Generics** business reported net sales of 1,746 million in 2011, up 16.2% at constant exchange rates. This growth was underpinned by sales in Emerging Markets (1,092 million, up 14.0% at constant exchange rates), especially in Latin America (up 21.4% at constant exchange rates), and the United States (up 79.4% at constant exchange rates) where Sanofi launched its own approved generics of Ambien® CR, Taxotere® and Lovenox®.

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Net sales of **Genzyme** products in 2011 (since the acquisition date beginning of April) were up 7.7% on a constant structure basis and at constant exchange rates, to 2,395 million. Net sales are recognized as from the acquisition date and comparisons are with the net sales reported by Genzyme in 2010 for the same period.

Net sales of **Cerezyme®** were up 11.1% (on a constant structure basis and at constant exchange rates) to 441 million, which reflects the higher production in 2011 following a reduction in availability of the product in 2010 due to manufacturing issues. **Myozyme®/Lumizyme®** posted sharp growth (27.4% on a constant structure basis and at constant exchange rates, to 308 million), bolstered mainly by the performance of Lumizyme® in the United States and volume growth worldwide. Growth in **Fabrazyme®** sales (9.4% on a constant structure basis and at constant exchange rates, to 109 million) was sparked by the increase in the product s availability following on-going resolution of manufacturing issues. For more information regarding the manufacturing issues related to Cerezyme® and Fabrazyme® see Item 4 Information on the Company Production and Raw Materials.

Renagel®/Renvela ® posted net sales of 415 million, up 10.2% on a constant structure basis and at constant exchange rates, associated with growth in the market share in the U.S.

Net sales of **Synvisc®** totaled 256 million (up 14.7% on a constant structure basis and at constant exchange rates), supported by the solid performance of **Synvisc One®** in the U.S. and Japan.

Net sales of the other products in the portfolio were down 3.4% at constant exchange rates, to 5,773 million. For a description of our other pharmaceutical products, see Item 4. Information on the Company B. Business Overview Pharmaceutical Products.

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The following table breaks down our 2011 and 2010 net sales for the Pharmaceuticals business by product:

(million)		2011	2010	Change on a reported basis (%)	Change at constant exchange rates (%)
Product	**Indication**	**Reported**	**Reported**		
Lantus®	Diabetes	3,916	3,510	+11.6%	+15.0%
Apidra®	Diabetes	190	177	+7.3%	+9.6%
Insuman®	Diabetes	132	133	-0.8%	-0.8%
Amaryl®	Diabetes	436	478	-8.8%	-7.9%
Other products	Diabetes	10			
Sub-total: Diabetes		**4,684**	**4,298**	**+9.0%**	**+12.0%**
Lovenox®	Thrombosis	2,111	2,806	-24.8%	-23.4%
Plavix®	Atherothrombosis	2,040	2,083	-2.1%	-2.9%
Taxotere®	Breast, lung, prostate, stomach, and head & neck cancer	922	2,122	-56.6%	-57.0%
Aprovel®/CoAprovel ®	Hypertension	1,291	1,327	-2.7%	-2.4%
Eloxatin®	Colorectal cancer	1,071	427	+150.8%	+160.9%
Multaq®	Atrial fibrillation	261	172	+51.7%	+56.4%
Jevtana®	Prostate cancer	188	82	+129.3%	+135.4%
Stilnox®/Ambien ® / Myslee®	Sleep disorders	490	819	-40.2%	-41.4%
Allegra®	Allergic rhinitis, urticaria	580	607	-4.4%	-8.6%
Copaxone®	Multiple sclerosis	436	513	-15.0%	-15.4%
Tritace®	Hypertension	375	410	-8.5%	-6.3%
Depakine®	Epilepsy	388	372	+4.3%	+5.4%
Xatral®	Benign prostatic hypertrophy	200	296	-32.4%	-30.7%
Actonel®	Osteoporosis, Paget s disease	167	238	-29.8%	-29.8%
Nasacort®	Allergic rhinitis	106	189	-43.9%	-41.8%
Other products		**5,773**	**6,064**	**-4.8%**	**-3.4%**
Consumer Health Care		**2,666**	**2,217**	**+20.3%**	**+22.8%**
Generics		**1,746**	**1,534**	**+13.8%**	**+16.2%**
Genzyme		**2,395**			
Total pharmaceuticals		**27,890**	**26,576**	**+4.9%**	**+6.7%**

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The following table breaks down our 2011 and 2010 net sales for the products acquired with Genzyme:

(million)		2011	2010	Change on a constant structure basis and at constant exchange rates
Product	**Indication**	**Reported**	**Reported**	**(%)**
Cerezyme®	Gaucher disease	441		+11.1%
Myozyme®/Lumizyme®	Pompe disease	308		+27.4%
Fabrazyme®	Fabry disease	109		+9.4%
Renagel®/Renvela®	Hyperphosphatembosis	415		+10.2%
Synvisc®	Atherothrombosis	256		+14.7%
Other Genzyme products		866		-2.2%
Total Genzyme		**2,395**		**+7.7%**

The following table breaks down net sales of our Pharmaceutical business products by geographical region in 2011:

(million)	Western	Change at constant exchange	United	Change at constant exchange	Emerging	Change at constant exchange	Other	Change at constant exchange
Product	**Europe (1)**	**rates**	**States**	**rates**	**Markets (2)**	**rates**	**countries (3)**	**rates**
Lantus®	730	+6.4%	2,336	+14.6%	617	+26.0%	233	+22.3%
Apidra®	68	0.0%	65	+11.3%	37	+8.6%	20	+58.3%
Insuman®	103	-4.6%			29	+20.0%		
Amaryl®	32	-23.8%	4	-33.3%	228	+8.6%	172	-21.6%
Other products	10							
Sub-total: Diabetes	**943**	**+4.3%**	**2,405**	**+14.4%**	**911**	**+20.1%**	**425**	**+0.5%**
Lovenox®	833	+6.4%	633	-54.3%	551	+14.0%	94	+3.5%
Plavix®	414	-35.6%	196*	-8.0%	706	+11.9%	724	+18.6%
Taxotere®	189	-73.6%	243	-69.2%	294	-24.6%	196	-20.2
Aprovel®/CoAprovel®	753	-9.1%	49*	+25.6%	363	+6.7%	126	+8.6%
Eloxatin®	38	-19.6%	806	+393.0%	162	+9.3%	65	+10.2%
Multaq®	66	+66.7%	184	+50.8%	7	+250.0%	4	+33.3%
Jevtana®	44		131	+65.9%	13			
Stilnox®/Ambien® /Myslee®	53	-3.6%	82	-80.6%	65	-1.5%	290	+8.3%
Allegra®	13	-18.8%	3	-98.6%	99	+19.3%	465	+22.2%
Copaxone®	415	-14.1%				-100.0%	21	+11.1%
Tritace®	170	-10.1%			181	0.0%	24	-23.3%
Depakine®	145	-2.0%			227	+11.5%	16	-6.7%
Xatral®	58	-12.1%	75	-49.7%	63	-7.1%	4	-20.0%
Actonel®	54	-48.1%			78	-12.9%	35	-22.0%
Nasacort®	25	-10.7%	54	-57.7%	23	0.0%	4	-20.0%
Other products	**2,417**	**-8.9%**	**497**	**-19.9%**	**2,106**	**+7.4%**	**753**	**+1.4%**
Consumer Health Care	**651**	**+3.2%**	**549**	**+80.0%**	**1,225**	**+20.8%**	**241**	**+5.1%**
Generics	**443**	**+9.4%**	**177**	**+79.4%**	**1,092**	**+14.0%**	**34**	**-20.0%**
Genzyme	**621**		**1,180**		**347**		**247**	
Total pharmaceuticals	**8,345**	**-3.9%**	**7,264**	**+8.5%**	**8,513**	**+15.0%**	**3,768**	**+14.0%**

(1) *France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark.*
(2) *World excluding United States, Canada, Western Europe, Japan, Australia and New Zealand.*
(3) *Japan, Canada, Australia and New Zealand.*
* *Sales of active ingredient to the entity majority-owned by BMS in the United States.*

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Net Sales Human Vaccines (Vaccines)

In 2011, the Vaccines segment reported net sales of 3,469 million, an 8.9% drop on a reported basis, and 5.5% at constant exchange rates. The business suffered in 2011 from the absence of sales of A/H1N1 pandemic influenza vaccines (452 million in 2010). If we exclude these sales, growth for the Vaccines business reached 7.2% at constant exchange rates, driven primarily by Emerging Markets (up 10.7%).

The drop in vaccines sales in 2011 in Western Europe (down 18.4% at constant exchange rates) and in Emerging Markets (down 18.1% at constant exchange rates) was primarily due to the lack of sales of pandemic influenza vaccines. Strong growth in the Other Countries region (up 24.2% at constant exchange rates) was driven by sales of Polio/Pertussis/Hib Vaccines in Japan.

Polio/Pertussis/Hib vaccines net sales were up 12.0% (at constant exchange rates) to 1,075 million, based on the solid performance of Pentaxim® (up 30.2% at constant exchange rates to 238 million) related to product launches in Russia, India and China, and of *Haemophilus influenzae type b* (Hib) vaccines (up 20.7% at 178 million) primarily in Emerging Markets and Japan.

Net sales of **influenza** in 2011 were down 33.2% at constant exchange rates to 826 million, tied to the 2011 lack of sales of pandemic influenza vaccines achieved in 2010 primarily in Latin America and Western Europe. Sales of seasonal influenza vaccines were up 2.5% at constant exchange rates, supported by the performance of Latin America.

Meningitis/Pneumonia vaccines generated net sales of 510 million, up 2.3% at constant exchange rates. The increase was limited by the temporary reduction in catch-up immunization programs for the Menactra® quadrivalent vaccine against meningococcal meningitis in the United States during the first half of 2011, however supported by booster vaccinations at the end of the year.

Net sales of **Adult booster** vaccines reached 465 million (up 7.3% at constant exchange rates), driven by Adacel® (314 million, up 9.2% at constant exchange rates).

Net sales of **Travel and other endemics** Vaccines fell by 1.6% at constant exchange rates to 370 million.

The following table presents the 2011 and 2010 sales of our Vaccines business by range of products:

(million)	2011 Reported	2010 Reported	Change on a reported basis (%)	Change at constant exchange rates (%)
Polio/Pertussis/Hib Vaccines (*including Pentacel® and Pentaxim®*)	1,075	984	+9.3 %	+12.0 %

Influenza Vaccines (*including Vaxigrip® and Fluzone®*)	826	1,297	-36.3 %	-33.2 %
of which seasonal influenza vaccines	*826*	*845*	*-2.2 %*	*+2.5 %*
of which pandemic influenza vaccines		*452*	*-100.0 %*	*-100.0 %*
Meningitis/Pneumonia Vaccines (*including Menactra®*)	510	527	-3.2 %	+2.3 %
Adult Booster Vaccines (*including Adacel®*)	465	449	+3.6 %	+7.3 %
Travel and Other Endemics Vaccines	370	382	-3.1 %	-1.6 %
Other Vaccines	223	169	+32.0 %	+37.8 %
Total Vaccines	**3,469**	**3,808**	**-8.9%**	**-5.5%**

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The following table presents the 2011 sales of our Vaccines business 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®*)	36	-41.0 %	463	+2.8%	457	+21.9%	119	+66.7%
Influenza Vaccines[4] (*inc. Vaxigrip® and Fluzone®*)	77	-39.8 %	435	-11.2%	296	-51.1%	18	-21.7%
Meningitis/Pneumonia Vaccines (*inc. Menactra®*)	3	-40.0 %	390	+2.7%	104	+4.0%	13	-6.6%
Adult Booster Vaccines (*inc. Adacel®*)	76	+40.7 %	339	+3.5%	30	-9.1%	20	+11.8%
Travel and Other Endemics Vaccines	24	+33.3 %	89	+17.5%	210	-9.4%	47	-8.2%
Other Vaccines	15	-12.5 %	176	+45.3%	16	+13.3%	16	+58.7%
Total Vaccines	**231**	**-18.4 %**	**1,892**	**+2.5%**	**1,113**	**-18.1%**	**233**	**+24.2%**

[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 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 791 million in 2011, down 13.8% on a reported basis. Sales generated by Sanofi Pasteur MSD are not included in our consolidated net sales. The decrease in 2011 reflects the drop in sales of Gardasil®, a vaccine that prevents papillomavirus infections known to cause cervical cancer (down 31.1% on a reported basis, to 181 million), and a decline in sales of influenza vaccines (down 23.7% on a reported basis, to 129 millions), primarily of seasonal influenza vaccines.

Net Sales Animal Health

The Animal Health business is carried out by Merial, which has been a wholly-owned subsidiary of Sanofi since September 18, 2009. On March 22, 2011 Merck and Sanofi announced that they had mutually terminated their agreement to form a new animal health joint venture and decided to maintain Merial and Intervet/Schering-Plough as two separate entities, operating independently. This decision was mainly due to the increasing complexity of implementing the proposed transaction. Merial is no longer presented separately on the consolidated balance sheet and the income statement since January 1, 2011 and net income from Merial has been reclassified and included in the income from continuing operations for all periods reported. Detailed information about the impact of Merial on the consolidated financial statements of Sanofi as of December 31, 2011 is provided in Note D.2. and Note D.8.1. to our consolidated financial statements included at Item 18 of this annual report.

Merial generated net sales of 2,030 million in 2011, up 4.3% at constant exchange rates and 2.4% on a reported basis, led by the performance in Emerging Markets.

Net sales for the companion animals franchise were marked by moderate growth in sales of the Frontline® product range (up 0.9% at constant exchange rates, to 764 million), reflecting the temporary impact from generic Frontline® Plus competitors in the United States and the arrival of competitor products in the United States and Western Europe. Sales of vaccines showed sustained growth (7.2% at constant exchange rates), especially in Emerging Markets (up 14.2%) with the success of the Vaxxitex® vaccine.

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The following table presents the 2011 and 2010 sales of our Animal Health business by range of products:

(million)	2011 Reported	2010 Reported	Change on a reported basis	Change at constant exchange rates
Frontline® and other fipronil-based products	764	774	-1.3%	+0.9%
Vaccines	662	627	+5.6%	+7.2%
Avermectin	372	355	+4.8%	+6.5%
Other products	232	227	+2.2%	+4.4%
Total Animal Health	**2,030**	**1,983**	**+2.4%**	**+4.3%**

The following table breaks down net sales of our Animal Health business products by geographical region in 2011:

(million)		Change at constant		Change at constant		Change at constant		Change at constant
Product	**Western Europe [1]**	**exchange rates**	**United States**	**exchange rates**	**Emerging Markets [2]**	**exchange rates**	**Other countries [3]**	**exchange rates**
Frontline® and other fipronil-based products	206	+4.5%	411	-2.1%	86	+8.8%	61	0.0%
Vaccines	195	+2.6%	126	+2.3%	325	+14.2%	16	-21.1%
Avermectin	64	+8.5%	177	+2.8%	60	+8.9%	71	+13.6%
Other products	89	-6.4%	87	+24.3%	36	+11.8%	20	-24.0%
Total Animal Health	**554**	**+2.4%**	**801**	**+2.1%**	**507**	**+12.4%**	**168**	**-1.2%**

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

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

[3] Japan, Canada, Australia and New Zealand.

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

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 2011 and 2010 net sales by region:

(million)	2011 Reported	2010 Reported	Change on a reported basis	Change at constant exchange rates

Western Europe [1]	9,130	9,539	-4.3%	-4.0%
United States	9,957	9,790	+1.7%	+6.8%
Emerging Markets [2]	10,133	9,533	+6.3%	+10.1%
Of which Eastern Europe and Turkey	*2,666*	*2,659*	*+0.3%*	*+3.7%*
Of which Asia (excl. Pacific region [3])	*2,416*	*2,095*	*+15.3%*	*+16.5%*
Of which Latin America	*3,111*	*2,963*	*+5.0%*	*+11.8%*
Of which Africa	*949*	*880*	*+7.8%*	*+9.7%*
Of which Middle East	*872*	*825*	*+5.7%*	*+8.6%*
Other Countries [4]	4,169	3,505	+18.9%	+13.8%
Of which Japan	*2,865*	*2,275*	*+25.9%*	*+20.2%*
Total	**33,389**	**32,366**	**+3.2%**	**+5.3%**

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(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.*

Western Europe posted a 4% decrease in net sales at constant exchange rates to 9,130 million, hit by competition from generics of Taxotere® (down 73.6% at constant exchange rates) and Plavix® (down 35.6% at constant exchange rates), the transfer of the Copaxone® business to Teva in certain countries, as well as the impact of austerity measures. Excluding A/H1N1 vaccines and Genzyme, the decline was 10.5% at constant exchange rates.

The United States posted a 6.8% increase in net sales at constant exchange rates to 9,957 million but excluding A/H1N1 vaccines and Genzyme, showed a 5.7% decline. Sales were affected by competition from generic versions of Lovenox®, Taxotere® and Ambien® CR, which were partially offset by the performance of Lantus® and Eloxatin® as well as by the successful launch of Allegra® as an over-the-counter product.

In Emerging Markets, net sales totaled 10,133 million, up 10.1% at constant exchange rates. Growth at constant exchange rates reached 10.4% excluding sales of A/H1N1 vaccines posted in 2010 (361 million, primarily in Latin America) and Genzyme. In Brazil, net sales hit 1,522 million, up 4.9% at constant exchange rates, or 21.9% if we exclude A/H1N1 vaccines, thereby reflecting the solid performance of generics and the contribution made by Genzyme. In China, net sales totaled 981 million (up 40.4% at constant exchange rates), supported by the performance of Plavix® and Lantus®. In Eastern Europe and Turkey, growth (3.7% at constant exchange rates) suffered from lower prices and competition from Taxotere® generics in Turkey; Russia posted sales of 732 million, a growth of 11.2% at constant exchange rates.

In the Other Countries region, net sales totaled 4,169 million, up 13.8% at constant exchange rates. Excluding A/H1N1 vaccines and Genzyme, net sales increased by 6.2%. Japan recorded net sales of 2,865 million (up 20.2% at constant exchange rates), buoyed by the solid performance of Plavix® (up 22.9% to 671 million), Allegra® (up 22.2% to 465 million) and Hib vaccines, as well as the contribution from Genzyme.

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 which is described in 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 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 profit/loss of entities included in the BMS Alliance and under our operational management.

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The table below sets forth the worldwide sales of Plavix® and Aprovel® in 2011 and 2010, by geographic region:

(million)	2011			2010			Change on a reported basis	Change at constant exchange rates
	Sanofi [2]	BMS [3]	Total	Sanofi [2]	BMS [3]	Total		
Plavix®/Iscover ® [1]								
Europe	530	44	**574**	724	98	**822**	-30.2%	-29.8%
United States		4,759	**4,759**		4,626	**4,626**	+2.9%	+7.8%
Other countries	1,370	286	**1,656**	1,165	282	**1,447**	+14.4%	+13.8%
Total	**1,900**	**5,089**	**6,989**	**1,889**	**5,006**	**6,895**	**+1.4%**	**+4.5%**
Aprovel®/Avapro®								
/Karvea®/Avalide® [4]								
Europe	694	130	**824**	789	158	**947**	-13.0%	-13.0%
United States		374	**374**		482	**482**	-22.4%	-18.8%
Other countries	451	156	**607**	411	216	**627**	-3.2%	-2.1%
Total	**1,145**	**660**	**1,805**	**1,200**	**856**	**2,056**	**-12.2%**	**-11.0%**

[1] Plavix® is marketed under the trademarks Plavix® and Iscover®.
[2] Net sales of Plavix® consolidated by Sanofi, excluding sales to BMS (208 million in 2011 and 273 million in 2010). Net sales of Aprovel® consolidated by Sanofi, excluding sales to BMS (150 million in 2011 and 129 million in 2010).
[3] Translated into euros by Sanofi using the method described in Note B.2. Foreign currency translation to our consolidated financial statements included at Item 18 in this annual report.
[4] Aprovel® is marketed under the trademarks Aprovel®, Avapro®, Karvea® and Avalide®.

Worldwide sales of Plavix®/Iscover® totaled 6,989 million in 2011, up 4.5 % at constant exchange rates. Sales in the U.S. (consolidated by BMS) were up a sustained 7.8% at constant exchange rates, to 4,759 million. In Japan and China, Plavix® realized continued success with sales of 671 million (+22.9% at constant exchange rates) and 277 million (+27.7% at constant exchange rates) respectively. These results sharply offset the decline of Plavix® in Europe caused by competition from generics (down 29.8% at constant exchange rates, to 574 million).

Worldwide sales of Aprovel®/Avapro®/Karvea®/Avalide® totaled 1,805 million in 2011, down 11.0% at constant exchange rates, with the impact of increasing penetration of generic losartan on the market for anti-hypertensives.

Other Revenues

Other revenues, made up primarily of royalty income under licensing agreements contracted in connection with ongoing operations, remained stable at 1,669 million in 2011 and 2010.

Revenues from licensing under the worldwide alliance with BMS on Plavix® and Aprovel® represented 1,275 million in 2011 versus 1,303 million in 2010 (down 2.1% on a reported basis). These licensing revenues suffered the effect of the U.S. dollar depreciation against the

euro, despite the increase in Plavix® sales in the United States (up 7.8% at constant exchange rates).

Gross Profit

Gross profit for the year ended December 31, 2011 came to 24,156 million (72.3% of net sales), 2.0% down on the 2010 figure of 24,638 million (76.1% of net sales), and a decline of 3.8 points in the gross profit reported under sales.

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The gross margin ratio of the Pharmaceuticals segment was down 2.8 points to 75.8%, reflecting both the decrease in royalty income (-0.3 point) and the unfavorable trend in the cost of sales to net sales ratio (-2.5 points). The latter was primarily due to the unfavorable impact of new generics (especially Lovenox®, Ambien® CR and Taxotere® in the United States, and Plavix® and Taxotere® in Europe).

The gross margin ratio of the Vaccines segment was down 4.5 points to 60.2%. This change was principally due to the absence of 2011 profits from pandemic influenza vaccines, which had trended favorably in 2010.

The gross margin ratio of the Animal Health segment was down 1.0 point to 68.9%.

The Group s consolidated gross profit was also impacted in 2011 by a 476 million expense (or 1.4 points) arising from the workdown of inventories remeasured at fair value in connection with acquisitions, principally Genzyme (473 million). In 2010, this expense represented 142 million (0.4 point) and for the most part affected the workdown of Merial s inventories.

Research and Development Expenses

Research and development (R&D) expenses totaled 4,811 million in 2011 (14.4% of net sales), up 5.8% on the 2010 figure of 4,547 million (14.0% of net sales).

In the Pharmaceuticals segment, R&D expenses rose by 217 million or an increase of 5.6%. Excluding Genzyme, R&D expenses decreased by 4.3% at constant exchange rates as a result of reorganizations initiated in 2009, and of the streamlining of the project portfolio.

In the Vaccines segment, R&D expenses rose by 47 million year-on-year (to 564 million) or an increase of 9.1%, due mainly to the clinical trials of vaccines against dengue fever and Clostridium difficile.

In the Animal Health segment, R&D expenses declined by 9 million year-on-year or a decrease of 5.8%.

Selling and General Expenses

Selling and general expenses amounted to 8,536 million (25.6% of net sales), an increase of 4.7% on the prior-year figure of 8,149 million (25.2% of net sales).

The Pharmaceuticals segment generated a 414 million increase, or 5.9%, primarily from the consolidation of Genzyme. Excluding Genzyme, selling and general expenses dropped by 2.9% at constant exchange rates, due both to reduced costs for genericized products in Europe and the

United States and tight control of general expenses.

In the Vaccines segment, selling and general expenses were down 61 million or 10.1% due to the decline in selling expenses for pandemic influenza vaccines.

In the Animal Health business, selling and general expenses were up 13 million (+2.2%), in line with the increase in net sales.

Other Operating Income and Expenses

Other operating income totaled 319 million in 2011 (versus 369 million in 2010), and other operating expenses accounted for 315 million (compared with 292 million in 2010).

The balance of other operating income and expenses represented a net profit of 4 million in 2011, compared with 77 million in 2010. The year-on-year decrease of 73 million was essentially due to the discontinuation of royalty payments from Teva on North American sales of Copaxone® from the second quarter of 2010.

This line item also includes expenses for the 2011 acquisition of Genzyme (65 million), as well as a net operational foreign exchange loss of 5 million compared to 138 million in 2010: the latter occurred in the middle of a highly volatile exchange environment.

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Amortization of Intangible Assets

Amortization charged against intangible assets in the year ended December 31, 2011 amounted to 3,314 million, compared with 3,529 million in the previous year. The decline of 215 million was mainly due to a drop in amortization charged against intangible assets recognized on the acquisition of Aventis (1,788 million in 2011, versus 3,070 million in 2010, as products have reached the end of their life cycles and faced competition from generics), that was partly compensated by new amortization charges in 2011 generated by intangible assets recognized on the acquisition of Genzyme in the second quarter of 2011 and on the consolidation of Merial in the first quarter of 2011 (709 million and 353 million, respectively).

Impairment of Intangible Assets

This line recorded net impairment losses against intangible assets of 142 million in 2011, compared with 433 million in 2010. Impairment losses booked in 2011 were mainly associated with (i) discontinuing a Genzyme research project, (ii) Zentiva generics for which the sales outlook was adjusted downward, and (iii) discontinuing a project developed jointly with Metabolex in the field of diabetes. It also includes an impairment reversal in connection with Actonel®, pursuant to confirmation of the terms of the collaboration agreement with Warner Chilcott (see Note C.2. to the consolidated financial statements included at Item 18 of this annual report).

In 2010, impairments were primarily related to (i) Actonel® due to planned changes to the terms of the collaboration agreement with Warner Chilcott; (ii) the pentavalent vaccine Shan5®, for which sales projections had been revised to factor in the need for another WHO pre-qualification following a flocculation problem encountered in some batches; (iii) the BSI-201 project in which the development plan was revised following the announcement of the initial Phase III trial results in metastatic triple negative breast cancer; and (iv) certain generics and Zentiva consumer health products for which sales projections in Eastern Europe were revised downwards.

Fair Value Remeasurement of Contingent Consideration Liabilities

This line item records fair value remeasurements of liabilities related to business combinations accounted for in accordance with IFRS 3R. Such remeasurements generated a new profit of 15 million in 2011, and were mainly related to a contingent purchase consideration on the acquisition of TargeGen, the contingent value rights (CVRs) issued as part of the Genzyme acquisition, and the contingent consideration to be paid to Bayer on certain Genzyme products (see Note D.18. to the consolidated financial statements included at Item 18 of this annual report).

Restructuring Costs

Restructuring costs accounted for a 1,314 million expense in 2011, compared with 1,384 million in 2010.

In 2011, these were mainly employee-related expenses incurred under plans to adjust headcount in support functions and sales forces in Europe, and in Research & Development in Europe and the United States, and measures to adapt the Group s manufacturing facilities in Europe.

In 2010, these costs related mainly to measures taken to adapt our industrial operations in France, and our sales and R&D functions in the United States and some European countries.

Other Gains and Losses, and Litigation

This line item included a net expense of 327 million, which mainly represented (i) a backlog of depreciation and amortization expense against Merial s tangible and intangible assets in the amount of 519 million, that had not been recognized from September 18, 2009 through December 31, 2010 because these assets had been classified as held for sale or exchange in accordance with IFRS 5 (see Note D.8.1. to the consolidated financial statements included at Item 18 of this annual report), (ii) proceeds of 210 million in damages with regard to a Plavix® patent and (iii) the impact of the disposal of the Dermik dermatology business (see Note D.28. to the consolidated financial statements).

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In 2010, this line item reported a 138 million expense for adjustment of warranty provisions associated with prior disposals of operations.

Operating Income

Operating income totaled 5,731 million for 2011, versus 6,535 million for 2010, down 12.3% mainly as a result of the competition from generics and the absence of A/H1N1 pandemic influenza vaccine sales in 2011.

Financial Income and Expenses

Net financial expenses came to 412 million in 2011 versus 362 million in 2010, an increase of 50 million.

Financial expenses directly related to net debt (defined as short-term and long-term debt, plus related interest rate and currency derivatives, minus cash and cash equivalents) were 325 million in 2011 versus 324 million in 2010. This stabilization was a result of:

- a drop in the average interest rate due to the sharply lower rate on the debt to fund the acquisition of Genzyme in the first quarter of 2011, which, despite the spike in average debt, generated a slight increase in the interest expense;
- a rise in the Group s financial income due to the increase in average level of cash the Group held during the year and a higher average rate of return.

Provisions against securities and receivables totaled 58 million in 2011 (versus 6 million in 2010); in 2011, these provisions were primarily related to the impairment of Greek bonds.

Gains on disposals of non-current financial assets came to 25 million versus 61 million in 2010. These were essentially related to the 2011 change in the consolidation method for Yves Rocher securities associated with the loss of significant influence (see Note D.6. to the consolidated financial statements), and the Group s 2010 sale of its equity interest in Novexel.

Lastly, net financial foreign exchange gains totaled 10 million in 2011 (versus a net loss of 20 million in 2010).

Income before Tax and Associates and Joint Ventures

Income before tax and associates and joint ventures was 5,319 million in 2011, versus 6,173 million in 2010, a decrease of 13.9%.

Income Tax Expense

Income tax expense totaled 455 million in 2011, compared with 1,430 million in 2010. The decrease was mainly due to the change in deferred taxes following changes in both the rate and the laws (mainly in the UK), and the effect of the Franco-American Advance Pricing Agreements (APA) for the 2006-2011 period (see Note D.30. to the consolidated financial statements).

This line item also includes the tax effects of the amortization of intangible assets (1,178 million in 2011 versus 1,183 million in 2010) and of restructuring costs (399 million in 2011 versus 466 million in 2010).

The effective tax rate is calculated on the basis of business operating income minus net financial expenses and before the share of profit/loss of associates and joint ventures and net income attributable to non-controlling interests. The effective tax rate was 27.0% in 2011, versus 27.8% in 2010. The difference relative to the corporate income tax rate applicable in France (34.4%) was mainly due to lower taxes on patent royalties in France.

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Share of Profit/Loss of Associates and Joint Ventures

Our share of profits and losses from associates and joint ventures totaled 1,070 million in 2011, compared with 978 million in 2010. This line mainly includes our share of after-tax profits generated in territories managed by BMS under the Plavix® and Avapro® alliance, which advanced by 9.2% to 1,070 million compared with 980 million in 2010. The increase in 2011 in this share was partly related to growth in Plavix® sales in the United States (up 2.9%).

Net Income

Net income for the year was 5,934 million in 2011, compared with 5,721 million in 2010.

Net Income Attributable to Non-Controlling Interests

Net income attributable to non-controlling interests amounted to 241 million in 2011, compared with 254 million in 2010. This line mainly includes the share of pre-tax profits paid to BMS generated in territories managed by Sanofi (225 million, versus 238 million in 2010); this decline is directly related to increased competition from clopidogrel (Plavix®) generics in Europe.

Net Income Attributable to Equity Holders of Sanofi

Net income attributable to equity holders of Sanofi totaled 5,693 million in 2011, against 5,467 million in 2010.

Basic earnings per share for 2011 was 4.31, 2.9% higher than the 2010 figure of 4.19, based on an average number of shares outstanding of 1,321.7 million in 2011 compared with 1,305.3 million in 2010. Diluted earnings per share was 4.29 in 2011 compared with 4.18 in 2010, based on an average number of shares outstanding after dilution of 1,326.7 million in 2011 and 1,308.2 million in 2010.

Business Operating Income

Business operating income for 2011 was 12,144 million, compared to 12,863 million in 2010. The table below shows trends in business operating income by business segment for 2011 and 2010:

(*million)*	**2011**	**2010**
Pharmaceuticals	10,496	10,965

Vaccines	985	1,379
Animal Health	627	621
Other	36	(102)
Business operating income	**12,144**	**12,863**

Business Net Income

Business net income is a non-GAAP financial measure that we use to evaluate our Group s performance (see Item 5. Operating and Financial Review and Prospects Business Net Income above).

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Business net income totaled 8,795 million in 2011 versus 9,215 million in 2010, a drop of 4.6%. It represented 26.3% of net sales compared with 28.5% in 2010.

(million)		**2011**	**2010 [1]**
Business net income		**8,795**	**9,215**
(i)	Amortization of intangible assets	(3,314)	(3,529)
(ii)	Impairment of intangible assets	(142)	(433)
(iii)	Fair value remeasurement of contingent consideration liabilities	15	
(iv)	Expenses arising from the impact of acquisitions on inventories [2]	(476)	(142)
(v)	Restructuring costs	(1,314)	(1,384)
(vi)	Other gains and losses, and litigation [3]	(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:	*1,905*	*1,856*
	amortization of intangible assets	*1,178*	*1,183*
	impairment of intangible assets	*37*	*143*
	fair value remeasurement of contingent consideration liabilities	*34*	
	expenses arising from the impact of acquisitions on inventories	*143*	*44*
	restructuring costs	*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 [4]	577	
(x)	Share of items listed above attributable to non-controlling interests	6	3
(iv)/(v)	Restructuring costs and expenses arising from the impact of acquisitions on associates and joint ventures [5]	(32)	(58)
Net income attributable to equity holders of Sanofi		**5,693**	**5,467**

[1] The results of operations of Merial, which was previously reported as a business held for exchange, have been reclassified and included in net results of continuing operations in accordance with paragraph 36 of IFRS 5, following the announcement that Merial and Intervet/Schering-Plough will be maintained as two separate businesses operating independently (see Notes D.2. and D.8.1. to our consolidated financial statements included at Item 18 of this annual report).

[2] This line comprises the workdown of inventories remeasured at fair value at the acquisition date.

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

[4] In 2011, related to Advance Pricing Agreement impact for 349 million and 228 million reflecting a decrease in deferred tax liabilities related to the remeasurement of intangible assets following changes in tax laws.

[5] This line shows the portion of major restructuring costs incurred by associates and joint ventures, and expenses arising from the impact of acquisitions on associates and joint ventures (workdown of acquired inventories, amortization and impairment of intangible assets, and impairment of goodwill).

Business Earnings Per Share

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

Business earnings per share for 2011 were 6.65 versus 7.06 in 2010, down 5.8% based on a weighted average number of shares outstanding of 1,321.7 million in 2011 compared with 1,305.3 million in 2010. Diluted business earnings per share for 2011 were 6.63 versus 7.04 in 2010, down 5.8% based on a weighted average number of shares outstanding of 1,326.7 million in 2011 and 1,308.2 million in 2010.

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Year Ended December 31, 2010 Compared with Year Ended December 31, 2009

The consolidated income statements for the years ended December 31, 2010 and December 31, 2009 break down as follows:

(under IFRS)		**as % of**		**as % of**
(million)	**2010 [1]**	**net sales**	**2009**	**net sales**
Net sales	**32,367**	**100.0%**	**29,785**	**100.0%**
Other revenues	1,669	5.2%	1,447	4.9%
Cost of sales	(9,398)	(29.0%)	(8,107)	(27.2%)
Gross profit	**24,638**	**76.1%**	**23,125**	**77.6%**
Research & development expenses	(4,547)	(14.0%)	(4,626)	(15.5%)
Selling & general expenses	(8,149)	(25.2%)	(7,464)	(25.1%)
Other operating income	369		861	
Other operating expenses	(292)		(481)	
Amortization of intangible assets	(3,529)		(3,528)	
Impairment of intangible assets	(433)		(372)	
Fair value remeasurement of contingent consideration liabilities				
Restructuring costs	(1,384)		(1,080)	
Other gains and losses, and litigation [2]	(138)			
Operating income	**6,535**	**20.2%**	**6,435**	**21.6%**
Financial expenses	(468)		(325)	
Financial income	106		27	
Income before tax and associates and joint ventures	**6,173**	**19.1%**	**6,137**	**20.6%**
Income tax expense	(1,430)		(1,399)	
Share of profit/(loss) of associates and joint ventures	978		953	
Net income	**5,721**	**17.7%**	**5,691**	**19.1%**
Net income attributable to non-controlling interests	254		426	
Net income attributable to equity holders of Sanofi	**5,467**	**16.9%**	**5,265**	**17.7%**
Average number of shares outstanding (million)	1,305.3		1,305.9	
Average number of shares outstanding after dilution (million)	1,308.2		1,307.4	
Basic earnings per share (in euros)	4.19		4.03	
Diluted earnings per share (in euros)	4.18		4.03	

[1] *The results of operations of Merial, previously reported as a business held for exchange, have been reclassified and included in net results of continuing operations in accordance with IFRS 5.36., following the announcement that Merial and Intervet/Schering-Plough will be maintained as separate businesses operating independently (see Note D.2. to our consolidated financial statements included at Item 18 of this annual report).*

[2] *See Note B.20.2. to our consolidated financial statements included at Item 18 of this annual report.*

Net Sales

Net sales for the year ended December 31, 2010 were 32,367 million, up 8.7% on 2009. Growth was sustained by both the appreciation of the U.S. dollar and the yen against the euro, and changes in structure (mainly the consolidation of Zentiva from the second quarter of 2009, of Merial from September 18, 2009, and of Chattem from the first quarter of 2010).

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

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The following table breaks down our 2010 and 2009 net sales by business segment:

(million)	2010 Reported	2009 Reported	Change on a reported basis (%)
Pharmaceuticals	26,576	25,823	+2.9%
Vaccines	3,808	3,483	+9.3%
Animal Health	1,983	479	+314.0%
Total	**32,367**	**29,785**	**+8.7%**

Net Sales by Product Pharmaceuticals

Net sales generated by our Pharmaceuticals segment were 26,576 million in 2010, up 2.9% on a reported basis but down 1.6% at constant exchange rates.

Flagship Products

Our flagship products (Lantus® and other Diabetes business products, Lovenox®, Plavix®, Taxotere®, Aprovel®/CoAprovel®, Eloxatin®, Multaq® and Jevtana®) are discussed below. Sales of Plavix® and Aprovel® are discussed further below under Worldwide Presence of Plavix® and Aprovel® .

Net sales for the Diabetes business came to 4,298 million, up 9.2% at constant exchange rates, driven by growth for Lantus®, Apidra® and Amaryl®.

Lantus®, the world s leading diabetes brand (source: IMS 2011 sales), posted a 9.1% rise in net sales at constant exchange rates in 2010 to 3,510 million. Growth was strong in Emerging Markets (18.2% at constant exchange rates), but slowed in the United States (7.4% at constant exchange rates) due to healthcare reforms, despite higher sales of the SoloSTAR® injection pen. Lantus® achieved particularly strong growth at constant exchange rates in Japan (32.3%), Russia (25.9%), and Brazil (30.6%).

Net sales of the rapid-acting insulin analog **Apidra®** advanced by 24.1% at constant exchange rates in 2010 to 177 million, buoyed by solid performances in Western Europe (21.8% growth) and Emerging Markets (37.5% growth).

Lovenox® saw net sales decrease by 10.5% at constant exchange rates in 2010 to 2,806 million. In the United States, sales fell by 22.7% to 1,439 million following the introduction of a generic version of enoxaparin at the end of July 2010. Excluding the United States, net sales were up 7.8% at constant exchange rates at 1,367 million (representing 48.7% of worldwide 2010 sales of Lovenox®), with good performances in Western Europe (up 7.3%) and Eastern Europe (up 14.0%).

Taxotere® reported net sales of 2,122 million, down 6.4% at constant exchange rates. The drop in sales came in the United States and Western Europe, where the patents expired in November 2010. Generic docetaxel became available throughout Western Europe by November 2010. In the United States, distributors commenced a work down of Taxotere® inventories in late 2010 in anticipation of the expected arrival of generic docetaxel in 2011. However, the product saw modest growth in Emerging Markets and in the Other Countries region (1.4% and 2.5% respectively).

Net sales of **Eloxatin®** fell by 58.8% at constant exchange rates in 2010 to 427 million, hit by competition from generics. Following a court ruling, generics manufacturers have been under order to stop selling their unauthorized Eloxatin® generics in the U.S. market since June 30, 2010. The workdown of existing inventories of generics impaired our Eloxatin® sales performance in the second half of 2010.

Multaq®, which began to be marketed at the end of 2009, reported net sales of 172 million, mainly in the United States. The product is now available in over 20 countries, and further launches are ongoing.

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Jevtana®, which has been available in the U.S. market since July 2010, registered net sales of 82 million in 2010.

Our other major products are described below.

Net sales of the hypnotic **Stilnox®/Ambien®/Myslee®** fell by 10.9% at constant exchange rates to 819 million. In the United States, net sales were 443 million (including 375 million for Ambien® CR), down 21.6% at constant exchange rates, following FDA approval of a generic version of Ambien® CR in October 2010; we responded by launching our own generic version in the United States. In Japan, Myslee® again performed well, with net sales up 14.5% at constant exchange rates at 247 million.

Allegra® reported a 22.4% drop in net sales (at constant exchange rates) to 607 million, due to the effect of generics of Allegra® D-12, which have been available on the U.S. market since the end of 2009. Sales in Japan were down 2.0% at constant exchange rates, at 356 million.

Net sales of **Copaxone®**, generated mainly in Western Europe, grew by 8.4% at constant exchange rates to 513 million.

The **Consumer Health Care** business posted year-on-year growth of 45.7% at constant exchange rates to 2,217 million, driven by Emerging Markets where net sales rose by 44.4% at constant exchange rates to 1,050 million. These figures consolidate the consumer health products of Zentiva from April 2009, Oenobiol from December 2009, Chattem from February 2010, and Nepentes from August 2010.

The **Generics** business reported 2010 net sales of 1,534 million, up 41.5% at constant exchange rates. Growth was driven by Emerging Markets, due to the acquisition and consolidation of Zentiva and Kendrick (from April 2009) and Medley (from May 2009), and by the United States, following the launch of our generic version of Ambien® CR.

Net sales of the other products in the portfolio were down 1.9% (at constant exchange rates) year-on-year at 6,064 million. For a description of our other pharmaceutical products, see Item 4. Information on the Company B. Business Overview Pharmaceutical Products.

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The following table breaks down our 2010 and 2009 net sales for the Pharmaceuticals business by product:

(million)		2010	2009	Change on a reported	Change at constant exchange
Product	**Indication**	**Reported**	**Reported**	**basis (%)**	**rates (%)**
Lantus®	Diabetes	3,510	3,080	+14.0%	+9.1%
Apidra®	Diabetes	177	137	+29.2%	+24.1%
Amaryl®	Diabetes	478	416	+14.9%	+7.7%
Insuman®	Diabetes	133	131	+1.5%	+1.5%
Sub-total: Diabetes		**4,298**	**3,764**	**+14.2%**	**+9.2%**
Lovenox®	Thrombosis	2,806	3,043	-7.8%	-10.5%
Plavix®	Atherothrombosis	2,083	2,623	-20.6%	-24.6%
Taxotere®	Breast, lung, prostate, stomach, and head & neck cancer	2,122	2,177	-2.5%	-6.4%
Aprovel®/CoAprovel®	Hypertension	1,327	1,236	+7.4%	+4.2%
Eloxatin®	Colorectal cancer	427	957	-55.4%	-58.8%
Multaq®	Atrial fibrillation	172	25	+588.0%	+560.0%
Jevtana®	Prostate cancer	82			
Stilnox® / Ambien®/Myslee®	Sleep disorders	819	873	-6.2%	-10.9%
Allegra®	Allergic rhinitis, urticarial	607	731	-17.0%	-22.4%
Copaxone®	Multiple sclerosis	513	467	+9.9%	+8.4%
Tritace®	Hypertension	410	429	-4.4%	-7.2%
Depakine®	Epilepsy	372	329	+13.1%	+7.6%
Xatral®	Benign prostatic hypertrophy	296	296	0.0%	-3.4%
Actonel®	Osteoporosis, Paget s disease	238	264	-9.8%	-16.3%
Nasacort®	Allergic rhinitis	189	220	-14.1%	-16.8%
Other products		**6,064**	**5,947**	**+2.0%**	**-1.9%**
Consumer Health Care		**2,217**	**1,430**	**+55.0%**	**+45.7%**
Generics		**1,534**	**1,012**	**+51.6%**	**+41.5%**
Total pharmaceuticals		**26,576**	**25,823**	**+2.9%**	**-1.6%**

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The following table breaks down net sales of our Pharmaceutical business products by geographical region in 2010:

(million)	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
Product								
Lantus®	684	+5.3%	2,134	+7.4%	508	+18.2%	184	+25.2%
Apidra®	68	+21.8%	62	+11.1%	35	+37.5%	12	+150.0%
Amaryl®	42	-17.6%	6	-33.3%	222	+21.7%	208	+3.3%
Insuman®	108	-0.9%			25	+19.0%		-100.0%
Sub-total: Diabetes	**902**	**+4.2%**	**2,202**	**+7.4%**	**790**	**+20.0%**	**404**	**+13.7%**
Lovenox®	782	+7.3%	1,439	-22.7%	499	+6.9%	86	+19.4%
Plavix®	641	-53.9%	213*	-4.1%	648	+0.7%	581	+25.4%
Taxotere®	709	-10.6%	786	-8.0%	394	+1.4%	233	+2.5%
Aprovel®/CoAprovel®	825	-5.0%	39*	+457.1%	358	+8.3%	105	+67.3%
Eloxatin®	46	-42.9%	172	-76.4%	150	-9.8%	59	+4.0%
Multaq®	39		128		2		3	
Jevtana®			82					
Stilnox®/Ambien® /Myslee®	55	-8.3%	443	-21.6%	68	+5.0%	253	+13.6%
Allegra®	16	-5.9%	147	-53.6%	88	+17.4%	356	-3.2%
Copaxone®	482	+9.1%			13	-13.3%	18	+7.7%
Tritace®	189	-4.1%			191	-2.6%	30	-41.9%
Depakine®	148	+2.1%			209	+12.0%	15	+9.1%
Xatral®	66	-14.3%	155	+2.7%	70	+0.0%	5	-50.0%
Actonel®	104	-23.5%			93	-12.4%	41	+3.2%
Nasacort®	28	-3.4%	130	-20.3%	26	-10.7%	5	-20.0%
Other products	**2,649**	**-2.3%**	**652**	**+3,3%**	**2,052**	**+0.4%**	**711**	**-10.9%**
Consumer Health Care	**630**	**+1.1%**	**320**		**1,050**	**+44.4%**	**217**	**+31.3%**
Generics	**404**	**+11.1%**	**102**		**988**	**+42.8%**	**40**	**+61.9%**
Total pharmaceuticals	**8,715**	**-8.5%**	**7,010**	**-7,5%**	**7,689**	**+11.9%**	**3,162**	**+6.9%**

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

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

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

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

Net Sales Human Vaccines (Vaccines)

In 2010, the Vaccines segment reported net sales of 3,808 million, up 4.8% at constant exchange rates and 9.3% on a reported basis. Growth was driven by sales of seasonal influenza vaccines (845 million, versus 597 million in 2009). Sales of pandemic influenza vaccines (mainly against the A/H1N1 virus) were flat; excluding their impact, growth for the Vaccines segment reached 5.5% at constant exchange rates.

Although the Vaccines segment saw net sales decrease in Western Europe and the United States (by 15.6% and 11.5% at constant exchange rates, respectively), the effect was amply offset by strong growth in Emerging Markets and in the Other Countries region (of 46.2% and 23.0% at constant exchange rates, respectively).

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Net sales of **influenza** vaccines rose by 18.7% at constant exchange rates to 1,297 million in 2010, boosted by the performance of the Fluzone® seasonal influenza vaccine in the U.S. market. Excluding pandemic influenza vaccines (net sales of 452 million, flat year-on-year), growth reached 33.3% at constant exchange rates.

Polio/Pertussis/Hib vaccines net sales fell by 2.9% (at constant exchange rates) to 984 million, reflecting a decline in sales of Pentacel® (down 11.4% at 317 million at constant exchange rates) but also the performance of Pentaxim® (up 43.9% at 190 million at constant exchange rates).

Meningitis/Pneumonia vaccines generated net sales of 527 million, down 6.7% at constant exchange rates, mainly due to a reduction in catch-up vaccination programs with the Menactra® quadrivalent meningococcal meningitis vaccine in the United States.

Net sales of **Adult booster** vaccines reached 449 million (up 4.7% at constant exchange rates), driven by Adacel® (301 million, up 6.1% at constant exchange rates).

Net sales of **Travel and other endemics** Vaccines rose by 15.7% at constant exchange rates to 382 million, mainly due to growth in anti-rabies vaccines.

The following table presents the 2010 and 2009 sales of our Vaccines business by range of products:

(million)	**2010 Reported**	**2009 Reported**	**Change on a reported basis (%)**	**Change at constant exchange rates (%)**
Influenza Vaccines (*including Vaxigrip® and Fluzone®*)	1,297	1,062	+22.1%	+18.7%
of which seasonal influenza vaccines	845	597	+41.5%	+33.3%
of which pandemic influenza vaccines	452	465	-2.8%	0.0%
Polio/Pertussis/Hib Vaccines (*including Pentacel® and Pentaxim®*)	984	968	+1.7%	-2.9%
Meningitis/Pneumonia Vaccines (*including Menactra®*)	527	538	-2.0%	-6.7%
Adult Booster Vaccines (*including Adacel®*)	449	406	+10.6%	+4.7%
Travel and Other Endemics Vaccines	382	313	+22.0%	+15.7%
Other Vaccines	169	196	+13.8%	-18.4%
Total Vaccines	**3,808**	**3,483**	**+9.3%**	**+4.8%**

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The following table presents the 2010 sales of our Vaccines business 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
Influenza Vaccines [4] (*inc. Vaxigrip® and Fluzone®*)	128	-7.9%	528	-20.2%	618	+116.4%	23	+5.6%
Polio/Pertussis.Hib Vaccines (inc. *Pentacel® and Pentaxim®*)	61	-16.2%	470	-14.6%	384	+11.4%	69	+56.4%
Meningitis/Pneumonia Vaccines (*inc. Menactra®*)	5	-54.5%	407	-11.4%	101	+25.6%	14	0.0%
Adult Booster Vaccines (*inc. Adacel®*)	54	-3.6%	345	+5.2%	33	+32.0%	17	-20.0%
Travel and Other Endemics Vaccines	18	+20.0%	80	+11.6%	235	+15.8%	49	+21.2%
Other Vaccines	16	-63.2%	128	-10.4%	15	+0.0%	10	+22.2%
Total Vaccines	**282**	**-15.6%**	**1,958**	**-11.5%**	**1,386**	**+46.2%**	**182**	**+23.0%**

(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 addition to the Vaccines activity reflected in our consolidated net sales, sales at Sanofi Pasteur MSD, our joint venture with Merck & Co., Inc. in Europe, amounted to 918 million, down 18.9% on a reported basis. Sales generated by Sanofi Pasteur MSD are not included in our consolidated net sales. Sales of Gardasil®, a vaccine that prevents papillomavirus infections (a cause of cervical cancer), totaled 263 million in 2010, compared with 395 million in 2009. This decrease of 33.5% was mainly due to a reduction in catch-up vaccination programs.

Net Sales Animal Health

The Animal Health business is carried out by Merial, which has been a wholly-owned subsidiary of Sanofi since September 18, 2009. Following the mutual termination by Sanofi and Merck of their agreement to create a new animal health joint venture, Merial s results have since been included in the results from continuing operations for all periods reported (see note D.2. to our consolidated financial statements included at Item 18 of this annual report).

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Merial generated net sales of 1,983 million in 2010, up 314.0% on a reported basis. 2009 net sales were consolidated from September 18, 2009. The following table presents the 2010 and 2009 sales of our Animal Health business by range of products:

(million)	2010 Reported	2009 Reported	Change on a Reported basis
Frontline® and other fipronil-based products	774	195	+296.9%
Vaccines	627	131	+378.6%
Avermectin	355	90	+294.4%
Other products	227	63	+260.3%
Total Animal Health	**1,983**	**479**	**+314.0%**

The following table breaks down net sales of our Animal Health business products by geographical region in 2010:

(million)	2010	Western	United	Emerging	Other
Product	**Net sales**	**Europe (1)**	**States**	**Markets (2)**	**countries (3)**
Frontline® and other fipronil-based products	774	198	438	80	58
Vaccines	627	191	129	288	19
Avermectin	355	59	181	56	59
Other products	227	94	74	34	25
Total Animal Health	**1,983**	**542**	**822**	**458**	**161**

(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 2010 and 2009 net sales by region:

(million)	2010 Reported	2009 Reported	Change on a Reported basis
Western Europe (1)	9,539	9,938	-4.0%
United States	9,790	9,573	+2.3%
Emerging Markets (2)	9,533	7,493	+27.2%
Of which Eastern Europe and Turkey	*2,659*	*2,279*	*+16.7%*
Of which Asia (excl. Pacific region (3))	*2,095*	*1,638*	*+27.9%*
Of which Latin America	*2,963*	*1,991*	*+48.8%*
Of which Africa	*880*	*782*	*+12.5%*
Of which Middle East	*825*	*658*	*+25.4%*
Other Countries (4)	3,505	2,781	+26.0%

Of which Japan	*2,275*	*1,871*	*+21.6%*
Total	**32,367**	**29,785**	**+8.7%**

(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.*

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Western Europe saw net sales decrease by 4.0% in 2010 to 9,539 million, hit by competition from generics of Plavix® and Taxotere®, and by price pressure from the healthcare authorities.

In the United States, net sales grew by 2.3% at 9,790 million, despite the arrival of generic competition for Lovenox® and Ambien® CR, the workdown of inventories of generic versions of Eloxatin® during the second half of 2010 and the effects of healthcare reform. These figures include net sales generated by Chattem from February 2010 and by Merial from September 18, 2009.

Emerging Markets net sales were 9,533 million, representing robust growth of 27.2%. This performance reflected solid organic growth and the impact of acquisitions (primarily Merial, Zentiva in Eastern Europe and Medley in Brazil). Emerging Markets accounted for 29.5% of total consolidated net sales in 2010. The main growth drivers were Latin America, Russia and China. In Latin America (primarily Brazil and Mexico), growth was fueled by sales of influenza vaccines, which virtually trebled (189% growth).

In the Other Countries region, net sales rose by 26.0% to 3,505 million. Net sales in Japan reached 2,275 million, up 21.6%, thanks largely to the success of Plavix®, the performance of the Vaccines business and the integration of Merial.

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 which is described in 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 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 profit/loss of entities included in the BMS Alliance and under our operational management.

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The table below sets forth the worldwide sales of Plavix® and Aprovel® in 2010 and 2009, by geographic region:

	2010			2009				Change at constant exchange rates
(million)	Sanofi [2]	BMS [3]	Total	Sanofi [2]	BMS [3]	Total	Change on a reported basis	
Plavix®/Iscover® [1]								
Europe	724	98	822	1,443	161	1,604	-48.8%	-49.2%
United States		4,626	4,626		4,026	4,026	+14.9%	+10.8%
Other countries	1,165	282	1,447	897	255	1,152	+25.6%	+13.7%
Total	**1,889**	**5,006**	**6,895**	**2,340**	**4,442**	**6,782**	**+1.7%**	**-2.9%**
Aprovel®/Avapro® /Karvea®/Avalide® [4]								
Europe	789	158	947	810	172	982	-3.6%	-4.4%
United States		482	482		524	524	-8.0%	-10.4%
Other countries	411	216	627	314	192	506	+23.9%	+13.5%
Total	**1,200**	**856**	**2,056**	**1,124**	**888**	**2,012**	**+2.2%**	**-1.5%**

[1] Plavix® is marketed under the trademarks Plavix® and Iscover®.

[2] Net sales of Plavix® consolidated by Sanofi, excluding sales to BMS (273 million in 2010 and 311 million in 2009). Net sales of Aprovel® consolidated by Sanofi, excluding sales to BMS (129 million in 2010 and 113 million in 2009).

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

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

In the United States, sales of Plavix®/Iscover® (consolidated by BMS) grew by a robust 10.8% in 2010 to 4,626 million. Plavix® continued to perform well in Japan and China, where sales grew respectively by 37.1% (to 520 million) and by 36.6% (to 216 million) at constant exchange rates. These performances to some extent cushioned the effect of the decline in European sales of Plavix® (down 49.2% at constant exchange rates) caused by competition from generics.

Worldwide sales of Aprovel®/Avapro®/Karvea®/Avalide® were 2,056 million in 2010, down 1.5% at constant exchange rates. The performance in the Other Countries region, lifted by sales of active ingredient to our alliance partners in Japan, partially offset the drop in sales in the United States and Europe, where net sales fell by 10.4% and 4.4% respectively at constant exchange rates. At the end of 2010, sales were impacted by a voluntary recall of certain lots of Avalide® (irbesartan-hydrochlorothiazide) by Bristol-Myers Squibb and Sanofi from the U.S., Puerto Rican, Canadian, Mexican and Argentinean markets.

Other Revenues

Other revenues, which mainly comprise royalty income under licensing agreements contracted in connection with ongoing operations, totaled 1,669 million in 2010, 15.3% higher than the 2009 figure of 1,447 million.

This increase was mainly due to license revenues under the worldwide alliance with BMS on Plavix® and Aprovel®, which totaled 1,303 million in 2010 versus 1,155 million in 2009 (a 12.8% rise on a reported basis). These revenues were boosted by stronger sales of Plavix® in the United States (up 10.8% at constant exchange rates), and by favorable trends in the exchange rate of the U.S. dollar against the euro.

Gross Profit

Gross profit for the year ended December 31, 2010 came to 24,638 million (76.1% of net sales), 6.5% up on the 2009 figure of 23,125 million (77.6% of net sales).

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The gross margin ratio of the Pharmaceuticals segment fell by 1.6 points, reflecting the net effect of increased royalty income (+0.6 of a point) and erosion in the ratio of cost of sales to net sales (-2.2 points). This erosion was mainly due to genericization (primarily Plavix® in Europe and Lovenox® in the United States) and higher raw material prices for heparins. Nevertheless, the 2010 gross margin ratio for the Pharmaceuticals segment remained healthy at 78.6%.

The gross margin ratio of the Vaccines segment rose by 1.9 points to 64.7%, driven by a 2.1-point improvement in the ratio of cost of sales to net sales, thanks mainly to cost efficiencies in the production of pandemic influenza vaccines.

The Animal Health segment recorded a gross margin ratio of 1 386 million in 2010, up 5.8 points to 69.9% due to product mix.

Consolidated gross profit was also dented by a 142 million charge in 2010 (0.4 of a point) arising from the workdown during 2010 of inventories remeasured at fair value in connection with acquisitions (principally Merial and Chattem), against 90 million in 2009 (0.3 of a point, principally Merial).

Research and Development Expenses

Research and development expenses amounted to 4,547 million in 2010 (14.0% of net sales), compared with 4,626 million in 2009 (15.5% of net sales). This represents a year-on-year reduction of 1.7% on a reported basis.

The Pharmaceuticals segment generated savings of 5.1% as a result of the reorganization initiated in 2009, which has helped reorient some in-house resources towards third-party collaborations. These savings also reflect a rationalization of R&D projects following a full, objective review of the portfolio. Research and development expenses in the Vaccines segment rose by 26 million year-on-year, an increase of 5.3%. Research and development expenses in the Animal Health segment amounted to 155 million in 2010, compared to 46 million in 2009 (for the period starting September 18, 2009).

Selling and General Expenses

Selling and general expenses amounted to 8,149 million (25.2% of net sales), an increase of 9.2% on the prior-year figure of 7,464 million (25.1% of net sales), reflecting the first-time consolidation of companies acquired in 2010 (primarily Chattem) and the impact of the Jevtana® and Multaq® launches. Excluding these impacts, selling and general expenses show a decrease, which reflects the transformation program initiated in 2009, and was mainly driven by savings in marketing costs in the United States and Europe, and in general expenses.

Other Operating Income and Expenses

Other operating income amounted to 369 million in 2010 (2009: 861 million), and other operating expenses totaled 292 million (2009: 481 million). Overall, other operating income and expenses represented net income of 77 million in 2010, compared with 380 million in 2009. The year-on-year decrease of 303 million was mainly due to the discontinuation of royalty payments from Teva on North American sales of Copaxone® from the second quarter of 2010.

In addition, Sanofi recorded a net operational foreign exchange loss of 141 million due to highly volatile currency markets; this compares with a net gain of 40 million in 2009.

Amortization of Intangible Assets

Amortization charged against intangible assets in the year ended December 31, 2010 amounted to 3,529 million, compared with 3,528 million in the previous year. An increase in amortization expense in North America, related to trends in the U.S. dollar/euro exchange rate and the Chattem acquisition, was offset by a reduction in Europe as some intangible assets reached the end of their useful lives.

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This line item mainly comprises amortization charged against intangible assets remeasured at fair value on the acquisitions of Aventis (3,070 million in 2010, versus 3,175 million in 2009) and of Zentiva (130 million in 2010, versus 98 million in 2009).

Impairment of Intangible Assets

This line recorded impairment losses of 433 million in 2010, compared with 372 million in 2009. The losses booked in 2010 related mainly to (i) Actonel®, due to contemplated amendments to the terms of the collaboration agreement with Warner Chilcott; (ii) the pentavalent vaccine Shan5®, for which sales projections were revised to take account of the need to file a new application for WHO pre-qualification following a flocculation problem in some batches; (iii) the BSI-201 project, for which the development plan was revised following the announcement of the initial results from a Phase III trial in triple-negative metastatic breast cancer; and (iv) some of Zentiva s generics and consumer health products, whose sales projections in Eastern Europe were adjusted downwards.

The net impairment loss of 372 million recognized in 2009 related mainly to Actonel®, Benzaclin® and Nasacort®, and reflected the changing competitive environment and the approval dates of generics.

Restructuring Costs

Restructuring costs amounted to 1,384 million in 2010, compared with 1,080 million in 2009.

In 2010, these costs mainly related to measures taken to adapt our industrial operations in France, and our sales and R&D functions in the United States and some European countries.

In 2009, restructuring costs mainly related to measures aimed at transforming R&D operations to encourage innovation, and adapting central support functions to streamline the organizational structure. They mainly comprised employee-related expenses, in the form of early retirement benefits and termination benefits under voluntary redundancy plans. To a lesser extent, they reflected ongoing measures to adapt our industrial facilities in Europe and adjust our sales forces.

Other Gains and Losses, and Litigation

In 2010, this line item reported an expense of 138 million, relating to an adjustment to vendor s guarantee provisions in connection with past divestments.

We made no material divestments in 2010 or 2009.

Operating Income

Operating income for 2010 was 6,535 million, versus 6,435 million for 2009, an increase of 1.6%.

Financial Income and Expenses

Net financial expenses were 362 million in 2010, compared with 298 million in 2009, an increase of 21.5%.

Financial expenses directly related to net debt (defined as short-term and long-term debt, plus related interest rate and currency derivatives, minus cash and cash equivalents) were 325 million in 2010, versus 230 million in 2009. This year-on-year rise reflected the following factors:

- an increase in the average interest rate (due to a longer average maturity), charged on a higher level of average consolidated debt;
- a reduction in interest income, reflecting a lower average rate of return; and
- the 34 million of financial expenses incurred on the acquisition credit facilities contracted in October 2010 in connection with the launch of the public tender offer for Genzyme (see Item 8.B. Significant changes).

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Gains on disposals amounted to 61 million, mainly on the sale of the equity interest in Novexel.

Net foreign exchange losses on financial items totaled 20 million in 2010 (2009: 67 million).

Income before Tax and Associates and Joint Ventures

Income before tax and associates and joint ventures was 6,173 million in 2010, versus 6,137 million in 2009, an increase of 0.6%.

Income Tax Expense

Income tax expense totaled 1,430 million in 2010, compared with 1,399 million in 2009.

The effective tax rate is calculated on the basis of business operating income minus net financial expenses and before the share of profit/loss of associates and joint ventures and net income attributable to non-controlling interests. The effective tax rate was 27.8% in 2010, versus 28.2% in 2009. The difference relative to the standard income tax rate applicable in France in 2010 and 2009 (34.4%) was mainly due to royalty income being taxed at a reduced rate in France.

This line item also includes tax effects of amortization of intangible assets (1,183 million in 2010, 1,130 million in 2009) and of restructuring costs (466 million in 2010, 360 million in 2009).

Share of Profit/Loss of Associates and Joint Ventures

Our share of profits and losses from associates and joint ventures was 978 million in 2010, compared with 953 million in 2009. This line mainly includes our share of after-tax profits from territories managed by BMS under the Plavix® and Avapro® alliance, which rose by 24.8% from 785 million in 2009 to 980 million in 2010. This year-on-year increase was mainly related to stronger sales of Plavix® in the United States (up 10.8% at constant exchange rates) and to the appreciation of the U.S. dollar against the euro (positive impact of 3.7%).

Net Income

Net income for the year was 5,721 million in 2010, compared with 5,691 million in 2009.

Net Income Attributable to Non-Controlling Interests

Net income attributable to non-controlling interests amounted to 254 million in 2010, compared with 426 million in 2009. This line mainly comprises the share of pre-tax profits paid to BMS from territories managed by Sanofi (238 million, versus 405 million in 2009). The decrease in net income attributable to non-controlling interests in 2010 was directly related to increased competition from generics of clopidogrel (Plavix®) in Europe.

Net Income Attributable to Equity Holders of Sanofi

Net income attributable to equity holders of Sanofi totaled 5,467 million in 2010, against 5,265 million in 2009.

Basic earnings per share for 2010 was 4.19, 4.0% higher than the 2009 figure of 4.03, based on an average number of shares outstanding of 1,305.3 million in 2010 and 1,305.9 million in 2009. Diluted earnings per share was 4.18 in 2010 compared with 4.03 in 2009, based on an average number of shares outstanding after dilution of 1,308.2 million in 2010 and 1,307.4 million in 2009.

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Business Operating Income

Business operating income for 2010 was 12,863 million, compared to 12,076 million in 2009. The table below shows trends in business operating income by business segment for 2010 and 2009:

(million)	2010	2009
Pharmaceuticals	10,965	10,608
Vaccines	1,379	1,173
Animal Health	621	288
Other	(102)	7
Business operating income	**12,863**	**12,076**

Business Net Income

Business net income is a non-GAAP financial measure that we use to evaluate our Group s performance (see Item 5. Operating and Financial Review and Prospects Business Net Income above).

Business net income for 2010 was 9,215 million, an improvement of 6.8% on the 2009 figure of 8,629 million, and represented 28.5% of net sales compared with 29.0% in 2009. The increase was mainly due to our good operating performance, reflected in the increase in gross profit (24,638 million in 2010 versus 23,125 million in 2009).

	(million)	2010 [1]	2009 [1]
Business net income		**9,215**	**8,629**
(i)	Amortization of intangible assets	(3,529)	(3,528)
(ii)	Impairment of intangible assets	(433)	(372)
(iii)	Fair value remeasurement of contingent consideration liabilities		
(iv)	Expenses arising from the impact of acquisitions on inventories [2]	(142)	(90)
(v)	Restructuring costs	(1,384)	(1,080)
(vi)	Other gains and losses, and litigation [3]	(138)	
(vii)	Impact of the non-depreciation of the property, plant & equipment of Merial (IFRS 5)	77	21
(viii)	Tax effects on the items listed above, comprising:	1,856	1,644
	- amortization of intangible assets	1,183	1,130