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: