

SANOFI-AVENTIS  
Form 20-F  
March 01, 2011  
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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

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2010

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-Aventis**

(Exact name of registrant as specified in its charter)

N/A

(Translation of registrant's name into English)

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France

(Jurisdiction of incorporation or organization)

174, avenue de France, 75013 Paris, France

(Address of principal executive offices)

Karen Linehan, Senior Vice President Legal Affairs and General Counsel

174, avenue de France, 75013 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
American Depositary Shares, each	on which registered: New York Stock Exchange
representing one half of one ordinary share, par	
value 2 per share	
Ordinary shares, par value 2 per share	New York Stock Exchange
	(for listing purposes only)

Securities registered pursuant to Section 12(g) of the Act:

American Depositary Shares, each representing one quarter of a Participating Share Series A, par value 70.89 per share (removed from listing and registration on the New York Stock Exchange effective July 31, 1995).

The number of outstanding shares of each of the issuer's classes of capital or

common stock as of December 31, 2010 was:

Ordinary shares: 1,310,997,785

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405

of the Securities Act.

YES  NO

If this report is an annual or transition report, indicate by check mark if the registrant is not

required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

YES  NO

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

Yes  No

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

Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

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

U.S. GAAP

International Financial Reporting Standards as issued by the International Accounting Standards Board

Other

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

Item 17  Item 18

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

YES  NO

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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, 2010.

Unless the context requires otherwise, the terms sanofi-aventis, the Company, the Group, we, our or us refer to sanofi-aventis and its consolidated subsidiaries.

All references herein to United States or U.S. are to the United States of America, references to dollars or \$ are to the currency of the United States, references to France are to the Republic of France, and references to euro and are to the currency of the European Union member states (including France) participating in the European Monetary Union.

Brand names appearing in this annual report are trademarks of sanofi-aventis and/or its affiliates, with the exception of:

trademarks used or that may be or have been used under license by sanofi-aventis and /or its affiliates, such as Acrel<sup>®</sup> and Actonel<sup>®</sup> trademarks of Warner Chilcott ; BiTE<sup>®</sup> a trademark of Micromet Inc., Copaxone<sup>®</sup> a trademark of Teva Pharmaceuticals Industries ; Cortizone-10<sup>®</sup> a trademark of Johnson & Johnson (except in the United-States where it is a trademark of the Group) ; epiCard a trademark of Intelliject ; Gardasil<sup>®</sup> a trademark of Merck&Co. ; Mutagrip<sup>®</sup> a trademark of Institut Pasteur ; Optinate<sup>®</sup> a trademark of Warner Chilcott on certain geographical areas and of Shionogi Pharma Inc. in the United States ; Pancréate a trademark of CureDM ; and RotaTeq<sup>®</sup> a trademark of Merck&Co. ;

trademarks sold by sanofi-aventis and/or its affiliates to a third party, such as DDAVP<sup>®</sup> a trademark of Ferring (except in the United States where it is a trademark of the Group) ; Liberty<sup>®</sup>, LibertyLink<sup>®</sup> and StarLink<sup>®</sup> trademarks of Bayer ; and Maalox<sup>®</sup> a trademark of Novartis in the United States, Canada and Puerto Rico; and,

other third party trademarks such as ACT<sup>®</sup> a trademark of Johnson & Johnson on certain geographical areas (except the United States where it is a trademark of the Group) ; Aspirine<sup>®</sup> and Cipro<sup>®</sup> trademarks of Bayer ; Humaneered a trademark of KaloBios Pharmaceuticals ; IC31<sup>®</sup> a trademark of Intercell ; LentiVector<sup>®</sup> and RetinoStat<sup>®</sup> trademarks of Oxford BioMedica ; Libertas a trademark of APOTEX in the United States and of International Contraceptive & SRH Marketing Limited in the United Kingdom ; MIMIC<sup>®</sup> a trademark of ROHM AND HAAS COMPANY ; Rotarix<sup>®</sup> a trademark of GSK ; Unisom<sup>®</sup> a trademark of Johnson & Johnson on certain geographical areas (except the United States where it is a trademark of the Group) ; and Cerezyme<sup>®</sup>, Fabrazyme<sup>®</sup> and Lemtrada trademarks of Genzyme Corporation.

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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 2010, in constant euros (unless otherwise indicated).

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

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

- (i) sales as published by IMS excluding sanofi-aventis sales generated by the vaccines business, equating to the scope of our pharmaceutical operations;
- (ii) adjustments to data for Germany, the Netherlands, Denmark, Norway and Sweden, to reflect the significant impact of parallel imports;
- (iii) 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;

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- (iv) 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; and
  
- (v) sales of Brazilian panel at constant wholesalers perimeter.

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 plans, objectives or goals, including those relating to products, clinical trials, regulatory approvals and competition; and

statements about our future 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 and undue reliance should not be placed on such statements.

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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. We caution you that a number of important factors could cause actual results to differ materially from those contained in any forward-looking statements. Such factors, some of which are discussed under Item 3. Key Information D. Risk Factors below, include but are not limited to:

approval of generic versions of our products in one or more of their major markets;

product liability claims;

our ability to renew our product portfolio;

the increasingly challenging regulatory environment for the pharmaceutical industry;

uncertainties over the pricing and reimbursement of pharmaceutical products;

fluctuations in currency exchange rates; and

slowdown of global economic growth.

We caution you that the foregoing list of factors is not exclusive and that other risks and uncertainties may cause actual results to differ materially from those in forward-looking statements. Additional risks, not currently known or considered immaterial by the Company, 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-aventis. These financial data are derived from the sanofi-aventis consolidated financial statements. The sanofi-aventis consolidated financial statements for the years ended December 31, 2010, 2009 and 2008 are included in Item 18 of this annual report.

The consolidated financial statements of sanofi-aventis for the years ended December 31, 2010, 2009 and 2008 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, 2010. 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, 2010.

Sanofi-aventis reports its financial results in euros.

**Table of Contents****SELECTED CONDENSED FINANCIAL INFORMATION**

( million, except per share data)	As of and for the year ended December 31,				
	2010	2009	2008	2007	2006
<b>IFRS Income statement data</b>					
Net sales	30,384	29,306	27,568	28,052	28,373
Gross profit	23,318	22,869	21,480	21,636	21,902
Operating income	5,961	6,366	4,394	5,911	4,828
Net income excluding the held-for-exchange Merial business attributable to equity holders of sanofi-aventis <sup>(a)</sup>	5,081	5,090	3,731	5,112	3,918
Net income attributable to equity holders of sanofi-aventis	5,467	5,265	3,851	5,263	4,006
<b>Basic earnings per share ( ¢) <sup>(b)</sup> :</b>					
Net income excluding the held-for-exchange Merial business attributable to equity holders of sanofi-aventis <sup>(a)</sup>	3.89	3.90	2.85	3.80	2.91
Net income attributable to equity holders of sanofi-aventis	4.19	4.03	2.94	3.91	2.97
<b>Diluted earnings per share ( ¢) <sup>(c)</sup> :</b>					
Net income excluding the held-for-exchange Merial business attributable to equity holders of sanofi-aventis <sup>(a)</sup>	3.88	3.90	2.85	3.78	2.88
Net income attributable to equity holders of sanofi-aventis	4.18	4.03	2.94	3.89	2.95
<b>IFRS Balance sheet data</b>					
Goodwill and other intangible assets	44,411	43,480	43,423	46,381	52,210
Total assets	85,264	80,251 <sup>(g)</sup>	71,987	71,914	77,763
Outstanding share capital	2,610	2,618	2,611	2,657	2,701
Equity attributable to equity holders of sanofi-aventis	53,097	48,322 <sup>(g)</sup>	44,866	44,542	45,600
Long-term debt	6,695	5,961	4,173	3,734	4,499
Cash dividend paid per share ( ¢) <sup>(d)</sup>	2.50 <sup>(e)</sup>	2.40	2.20	2.07	1.75
Cash dividend paid per share (\$) <sup>(d)(f)</sup>	3.34 <sup>(e)</sup>	3.46	3.06	3.02	2.31

<sup>(a)</sup> Refer to definition in Notes D.1. and D.8.1. to our consolidated financial statements included at Item 18 of this annual report.

<sup>(b)</sup> Based on the weighted average number of shares outstanding in each period used to compute basic earnings per share, i.e., 1,305.3 million shares in 2010, 1,305.9 million shares in 2009, 1,309.3 million shares in 2008, 1,346.9 million shares in 2007, and 1,346.8 million shares in 2006.

<sup>(c)</sup> Based on the weighted average number of shares outstanding in each period plus stock options and restricted shares with a potentially dilutive effect; i.e., 1,308.2 million shares in 2010, 1,307.4 million shares in 2009, 1,310.9 million shares in 2008, 1,353.9 million shares in 2007, and 1,358.8 million shares in 2006.

<sup>(d)</sup> Each American Depositary Share, or ADS, represents one half of one share.

<sup>(e)</sup> Dividends for 2010 will be proposed for approval at the annual general meeting scheduled for May 6, 2011.

<sup>(f)</sup> Based on the relevant year-end exchange rate.

<sup>(g)</sup> In accordance with IFRS 3 (Business Combinations), sanofi-aventis adjusted the values of certain identifiable assets and liabilities of Merial during the purchase price allocation period (see Note D.1. to our consolidated financial statements included at Item 18 of this annual report).

**Table of Contents****SELECTED EXCHANGE RATE INFORMATION**

The following table sets forth, for the periods and dates indicated, certain information concerning the exchange rates for the euro from 2006 through February 2011 expressed in U.S. dollar 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.

	<b>Period- end Rate</b>	<b>Average Rate <sup>(1)</sup> (U.S. dollar per euro)</b>	<b>High</b>	<b>Low</b>
2006	1.32	1.27	1.33	1.19
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
Last 6 months				
2010				
August	1.27	1.29	1.33	1.27
September	1.36	1.31	1.36	1.27
October	1.39	1.39	1.41	1.37
November	1.30	1.37	1.42	1.30
December	1.33	1.32	1.34	1.31
2011				
January	1.37	1.34	1.37	1.29
February <sup>(2)</sup>	1.38	1.36	1.38	1.35

<sup>(1)</sup> 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 18, 2011, we have used European Central Bank Rates for the period from February 21, 2011 to February 25, 2011.

<sup>(2)</sup> In each case, measured through February 25, 2011.

On February 25, 2011 the European Central Bank Rate was 1.3762 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**

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

Competitors may file marketing authorization requests for generic versions of our products. Approval and market entry of a generic product would reduce 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 adversely affect our business, results of operations and financial condition. The market for our products could also be affected if a competitor's innovative drug in the same market were to become available as a generic. Additionally, a number of our products acquired through business combinations have substantial balance sheet carrying values, as disclosed at Note D.4. to our consolidated financial statements included in this annual report at Item 18, which could be substantially impaired by the introduction of a generic competitor, with adverse effects on our financial condition and the value of our assets.

Through patent and other proprietary rights, we hold exclusivity rights for a number of our research-based products. However, the patent protection that we are able to obtain varies from product to product and country to country and may not be sufficient to maintain product exclusivity. We are involved in litigation worldwide to enforce certain of these patent rights against generics and proposed generics (see Note D.22.b) to our consolidated financial statements included in this annual report at Item 18 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 do 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 **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.

Finally, 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 of the competing products, intervening developments in law or jurisprudence, or inconsistent judgments. Moreover, patents differ from country to country and a successful result in one country may not predict success in another country because of local variations in the patents and differences in national law or legal systems.

Many Group products are already subject to aggressive generic competition, and additional products of the Group could become subject to generic competition in the future.

**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 may increase our product liability exposure (see "The diversification of the Group's business exposes us to additional risks" below). Substantial damage awards have been made notably in the United States and other common law jurisdictions against pharmaceutical companies based upon claims for injuries allegedly caused by the use of their products. Sometimes side effects of pharmaceutical drugs cannot be adequately anticipated based on preapproval clinical studies involving only several hundred to several thousand

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patients. Routine review and analysis of the continually growing body of post-marketing safety surveillance and clinical trials provide additional information for example, potential evidence of rare, population-specific or long-term adverse reactions or of drug interactions that were not observed in preapproval clinical studies and may cause product labeling to evolve, including restrictions of therapeutic indications, new contraindications, warnings or precautions, and occasionally even the suspension or withdrawal of a product marketing authorization. Several pharmaceutical companies have withdrawn products from the market because of actual or suspected adverse reactions to their products, and currently 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.

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-aventis 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.



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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.

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 Risks of our Industrial Activities Environmental liabilities and compliance costs may have a significant adverse effect on our results of operations below.

## **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.**

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 2010, we spent 4,401 million on research and development, amounting to approximately 14.5% of our net sales.

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 and that we will have to abandon a product in which we have invested substantial amounts, including in late stage development (Phase III). Moreover, 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

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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.

As a complement to our portfolio of products, we pursue a strategy of 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 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.

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### **A substantial share of the revenue and income of sanofi-aventis depends 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, 2010 compared with year ended December 31, 2009 Net Sales by Product Pharmaceuticals ), which represented 43.8% of the Group's consolidated revenues in 2010. Among these products is Lantus®, which was the Group's leading product with revenues of \$3,510 million in 2010, representing 11.6% of the Group's consolidated revenues for the year. Lanfuis a flagship product of the Diabetes division, one of the Group's growth platforms. A reduction in sales or in the growth of sales of one or more of our flagship products (in particular sales of Lantus®) could affect our business, results of operations and financial condition.

### **We may lose market share to competing low-cost remedies or generic brands if they are perceived to be 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.

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

We have undertaken to transform our Group by 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, or integration costs that are higher than anticipated, could delay our growth objectives and prevent us from achieving expected synergies. Moreover, we may miscalculate the risks associated with these entities 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.

In addition to 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 entirely inactive. 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.

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 to 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, but third-party payers trying to limit health-care expenses may become less willing to support their per-unit cost.

Moreover, the nature, scope and level of losses that may be sustained or caused by these new businesses may differ 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.

**Successful completion of the Genzyme acquisition could temporarily lessen our strategic flexibility.**

While the proposed acquisition of Genzyme would provide the Group with attractive new opportunities, the diversification into new business lines and the management of substantial additional research, manufacturing and commercial operations may occupy significant organizational attention. Moreover, to acquire Genzyme, the

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Group will be required to incur a substantial amount of debt. As a result, we would be required to make significant payments to lenders. Our post-acquisition level of indebtedness could also cause our credit rating to be downgraded, increase our financing costs, limit our capacity to secure additional financing and limit our ability to engage in additional transactions.

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

The significant expansion of our activities in emerging markets may further expose us to more volatile economic conditions, political instability, competition from companies that are already well established in these markets, the inability to adequately respond to the unique characteristics of these markets, particularly with respect to their regulatory frameworks, difficulties in recruiting qualified personnel, potential exchange controls, weaker intellectual property protection, higher crime levels (particularly with respect to counterfeit products (see Counterfeit versions of our products could harm our business below)), corruption and fraud. Any difficulties in adapting to these 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.

### **The regulatory environment is increasingly challenging for the pharmaceutical industry.**

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, in particular the U.S. Food and Drug Administration (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. Marketed products are also subject to continual review even after regulatory approval. 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 routine 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, such as, for example, a recommendation to limit the patient scope of a drug's indication. In addition, 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 our Company are diminished.

### **We face uncertainties over the pricing and reimbursement of pharmaceutical products.**

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The commercial success of our products 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;

increased difficulty in obtaining and maintaining satisfactory drug reimbursement rates; and

the tendency of governments and private health care providers to favor generic pharmaceuticals.

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In addition to the pricing pressures they exert, state and private third-party payers and purchasers of pharmaceutical products may reduce volumes of sales by restricting access to formularies or otherwise discouraging physician prescriptions of our products. In the United States, the new health care reform law increased the government's role with respect to price, reimbursement and the coverage levels for healthcare-related expenses for the large government health care sector. Implementation of the new law could 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 ).

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.

### **A slowdown of global economic growth could have negative consequences for our business<sup>(1)</sup>.**

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 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 .

### **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<sup>®</sup> and Aprovel<sup>®</sup> in the United States and several other countries, with Warner Chilcott for the osteoporosis treatment Actonel<sup>®</sup>, with Teva for Copaxone<sup>®</sup>, 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 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 we may have with our partners may affect the marketing of certain of our products. Such difficulties may cause a decline in our revenues and affect our results of operations.

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

Many of our products are manufactured using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. Our vaccine products in particular are subject to the risk of manufacturing stoppages or the risk of loss of inventory



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because of the difficulties inherent to the sterile 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

- <sup>(1)</sup> 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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products. The complexity of these processes, as well as strict internal and government standards for the manufacture of our products, subject us to risks. The occurrence or suspected occurrence of out-of-specification production or storage can lead to lost inventories, and in some cases product recalls, with consequential reputational damage and the risk of product liability (See Risks Relating to Legal Matters 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.

### **We rely on third parties for the manufacture and supply of a substantial portion of our raw materials, active ingredients and medical devices.**

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. For example, in 2008 we recalled a limited number of batches of Lovenox<sup>®</sup> and wrote down significant unused inventory following the discovery of quality issues at a Chinese supplier of raw materials. 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, delay the launch of new products and adversely affect our operating results and financial condition above. 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.

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<sup>®</sup>. 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.

### **Counterfeit versions of our products could 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 could harm the business of companies such as sanofi-aventis. Additionally, it is possible that adverse events caused by unsafe counterfeit products will mistakenly be attributed to the authentic product. If a Group product were the subject of counterfeits, the Group could incur substantial reputational and financial harm. See Item 4. Information on the Company B. Business Overview Competition.

### **Use of biologically derived ingredients may face resistance from patients or the purchasers of these products, which could adversely affect sales and cause us to incur substantial costs.**

In line with industry practice, we manufacture our vaccines and many of our prescription pharmaceutical products with ingredients derived from animal or plant tissue. We subject our products incorporating these ingredients to extensive tests and believe them to be safe. There have been

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instances in the past where the use of biologically derived ingredients by the Group or its competitors has been alleged to be an actual or theoretical source of harm, including infection or allergic reaction, or instances where production facilities have been subject to prolonged periods of closure because of possible contamination. Such allegations have on occasion led to damage claims and increased resistance on the part of patients to such ingredients. A substantial claim of harm caused by a product incorporating biologically derived ingredients or a contamination event could lead us to

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incur potentially substantial costs as a result of, among other things, litigation of claims, product recalls, adoption of additional safety measures, manufacturing delays, investment in patient education, and development of synthetic substitutes for ingredients of biological origin. Such claims could also generate patient resistance, with a corresponding adverse effect on sales and results of operations.

### **We are subject to the risk of non-payment by our customers.<sup>(1)</sup>**

We run the risk of 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, which is our largest market in terms of sales, poses particular client credit risk issues, because of the concentrated distribution system in which approximately 73% of our consolidated U.S. pharmaceutical sales are accounted for by just three wholesalers. In addition, the Group's three main customers represent 20.6% of our 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).

### **Our pension liabilities are affected by factors such as the performance of plan assets, interest rates, actuarial data and experience and changes in laws and regulations.**

Our future funding obligations for our main defined-benefit pension plans depend on changes in the future performance of assets held in trust for these plans, the interest rates used to determine funding levels (or company liabilities), actuarial data and experience, inflation trends, the level of benefits provided for by the plans, as well as changes in laws and regulations. Adverse changes in those factors could increase our unfunded obligations under such plans, which would require more funds to be contributed and hence negatively affect our cash flow and results (see Note D.19.1 to our consolidated financial statements included at Item 18 of this annual report).

### **We are increasingly dependent on our technological infrastructure and computer networks.**

Our business depends on the use of computerized data, which means that certain key divisions such as research and development, production and sales are to a large extent dependent on our information technology network. Our inability to implement adequate security and memory storage systems for saved data could lead to their 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.

## **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.

<sup>(1)</sup> 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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Although we maintain property, business interruption and casualty insurance that we believe is in accordance with customary industry practices, we cannot assure you that this insurance will be adequate to cover fully all potential hazards incidental to our business.

### **Environmental liabilities and compliance costs may have a significant adverse effect on our results of operations.**

The environmental laws of various jurisdictions impose actual and potential obligations on our Group to remediate contaminated sites. These obligations may relate to sites:

that we currently own or operate;

that we formerly owned or operated; or

where waste from our operations was disposed.

These environmental remediation obligations could significantly reduce our operating results. Sanofi-aventis 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-aventis 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, for example, with Rhodia, over costs related to environmental liabilities 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, 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<sup>(1)</sup>**

**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 2010, approximately 30% 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

<sup>(1)</sup> 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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the impact of currency exchange rates on our revenues. As a result, currency exchange rate movements can have a considerable impact on our earnings. When deemed appropriate and when technically feasible, we enter into transactions to hedge our exposure to foreign exchange risks. These efforts, when undertaken, may fail to offset the effect of adverse currency exchange rate fluctuations on our results of operations or financial condition. For more information concerning our exchange rate exposure, see Item 11. Quantitative and Qualitative Disclosures about Market Risk.

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

As of December 31, 2010, the Group's net debt amounted to 1.6 billion, an amount which will increase substantially upon acquisition of Genzyme. 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 two largest shareholders own a significant percentage of the share capital and voting rights of sanofi-aventis.**



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As of December 31, 2010, L'Oréal and Total, our two largest shareholders, held approximately 9.02% and 5.51% of our issued share capital, respectively, accounting for approximately 15.61% and approximately 9.19%, respectively, of the voting rights (excluding treasury shares) of sanofi-aventis. 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-aventis 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 their intent to sell all or part of their stakes in our company, and have recently liquidated a significant part of their respective holdings. 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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### **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 2010, our net sales amounted to 30,384 million. We are the fifth largest pharmaceutical group in the world and the third largest pharmaceutical group in Europe (source: IMS sales 2010). Sanofi-aventis 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 two main activities: Pharmaceuticals, and Human Vaccines through sanofi pasteur. The Group is also present in animal health products through Merial Limited (Merial).

In our Pharmaceuticals activity, which generated net sales of 26,576 million in 2010, our major product categories are:

*Diabetes:* our products include Lantus<sup>®</sup>, a long acting analog of human insulin which is the leading brand in the insulin market; Apidra<sup>®</sup>, a rapid-acting analog of human insulin; Insuman<sup>®</sup>, a range of human insulin solutions and suspensions, and Amaryl<sup>®</sup>, an oral once-daily sulfonylurea.

*Oncology:* our leading products in the oncology market are Taxotere<sup>®</sup>, a taxane derivative representing a cornerstone therapy in several cancer types; Eloxatine<sup>®</sup>, a platinum agent, which is a key treatment for colorectal cancer; and Jevtana<sup>®</sup>, a new taxane derivative launched in the United States in 2010, indicated for patients with prostate cancer.

*Other flagship products:* our thrombosis medicines include two leading drugs in their categories: Plavix<sup>®</sup>, an anti-platelet agent indicated for a number of atherothrombotic conditions; and Lovenox<sup>®</sup>, 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<sup>®</sup>, a new anti-arrhythmic agent launched in 2009 and indicated for patients with atrial fibrillation; and Aprovel<sup>®</sup>/ CoAprovel<sup>®</sup>, a major hypertension treatment.

The global pharmaceutical portfolio of sanofi-aventis 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 3,808 million in 2010, 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. Its net sales for 2010 (which are not included in the Group's 2010 net sales) amounted to 1,983 million. The company's top-selling products include Frontline<sup>®</sup>, a topical anti-parasitic flea and tick brand for dogs and cats; Heartgard<sup>®</sup>, a parasiticide for control of heartworm in companion animals; and Ivomec<sup>®</sup>, a parasiticide for the control of internal and external parasites in livestock.

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<sup>®</sup> (sold in France as Telfast<sup>®</sup>), Tritace<sup>®</sup> (sold in France as Triatec<sup>®</sup>), Amaryl<sup>®</sup> (sold in France as Amarel<sup>®</sup>), Ambien<sup>®</sup> CR (an extended-release formulation of zolpidem tartrate, not sold in France), and Jevtana<sup>®</sup> (not currently sold in France).

For our pharmaceutical activity, except where otherwise stated, all market share percentages and rankings are based on full-year 2010 sales figures from IMS Health MIDAS (retail and hospital).

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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-aventis 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-aventis 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-aventis . Our registered office is located at 174, avenue de France, 75013 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 about 100,000 employees at year end 2010, not including an additional 5,600 employees of Merial. 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, Pasteur Mérieux Connaught in the area of vaccines 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, 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 and secured an option for combining Merial with Merck's Intervet/Schering Plough Animal Health business. On March 8, 2010, sanofi-aventis exercised its contractual right to combine the Intervet/Schering-Plough Animal Health business with Merial to form an animal health joint venture equally owned by Merck and sanofi-aventis. In addition to execution of final agreements, formation of the new animal health joint venture remains subject to approval by the relevant competition authorities and other closing conditions.

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The parties currently envisage a closing for the transaction in the third quarter of 2011. In accordance with IFRS 5, sanofi-aventis recognises 100% of the Merial income on a separate line of the income statement – Net income from the held-for-exchange Merial business – (Merial sales are not consolidated). For more information see Notes B.7., D.1. and D.8.1. to our consolidated financial statements included at Item 18 of this annual report.

The Prague-based branded generics group Zentiva was acquired by sanofi-aventis through a tender offer completed on March 11, 2009 followed by a squeeze out of all remaining minority shareholders.

On February 9, 2010, Sanofi-aventis 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-aventis held approximately 97% of Chattem's outstanding shares, and acquired the remaining shares in a short form merger on March 10, 2010.

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 October 4, 2010, we launched an unsolicited tender offer to acquire Genzyme Corp. of Massachusetts, a leading biotechnology group specialized in the treatment of rare diseases. On February 16, 2011, the two companies announced an agreement on the terms of an improved offer to acquire Genzyme. The agreement is described at Item 10. Additional Information – C. Material Contracts – and any acquisition remains subject to fulfillment of a number of conditions including acceptance by holders of a majority of shares on a diluted basis.

## ***B. Business Overview***

### **Strategy**

Sanofi-aventis is a diversified global healthcare leader with a number of core strengths: a strong and long-established presence in Emerging Markets<sup>(1)</sup>, a portfolio of diabetes drugs including the biggest selling insulin in the world (Lantus<sup>®</sup>), a market-leading position in Vaccines and Animal Health, a broad range of Consumer Health Care products and research that is increasingly focused on biological products, allied with a track record of adapting cost structures and a solid financial position.

Like most pharmaceutical companies, we are 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 and to tougher regulatory hurdles. We have decided to respond to these major challenges by developing our growth platforms.

Throughout 2010, we have implemented a wide-ranging transformation program launched in 2009, designed to secure sources of sustainable growth. Our strategy focuses on three key themes:

**Increasing innovation in Research & Development (R&D)**

We conducted a complete and objective review of our research portfolio in 2009, in order to reassess the allocation of resources. This review led to a rationalization of our portfolio, targeting the most promising projects. In February 2011, 53% of our development portfolio consisted of biological products and vaccines. We also redefined our decision-making processes so that new commercial potential and the scope for value creation are better integrated into our development choices. R&D is now based on an organizational structure that focuses on patient needs and encourages entrepreneurship and autonomy. This network-based organization, open to external opportunities, will enable our R&D to be more creative and make the most of innovation, wherever it comes from.

In line with this policy, we signed new alliance and licensing agreements in 2010 designed to give us access to new technologies, or to broaden or strengthen our existing fields of research (including diabetes, oncology and

<sup>(1)</sup> 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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vaccines). In February 2011, 64% of our development portfolio consisted of projects originated by external R&D. Finally, we have made progress on our objective of offering more products that add value for patients: the launches of the anti-arrhythmic drug Multaq® throughout the world, the anti-cancer agent Jevtana® in the United States and the influenza vaccines Intanza® and Fluzone® High-Dose are some examples.

### **Adapting our structures to meet the challenges of the future**

During 2009, we adapted our operating model, previously too focused on the best-selling prescription drugs in our traditional markets, to reflect 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. 30% of our 2010 sales were in emerging markets, where approximately 39% of our employees are located, and where we have strengthened our Consumer Health Care operations. We also realigned our industrial capacity to reflect our expectation of changes in volumes and our analysis of the opportunities for growth. Streamlining our structures and our operating model has also enabled us to further improve our operating ratios. In 2010, our cost control program allowed us to reduce the weight of our research and development expenses and our selling and general expenses compared to our net sales.

### **Exploring external growth opportunities**

Business development is wholly integrated into our overall strategy, and translates into disciplined acquisitions and alliances that create or strengthen platforms for long-term growth and create value for our shareholders. During 2010, we pursued this active and targeted policy, announcing 37 new transactions, including nine acquisitions or creations of joint ventures and 28 R&D alliances. We successfully completed our acquisition of Chattem, one of the leading manufacturers and distributors of branded consumer health products, toiletries and dietary supplements in the United States. We also strengthened our Consumer Health Care platform through the acquisition of Nepentes S.A. in Poland, as well as the creation of a joint venture with Minsheng Pharmaceutical Co., Ltd. and the acquisition of BMP Sunstone Corporation in China. In the generics sector, we created a joint venture with the Japanese company Nichi-Iko Pharmaceutical Co., Ltd. We also acquired two R&D companies: the U.S. biopharmaceutical company TargeGen Inc., which develops small molecule kinase inhibitors for the treatment of certain forms of leukemia, lymphoma and other hematological malignancies and blood disorders; and the U.S. biotechnology company VaxDesign, which develops in vitro models of the human immune system used for the development of vaccines. In Animal Health, on March 8, 2010, we exercised our contractual right to combine the Intervet/Schering-Plough Animal Health business with Merial to form a new animal health joint venture equally owned by the new Merck and sanofi-aventis, which when completed will create a global leader in Animal Health. On February 16, 2011, sanofi-aventis announced an agreement to acquire Genzyme Corp., a leading U.S.-based biotechnology company specializing in the treatment of rare diseases. The agreement is described at Item 10. Additional Information C. Material Contracts and any acquisition remains subject to fulfillment of a number of conditions including acceptance of the transaction by holders of a majority of shares of Genzyme common stock on a diluted basis.

We expect our sound financial position should give us significant potential to create value via external growth opportunities, with the aim of securing 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, oncology, and other flagship products in anti-thrombotics and cardiovascular fields.



The sections that follow provide additional information on the indications and market position of these products in their principal markets. 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 Note D.22.b) to our consolidated financial statements included at Item 18 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, 2010. These products are major contributors to public health.

<b>Therapeutic Area / Product Name</b>	<b>2010 Net Sales ( million)</b>	<b>Drug Category / Main Areas of Use</b>
<b>Diabetes</b>		
Lantus® (insulin glargine)	3,510	Long-acting analog of human insulin Type 1 and 2 diabetes mellitus
Apidra® (insulin glulisine)	177	Rapid-acting analog of human insulin Type 1 and 2 diabetes mellitus
Amaryl® (glimepiride)	478	Sulfonylurea Type 2 diabetes mellitus
Insuman® (insulin)	133	Human insulin (rapid and intermediate acting) Type 1 and 2 diabetes mellitus
<b>Oncology</b>		
Taxotere® (docetaxel)	2,122	Cytotoxic agent Breast cancer  Non small cell lung cancer  Prostate cancer  Gastric cancer  Head and Neck cancer
Eloxatine® (oxaliplatin)	427	Cytotoxic agent Colorectal cancer
Jevtana® (cabazitaxel)	82	Cytotoxic agent Prostate cancer
<b>Other Flagship products</b>		
Lovenox® (enoxaparin sodium)	2,806	Low molecular weight heparin Treatment and prevention of deep vein thrombosis  Treatment of acute coronary syndromes
Plavix® (clopidogrel bisulfate)	2,083	Platelet adenosine disphosphate receptor antagonist Atherothrombosis  Acute coronary syndrome with and without ST segment elevation
Aprovel® (irbesartan) / CoAprovel® (irbesartan & hydrochlorothiazide)	1,327	Angiotensin II receptor antagonist Hypertension
Multaq® (dronedarone)	172	Anti-arrhythmic drug Atrial Fibrillation
<b>Others</b>		
Stilnox® /Ambien®/Myslee® (zolpidem tartrate)	819	Hypnotic Sleep disorders
<i>of which Ambien® CR</i>	378	
Allegra® (fexofenadine hydrochloride)	607	Anti-histamine Allergic rhinitis  Urticaria



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<b>Therapeutic Area / Product Name</b>	<b>2010 Net Sales ( million)</b>	<b>Drug Category / Main Areas of Use</b>
Copaxone® (glatiramer acetate)	513	Non-interferon immunomodulating agent Multiple sclerosis
Tritace® (ramipril)	410	Angiotensin Converting Enzyme Inhibitor Hypertension  Congestive heart failure  Nephropathy
Depakine® (sodium valproate)	372	Anti-epileptic Epilepsy
Xatral® (alfuzosin hydrochloride)	296	Uroselective alpha 1-blocker Benign prostatic hypertrophy
Actonel® (risedronate sodium)	238	Biphosphonate Osteoporosis
Nasacort® (triamcinolone acetonide)	189	Local corticosteroid Allergic rhinitis  Paget s Disease

**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 the company expects to market the BGStar® solution range of Blood Glucose Monitors for insulin patients.

**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.

Lantus® is a well established treatment with over 30 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 the Lantus® SoloSTAR® disposable pen and the KlikSTAR® reusable pen:

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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 and is being reviewed by the U.S. Food and Drug Administration (FDA).

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

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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. Study data are expected to be released in the second quarter of 2011;

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 targeted for the second half of 2011; 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.

Routine analysis of the dataset for the ongoing large-scale ORIGIN randomized trial provided no cause for concern with respect to cancer incidence in the glargine group.

In January 2011, the FDA updated its ongoing safety review of Lantus®. In addition to the analysis of the four registry analyses mentioned above, 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.

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.

The American Diabetes Association (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, 2010 sales) and is available in over 70 countries worldwide. The three leading countries for sales of Lantus® in 2010 were the United States, France and Germany.

## **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<sup>®</sup> 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<sup>®</sup> can be administered subcutaneously using syringes or specific pens including the Apidra<sup>®</sup> SoloSTAR<sup>®</sup> disposable pen and the KlikSTAR<sup>®</sup> reusable pen.

Apidra<sup>®</sup> was launched in Germany in 2004, in other European countries in 2005, in the United States in 2006, and in Canada and Japan in 2009. Apidra<sup>®</sup> is available in over 60 countries worldwide.

### **Insuman<sup>®</sup>**

Insuman<sup>®</sup> (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*.

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Insuman<sup>®</sup> is supplied in vials, cartridges, or pre-filled disposable pens (OptiSet<sup>®</sup> and SoloStar<sup>®</sup>) containing the active substance human insulin. The Insuman<sup>®</sup> range is comprised of rapid-acting insulin solutions (Insuman<sup>®</sup> Rapid and Insuman<sup>®</sup> Infusat) that contain soluble insulin, an intermediate-acting insulin suspension (Insuman<sup>®</sup> Basal) that contains isophane insulin, and combinations of fast- and intermediate-acting insulins in various proportions (Insuman<sup>®</sup> Comb). Insuman<sup>®</sup> is mostly sold in Germany.

### **Amaryl<sup>®</sup>/Amarel<sup>®</sup>/Solosa<sup>®</sup>**

Amaryl<sup>®</sup> (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<sup>®</sup> 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<sup>®</sup> is a rational combination for counteracting the two defects seen in type 2 diabetes. It is one of the most prescribed combinations of diabetes drugs worldwide. Amaryl M<sup>®</sup>, a fixed-dose combination of Amaryl<sup>®</sup> plus metformin in a single presentation, was launched in 2007.

Our leading market for Amaryl<sup>®</sup> is Japan, where it is the best-selling oral anti-diabetes product by volume (source: IMS 2010 sales). A number of generics have received marketing authorization and have been launched in Europe and the United States. Generics recently became available in Japan (November 2010), but have not significantly impacted Amaryl<sup>®</sup> sales.

### **BGStar<sup>®</sup> / iBGStar**

Sanofi-aventis 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-aventis and are designed to be synergistic with our diabetes portfolio, with a positive effect on sales of Lantus<sup>®</sup> and other products expected.

BGStar<sup>®</sup> and iBGStar are blood glucose meters that feature Dynamic Electrochemistry<sup>®</sup>, 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 can often distort blood glucose results.

These monitoring devices are an important step towards our vision of becoming the leader in global diabetes care by integrating innovative monitoring technology, therapeutic innovations, personalized services and support solutions. The first blood glucose monitoring (BGM) devices, BGStar<sup>®</sup> and iBGStar, are scheduled to become commercially available in 2011.

BGStar<sup>®</sup> has received regulatory approval for the U.S. market (FDA) and for Europe. iBGStar has received regulatory approval for Europe, and was submitted in Q4 2010 in the United States.



**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 III). (lixisenatide is in-licensed from Zealand Pharma A/S). In Phase IIb, once-a-day dosing with lixisenatide was shown to be effective in lowering blood sugar and decreasing body weight with good tolerability. Enrollment to the nine studies of the GETGOAL Phase III program in adult patients with type 2 diabetes mellitus was completed at the end of 2009. Positive results were obtained from the first Phase III trials with AVE0010, and were presented at EASD in Stockholm. An initial study investigating use of AVE0010 on top of basal insulins confirmed improvement of HbA1C. A program evaluating the benefit of a combination of lixisenatide / Lantus® is currently in Phase I.

The GPR119 receptor agonist SAR260093, currently in Phase II, has a dual mode of action affecting both insulin and GLP-1 release. It is in-licensed from Metabolex.

**SAR236553**, co-developed with Regeneron (REGN727) entered Phase II in January 2011. The target indication is LDL reduction in patients with familial hypercholesterolemia not at goal with statins.

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### ***Oncology***

Sanofi-aventis is present in the oncology field, primarily in chemotherapy, with three major products: Taxotere<sup>®</sup>, Eloxatine<sup>®</sup>, and Jevtana<sup>®</sup>, which was launched commercially in the United States in July 2010.

#### **Taxotere<sup>®</sup>**

Taxotere<sup>®</sup> (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<sup>®</sup> promotes their assembly and blocks their disassembly, thereby preventing many cancer cells from dividing and resulting in death in some cancer cells.

Taxotere<sup>®</sup> is available in more than 100 countries as an injectable solution. It has gained approval for use in eleven indications in five different tumor types (breast, prostate, gastric, lung, and head and neck). Taxotere<sup>®</sup> 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 GEICAM 9805 study, published in December 2010 in the New England Journal of Medicine, demonstrated that women with node negative cancer benefited from the addition of Taxotere to anthracycline therapy, a commonly used regimen.

The single vial formulation (one vial IV route 20-80mg) was approved in the U.S. in August 2010 (approved in the European Union in November 2009). A dossier for the pediatric indication for Taxotere<sup>®</sup> (designed to be responsive to the FDA's prior written request for pediatric data) was approved by the FDA in May 2010. Taxotere<sup>®</sup> was also approved by China's State Food And Drug Administration in May 2010 for the treatment of patients with hormone-refractory metastatic prostate cancer.

The top four countries contributing to sales of Taxotere<sup>®</sup> in 2010 were the United States, France, Japan and Germany. Generics of docetaxel were launched at the end of 2010 in Europe. In the United States we anticipate that the FDA will grant final approval to one or more generics of docetaxel in 2011.

#### **Eloxatine<sup>®</sup>**

Eloxatine<sup>®</sup> (oxaliplatin) is a platinum-based cytotoxic agent. Eloxatine<sup>®</sup> 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.

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Following the end of the Eloxatine<sup>®</sup> European regulatory data exclusivity in April 2006, a number of oxaliplatin generics have received marketing authorization and 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 Eloxatine<sup>®</sup> generic in the United States. See Item 8. Financial Information A. Consolidated Financial Statements and other Financial Information .

Eloxatine<sup>®</sup> is in-licensed from Debiopharm and is marketed in more than 70 countries worldwide.

### **Jevtana<sup>®</sup>**

Jevtana<sup>®</sup> (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<sup>®</sup> was the result of a 14-year research and development program to address the significant unmet medical need after taxane-based treatment progression.

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The results of the TROPIC Phase III study were released for the first time at the 2010 Genitourinary Cancers Symposium in San Francisco in March 2010. The study was published in *The Lancet* on October 2, 2010. Updated study results as presented at the 2010 American Society of Clinical Oncology (ASCO) Annual Meeting in June 2010 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.

In the United States, filing of the rolling New Drug Approval (NDA) was completed on March 31, 2010. The Jevtana<sup>®</sup> NDA was assigned priority review and was approved by the FDA on June 17, 2010 with its commercial launch a month later.

Jevtana<sup>®</sup> has been well accepted by patients, physicians, and public and private oncology healthcare payers in the United States. Jevtana<sup>®</sup> 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 January 2011, the EMA's Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending marketing authorization in the European Union for Jevtana<sup>®</sup>.

Jevtana<sup>®</sup> was also approved in Brazil on October 26, 2010. Dossiers have been submitted in Canada, Australia, South Africa, Russia, Switzerland, Israel, Ukraine, Argentina, Chile, Colombia, Uruguay, Paraguay, Venezuela, Mexico, Malaysia, Philippines, Thailand, Taiwan, Singapore, India and Morocco. Submissions are expected next in China, Peru and Costa Rica.

Two large phase III studies in hormone-refractory resistant metastatic prostate cancer will begin recruiting patients in the first half of 2011. These include a study versus docetaxel in the first line setting and a study evaluating the optimal dose of cabazitaxel in the second line setting. In addition, cabazitaxel is also being readied for study in small-cell lung cancer, gastric cancer, and pediatric settings.

**The oncology pipeline** includes a broad spectrum of novel agents with a variety of mechanisms of action for treating cancer, including cytotoxic agents, anti-mitotic agents, anti-angiogenic agents, anti-vascular agents, targeted therapies and monoclonal anti-bodies.

**BSI-201** (iniparib: United States Adopted Name: INN pending) (Novel agent with PARP inhibitory activity, metastatic triple negative breast cancer (mTNBC) and advanced squamous non-small cell lung cancer; Phase III). Developed by BiPar Sciences, Inc. (BiPar), a leader in the emerging field of DNA (deoxyribonucleic acid) repair acquired by sanofi-aventis in 2009, BSI-201 is currently being evaluated for its potential to enhance the effect of chemotherapy induced DNA damage. In January 2011, we announced results from a phase III study that was being conducted with iniparib (BSI-201). Results showed that iniparib failed to meet primary end points of overall survival and progression-free survival in patients with metastatic triple-negative breast cancer. However, results suggested improvement of overall survival and progression-free survival in the second- and third-line settings, consistent with earlier Phase II results. The overall safety analysis indicated that the addition of BSI-201 did not significantly add to the toxicity profile of gemcitabine and carboplatin. We plan to discuss these data with the United States and European healthcare authorities in the near future. In parallel, BSI-201 is being developed in advanced squamous non-small cell lung cancer (Phase III) and in multiple additional solid tumors, including ovarian cancer and other breast and lung tumors, (Phase II).

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**Aflibercept** (the VEGF Trap, anti-angiogenic agent; solid tumors; Phase III). The VEGF (Vascular Endothelial Growth Factor) Trap is being developed under an alliance with Regeneron Pharmaceuticals, Inc (Regeneron). Aflibercept is a novel anti-angiogenic agent that acts as a decoy receptor or trap for circulating VEGF. Three double-blind comparative Phase III studies of aflibercept versus placebo in combination with chemotherapy are ongoing in the following indications: second line metastatic colorectal cancer (mCRC) in combination with irinotecan/5-FU/LV (FOLFIRI regimen), VELOUR trial; second line non squamous non-small cell lung cancer in combination with docetaxel, VITAL

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study; first line androgen independent metastatic prostate cancer in combination with docetaxel/prednisone, VENICE study. Patient recruitment has been completed for all trials. Recruitment to a fourth study in first line metastatic pancreas cancer was prematurely discontinued in September 2009 based on the recommendation of an Independent Data Monitoring Committee (IDMC). As part of a planned interim efficacy analysis, the IDMC determined that the addition of aflibercept to gemcitabine would be unable to demonstrate a statistically significant improvement in the primary endpoint of overall survival compared to placebo plus gemcitabine as it was unlikely to demonstrate superiority versus gemcitabine alone. Additional exploratory studies in earlier stage disease or other indications are being conducted either by sanofi-aventis and Regeneron or in collaboration with the U.S. National Cancer Institute.

**Omrabulin** (AVE8062; combretastatin derivative, a new anti-vascular agent in-licensed from Ajinomoto; sarcoma; Phase III). Single agent and combination studies with platinum and taxanes alone and in combination have been conducted with omrabulin. A Phase III study in soft tissue sarcoma in combination with cisplatin was initiated in 2008 and is over 90% enrolled.

**SAR245408** (XL147) was in-licensed from and is being developed under an alliance with Exelixis, Inc. This phosphoinositide-3-kinase (PI3K) inhibitor is under evaluation in a Phase II study of monotherapy for the treatment of advanced or recurrent endometrial cancer. Combinations with paclitaxel/carboplatin, erlotinib, letrozole and trastuzumab are also being evaluated. This oral agent is being developed for the treatment of women with endometrial or breast cancer.

**SAR245409** (XL765) was also in-licensed from and is being developed under an alliance with Exelixis, Inc. 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 has been initiated. Combinations with erlotinib and temozolomide are also being evaluated.

In December 2010, sanofi-aventis and Merck Serono (a division of Merck KGaA, Darmstadt, Germany) announced that they had signed a worldwide research and development agreement to collaboratively investigate novel combinations of investigational agents that could block specific pathways in cancer cells. The novel combinations involve Merck Serono's MEK inhibitor **MSC1936369B** (also known as AS703026), our PI3K/ mTOR inhibitor **SAR245409** (also known as XL765), and our class I PI3K inhibitor **SAR245408** (also known as XL147). Phase I dose escalation studies of these product candidates are projected for 2011.

**SAR256212** (MM-121). Under an exclusive global collaboration and licensing agreement, Merrimack and sanofi-aventis 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 broad applicability it has the potential to be used in a wide selection of tumors and settings. SAR256212 is in phase II stage of development (a proof of concept study in ER/PR+ breast cancer patients after failure of aromatase inhibitors), 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.

In 2010, we conducted several additional collaborations with other companies, universities and institutes to investigate novel oncology agents (see Pharmaceutical Research & Development Portfolio below).

***Other Flagship Products***

**Lovenox®/Clexane®**

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Lovenox® (enoxaparin sodium) is the most widely studied and prescribed low molecular weight heparin (LMWH) in the world. 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 LMWHs. 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).

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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. These indications represent only around 15% of Lovenox® usage in 2010. After two years, the impact on Lovenox® usage has been limited. The next expected indication for these new oral anticoagulants is stroke prevention in atrial fibrillation, replacing vitamin K antagonists (e.g. warfarin), with no direct impact expected on Lovenox® since stroke prevention in atrial fibrillation is not a Lovenox® approved indication.

On July 23, 2010, the FDA approved a generic of enoxaparin and rated it as fully substitutable for Lovenox®. Sanofi-aventis has expressed concern over potential implications for patient safety, since the approved product has not been subject to clinical comparison with Lovenox in order to demonstrate similar safety and efficacy. Clinical testing is considered by many experts and the EMA as the appropriate way to ensure sameness in the absence of clear demonstration of the identical composition, which is generally not possible to demonstrate for complex medicines of biological origin. Consequently, sanofi-aventis requested a U.S. district court to provide relief against the FDA review process.

In 2010, Lovenox® was the leading anti-thrombotic in the United States, Germany, France, Italy, Spain, and the United Kingdom (source: IMS 2010 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® 75mg 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® 75mg 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. This indication has also been granted by Canadian Authorities. A dossier supporting this indication is under review by the FDA.



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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-aventis an additional six month period of exclusivity to market Plavix<sup>®</sup> (clopidogrel bisulfate). Exclusivity for Plavix<sup>®</sup> in the U.S. is now scheduled to expire on May 17, 2012.

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

The extensive clinical program for Plavix<sup>®</sup>, including all completed, ongoing and planned studies, is among the largest of its kind, involving more than 130,000 patients overall. Plavix<sup>®</sup> indications are incorporated into

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major scientific guidelines in North America, Europe and Japan. Over 115 million patients in 115 countries 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.

In Europe, certain generic clopidogrel products have been affected by the recall recommended in March 2010 by the European Medicines Agency (EMA). Sanofi-aventis clopidogrel products were not affected by the recall. We manufacture all of our clopidogrel-containing products for Europe in full compliance with the relevant rules and regulations in force, including Good Manufacturing Practices (GMP).

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-aventis and are outside the scope of our alliance with BMS.

Plavix® is the leading anti-platelet in the U.S. and Chinese markets (source: IMS 2010 sales). In Europe, a number of generics have received marketing authorization and have been launched, but Plavix® sales have proved resilient in Germany and France, with market shares<sup>(1)</sup> by value of 44.8% in Germany and of 42.5% in France. Market share was 39.2% in Western Europe by value (IMS).

## **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.

**Alliance with BMS**

Plavix® and Aprove1® 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.

<sup>(1)</sup> *Plavix® market = oral platelet aggregants inhibitors + oral aspirin £325mg + oral dipyridamole.*

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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<sup>®</sup> 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<sup>®</sup> in Japan; sales of Plavix<sup>®</sup> in Japan are consolidated by sanofi-aventis.

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<sup>®</sup> and Plavix<sup>®</sup> and for certain Asian countries for Plavix<sup>®</sup>;

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

we have the exclusive right to market Aprovel<sup>®</sup> and Plavix<sup>®</sup> in Eastern Europe, Africa and the Middle East, and we have the exclusive right to market Aprovel<sup>®</sup> 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<sup>®</sup> and Aprovel<sup>®</sup> and in Colombia only for Plavix<sup>®</sup>; 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<sup>®</sup>**

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Multaq<sup>®</sup> (dronedarone) uniquely provides comprehensive management of Atrial Fibrillation (AF) with a view to improving cardiovascular outcomes.

Multaq<sup>®</sup> 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 Atrial Fibrillation/Atrial Flutter.

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

Multaq<sup>®</sup> is approved in over 50 countries worldwide and has been launched in 29 countries including the largest pharmaceutical markets: the United States, and in 2010 in the top 5 European markets (Germany, the United Kingdom, Italy, Spain and France).

In the United States, Multaq<sup>®</sup> is indicated to reduce the risk of cardiovascular hospitalization in patients with paroxysmal or persistent AF or AFL, with a recent episode of AF/AFL and associated cardiovascular risk factors.

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In Europe, Multaq<sup>®</sup> is indicated in adult clinically stable patients with a history of or with current non-permanent AF to prevent recurrence of AF or to lower ventricular rate.

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<sup>®</sup> was evaluated in patients with AF/AFL or a recent history of these conditions. Multaq<sup>®</sup> 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<sup>®</sup> significantly reduced the total number of hospital days versus placebo.

A Permanent Atrial fibrillation outcome Study (PALLAS) using dronedarone on top of standard therapy was initiated in the third quarter of 2010 to assess the potential clinical benefit in patients with permanent atrial fibrillation to reduce major adverse cardiovascular events. The multinational, randomized, double-blind Phase IIIb trial has two composite co-primary endpoints: 1. Major cardiovascular events (stroke, systemic arterial embolism, myocardial infarction or cardiovascular death). 2. Cardiovascular hospitalization or death from any cause. There will be 10,800 patients enrolled in 43 countries at 700 sites. The trial is event-driven with a fixed Common Study End Date, meaning that the study duration will depend upon the occurrence of a statistically required number of outcome events.

In September 2010, the European Society of Cardiology (ESC) issued their new Atrial Fibrillation guidelines that gave a clear and prominent first line use position to Multaq<sup>®</sup>. These were followed by the Canadian Cardiovascular Society's Guidelines which also recommended Multaq<sup>®</sup> as a first line treatment option for non-permanent AF patients with preserved heart function.

In January 2011, sanofi-aventis issued a Dear Health Care Professional Letter in the U.S. and in the European Union informing health care providers of several cases of hepatocellular liver injury and hepatic failure in patients receiving Multaq<sup>®</sup>, including two post-marketing reports of acute hepatic failure requiring transplantation. The FDA also issued a Drug Safety Communication on hepatic events reported in patients treated with Multaq<sup>®</sup>. In February 2011, both the EU Summary of Product Characteristics and U.S. Prescribing Information were updated to include liver function monitoring. In Europe, EMA is coordinating a review of all available data concerning the possible risks of liver injury associated with the use of Multaq<sup>®</sup> and their impact on its benefit-risk ratio.

### ***Other pharmaceutical products***

#### **Stilnox<sup>®</sup>/Ambien<sup>®</sup>/Myslee<sup>®</sup>**

Stilnox<sup>®</sup> (zolpidem tartrate) is indicated in the short-term treatment of insomnia. Stilnox<sup>®</sup> 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<sup>®</sup> CR.

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Stilnox<sup>®</sup> is marketed in over 100 countries. It was launched in Japan under the brand name Myslee<sup>®</sup> in December 2000. Myslee<sup>®</sup> has been co-promoted jointly with Astellas since 2006.

The top three markets contributing to sales of Stilnox<sup>®</sup> in 2010 (either immediate or controlled release formulations) were the United States, Japan and Italy. Generic zolpidem tartrate has been available in Europe since 2004. In the United States, generics of the immediate release formulation of Ambien<sup>®</sup> have been available since 2007. Ambien<sup>®</sup> CR generics entered the U.S. market in October 2010.

### **Allegra<sup>®</sup>/Telfast<sup>®</sup>**

Allegra<sup>®</sup> (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.

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We also market Allegra-D<sup>®</sup> 12 Hour and Allegra-D<sup>®</sup> 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<sup>®</sup>/Telfast<sup>®</sup> have been approved in our major markets, with the notable exception of Japan.

In January 2011, the FDA approved the Allegra<sup>®</sup> family for over-the-counter (OTC) use in adults and children two years of age and older.

Allegra<sup>®</sup>/Telfast<sup>®</sup> is marketed in approximately 80 countries. The largest market for Allegra<sup>®</sup> is Japan.

## **Copaxone<sup>®</sup>**

Copaxone<sup>®</sup> (glatiramer acetate) is a non-interferon immunomodulating agent indicated for reducing the frequency of relapses in patients with relapsing-remitting multiple sclerosis. Copaxone<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> to include the treatment of patients with clinically isolated syndrome suggestive of multiple sclerosis.

We market Copaxone<sup>®</sup> outside the United States and Canada through our alliance with Teva (see [Alliance with Teva](#) below).

## **Alliance with Teva**

We in-license Copaxone<sup>®</sup> from Teva and market it 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.

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



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*Exclusive marketing:* we have the exclusive right to market the product. This system is 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 is marketed under a single brand name. We use the co-promotion system in Germany, the United Kingdom, France, the Netherlands, Austria, Belgium, the Czech Republic and Spain.

In the United States and Canada, Copaxone<sup>®</sup> was sold and distributed by sanofi-aventis but marketed by Teva until March 31, 2008. On March 31, 2008, Teva assumed the Copaxone<sup>®</sup> business, including sales of the product, in the United States and Canada. As a result, we no longer record product sales or share certain marketing expenses with respect to the United States and Canada and, until March 31, 2010, we received a royalty from Teva of 25% of sales in these markets.

Under the terms of our agreement, the Copaxone<sup>®</sup> business in countries other than the U.S. and Canada is being transferred to Teva over a period running from the third quarter of 2009 to the first quarter of 2012 at the latest, depending on the country. Following the transfer, sanofi-aventis 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<sup>®</sup> business was transferred to Teva in Switzerland and Lichtenstein. In 2010, the Copaxone<sup>®</sup> business was transferred to Teva in Poland (September 2010), in the Czech Republic (October 2010) and in the United Kingdom (December 2010). 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 risks in connection with our alliance agreements.

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### **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, including the United States where it is marketed by King Pharmaceuticals. A number of generics have received marketing authorization and have been launched worldwide.

### **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 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, Chrono® (a sustained release formulation in tablets) and 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, including the United States, where it is licensed to Abbott.

### **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. Pediatric exclusivity was granted for Uroxatral® in the United States, prolonging the product's claim to exclusivity until July 18, 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).

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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.

In settlement of patent litigation, Barr has been granted a license to sell a generic triamcinolone acetonide in the United States as early as 2011.

## **Main compounds currently in Phase II or III clinical development:**

In the Ophthalmology field

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

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

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

a phase II intravitreal formulation of a protein inhibiting the kallikrein-kinin pathway for the treatment of retinal vein occlusion induced macular edema (**FOV2302**).

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Oxford BioMedica has entered into a new collaboration with sanofi-aventis to develop novel gene-based medicines, utilizing LentiVector® gene delivery technology, for the treatment of ocular disease. The new 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.

In the Thrombosis and Cardiovascular field:

**Otamixaban** (direct factor Xa inhibitor, interventional cardiology; Phase III initiation). 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.

**Semuloparin** (indirect factor Xa/IIa inhibitor, prevention of VTE; Phase III) is a selectively engineered injectable ultra-low-molecular-weight heparin with a novel anti-thrombotic profile combining a high anti-factor Xa activity and a residual anti-factor IIa activity. Development is primarily focused on primary prevention of venous thromboembolic events (VTE) in cancer patients undergoing

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chemotherapy, representing an attractive unmet medical need for VTE prevention. Data generated in prevention of VTE during surgery procedures have provided valuable information for appraising the risk/benefit profile of semuloparin, which was shown to be a safe and effective anticoagulant. The semuloparin Phase III program in medical cancer patients has completed recruitment and continues as planned, with results expected to be presented in 2011.

**Celivarone** (anti-arrhythmic; Phase IIb). Based upon the results of a previous trial, a new Phase II study in patients fitted with an implantable cardioverter/defibrillator is ongoing.

In the Central Nervous System field:

**Teriflunomide** (orally active dihydroorotate dehydrogenase inhibitor, multiple sclerosis; Phase III). An extensive Phase III monotherapy development program in relapsing forms of multiple sclerosis is ongoing. 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 presented atECTRIMS (European Committee for Treatment and Research in Multiple Sclerosis) in October 2010. 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).

**SSR125543** (a CRF1 receptor antagonist) is currently in phase II for major depressive disorders.

In the Internal Medicine field:

**Ferroquine** (4-aminoquinoline; malaria; Phase IIb). Ferroquine is a new 4-amino-quinoline being developed for the treatment of acute uncomplicated malaria. Ferroquine is active against chloroquine sensitive and chloroquine resistant Plasmodium strains, and due to its long half-life has the potential to be part of single dose cure regimens and the unified global treatment of both vivax and falciparum malaria. A Phase IIb study evaluating the optimal posology is currently ongoing.

Together with **SAR97276** (in Phase I see Pharmaceutical Research & Development below), ferroquine is part of our global commitment to fight neglected diseases which heavily impact populations of developing countries, as demonstrated by both our Access to Medicines group and the new Neglected Diseases Development Strategy and Realization unit created within R&D. Our Access to Medicines group and Medicines for Malaria Venture (MMV) are conducting an extensive pharmacovigilance study (the first in this setting) to monitor the use and tolerability of ASAQ (fixed-dose combination of artesunate and amodiaquine).

**SAR153191**, a monoclonal antibody against the Interleukin-6 Receptor (anti IL-6R mAb) derived from our alliance with Regeneron, has entered Phase IIb in rheumatoid arthritis and ankylosing spondylitis.

**Consumer Health Care (CHC)**

Consumer Health Care is a core growth platform identified in our broader strategy for achieving sustainable growth. In 2010, we recorded CHC sales of 2,217 million; nearly half of our CHC sales were in emerging markets, 28% in Europe, and 14% in the United States.

Organic growth in 2010 was supported by our CHC portfolio, which provides us with a strong presence in the analgesics, gastro-intestinal, and cough and cold 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. In August 2010, DolipraneLib® (500 mg paracetamol tablets) was launched in France in new easy-to-carry packaging.

Magne B6® is a product containing magnesium and vitamin B6, which was granted its first marketing authorization in France in 1970. It has now been granted marketing authorizations in more than

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40 countries around the world. MagneB6® has various therapeutic indications from irritability, anxiety and sleep problems to women's health issues like premenstrual syndrome or menopause discomfort. MagneB6® is available in tablets and vials of oral solution.

Enterogermina® is composed of two billion *Bacillus clausii* spores in a ready-to-drink oral suspension in vials of 5 ml and in capsules. Launched in liquid form in 1958 in Italy, the new two-billion dosage was launched in 2001; the capsule form was launched in 2006. 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.

Essentiale® is a herbal preparation for liver therapy, made of highly purified essential phospholipids extracted from soybeans and containing a high percentage of phosphatidylcholine, a major constituent of cellular membrane. Essentiale® is used to treat symptoms such as lack of appetite, sensation of pressure in the right epigastrium, toxico-nutritional liver damage and hepatitis. Essentiale® is sold mainly in Russia (37% growth) 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® was launched first in France in 1972 and is now present in 55 countries; in Europe, Latin America, Russia and in some Asian 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.

Lactacyd® is a range of liquid soaps for feminine hygiene. Lactacyd® is sold mainly in Brazil (28% growth) and Asia.

Chattem's products in the United States 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®.

In January 2011, the FDA approved the Allegra® family of allergy medication products for over-the-counter use in adults and children two years of age and older. The Allegra® family of OTC products will be 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.

Following the recent acquisitions of Laboratoire Oenobiol, Kernpharm and Chattem, and the signature of a joint-venture agreement with Minsheng Pharmaceutical Co., Ltd, we conducted several additional acquisitions and alliances in CHC in 2010:

The August 2010 acquisition of Nepentes S.A. was an important step in our diversification strategy in the fast-growing emerging European markets. Nepentes is an opportunity for us to create a leading Consumer Health Care business in Poland, and will consolidate our leading position in Central and Eastern Europe. We intend Nepentes to accelerate its growth by extending its product lines and developing outside Poland, with a diversified portfolio of dermocosmetics and medicines, including key brands like Iwostin and Emolium. The company has subsidiaries in Bulgaria and Romania.

On October 28, 2010 we took another strategic step by entering into a definitive agreement with BMP Sunstone (a NASDAQ listed company), under which sanofi-aventis acquired all outstanding shares of BMP Sunstone on February 24, 2011 for cash consideration of \$10 per share, or a total of approximately \$520.6 million on a fully diluted basis. BMP Sunstone markets the leading pediatric cough and cold brand, Haowawa® (which means "Goodbaby" in Chinese), with a portfolio of both western OTC drugs and traditional Chinese medicine (TCM) products. The acquisition will also bring sanofi-aventis a very well-established national distribution network providing unique access to the fast-growing prefecture level and rural level cities.



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The joint venture with Minsheng Pharmaceutical Co., together with the acquisition of BMP Sunstone, will make sanofi-aventis a leading consumer health care company in China, with a strong position in both Vitamins & Minerals Supplements and Cough & Cold, the two largest categories in this market source (Nicholas Hall, 2009). Sanofi-aventis will leverage its distribution strength to launch its own OTC brands in the very near future.

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### **Generics**

In 2010, sales of the generics business grew by 41.5% to 1,534 million. This growth was boosted in Emerging Markets, especially Eastern Europe and Brazil, by the acquisitions of Zentiva, Kendrick and Medley, all completed in 2009. Another growth driver was the United States, where we launched an authorized generic of Ambien® CR during the period, capturing more than 50% of total prescriptions of Zolpidem CR generics (source IMS TRx end December). On a constant structure basis and at constant exchange rates, our generic business enjoyed solid organic growth of 18.5%. See Item 5. Operating and Financial Review and Prospects Results of Operations Year Ended December 31, 2010 Compared with Year Ended December 31, 2009 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. We have decided to rebrand all our European generics businesses under the Zentiva name. This means that the existing generics businesses of Winthrop and Helvepharm in Europe will operate under the Zentiva brand. The rollout began in January 2011 in France, Germany, Italy, Switzerland, Portugal and the United Kingdom.

Following on from our 2009 acquisitions, we continued to expand our geographical reach in generics during 2010:

In May 2010, sanofi-aventis and Nichi-Iko Pharmaceutical Co., Ltd. (one of the fastest growing generics companies in Japan, and a market leader in that country) announced an agreement to establish a new joint venture, sanofi-aventis Nichi-Iko K.K., to develop a generics business in Japan. The new joint venture will be held 51% by sanofi-aventis K.K. and 49% by Nichi-Iko Pharmaceutical Co., Ltd. and will allow us to develop a strong presence in the fast-growing Japanese generics market.

### **Vaccine Products**

Sanofi Pasteur is a fully integrated vaccines division offering the broadest range of vaccines in the industry (source: internal estimates). In 2010, sanofi pasteur immunized over 500 million people against 20 serious diseases and generated net sales of 3,808 million. Sales were favorably impacted by strong growth in markets outside North America and Europe, A(H1N1) pandemic influenza sales, 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, 2010 Compared with Year Ended December 31, 2009 Net Sales Human Vaccines (Vaccines).

Sanofi Pasteur is a world leader in the vaccine industry in terms of sales. In the United States and Canada, sanofi pasteur is the market leader in the segments where we compete.

In Europe, sanofi pasteur vaccine products are 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. In addition to sanofi pasteur products, Sanofi Pasteur MSD also distributes such Merck & Co. vaccine products as Gardasil® in the joint venture's geographic scope. In 2010, Sanofi Pasteur MSD net sales, which are accounted for using the equity method, amounted to 918 million.

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Sanofi Pasteur has been expanding in Asia (China, India and Japan), Latin America (Mexico and Brazil), Africa, 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.

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

( million)	2010 Net Sales
Influenza Vaccines *	1,297
Polio/Pertussis/Hib Vaccines	984
Meningitis/Pneumonia Vaccines	527
Adult Booster Vaccines	449
Travel and Other Endemics Vaccines	382
Other Vaccines	169
<b>Total Human Vaccines</b>	<b>3,808</b>

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

Pediacel<sup>®</sup>, another acellular pertussis-based pentavalent vaccine, is the standard of care in the United Kingdom and the Netherlands for protecting against diphtheria, tetanus, pertussis, polio and *Haemophilus influenzae* type b disease. In November 2010, Pediacel<sup>®</sup> was approved in 29 countries across Europe.

Act-HIB<sup>®</sup>, 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<sup>®</sup> became the first Hib vaccine to be approved in Japan.

Hexaxim<sup>™</sup>, a hexavalent pediatric vaccine (expected to provide protection against diphtheria, tetanus, pertussis, poliomyelitis (polio), *Haemophilus influenzae* type b infections and hepatitis B) is aimed specifically at the international region and is under development. The vaccine is currently in Phase III clinical trials with regulatory submission anticipated in 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.

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 July 25, 2010, the World Health Organization withdrew the prequalification of Shan5 , a combination vaccine protecting against five diseases (diphtheria, pertussis, tetanus, *Haemophilus influenzae* type b and hepatitis B) and Shantetra™, a combination vaccine protecting against four diseases (diphtheria, pertussis, tetanus and hepatitis B) developed by Shantha. This decision was driven by the abnormal visual appearance of the product. According to WHO/UNICEF, none of the information available to date suggests a safety problem with Shan5 or Shantetra™. No adverse events following immunization with Shan5 or Shantetra have been reported to the WHO. Sanofi Pasteur has designed an action plan geared to improving the robustness of the processes used by Shantha. A remediation plan was submitted to the WHO at the end of June 2010. Sanofi Pasteur is dedicating its highest expertise to help Shantha regain the pre-qualification of Shan5 as early as possible.

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### **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 2010 to better meet increasing demand. Sanofi Pasteur expects the global demand for influenza vaccines to continue to grow within the next decade due to increased disease awareness as a result of the A(H1N1) influenza pandemic, growth in emerging markets and wider government immunization recommendations.

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 this trend to continue over the coming years. Sanofi Pasteur will remain focused on maintaining its leadership in the influenza market and on meeting the increasing demand for both pandemic and seasonal vaccines through the launch of innovative vaccines. In 2010, sanofi pasteur inaugurated its influenza vaccine facilities in Shenzhen (Guangdong Province, China) Ocoyoacac (Mexico) with the goal of producing influenza vaccines for those markets by 2012/2013.

In 2009, the European Commission granted marketing authorization for sanofi pasteur's Intanza®/IDflu®, the first intradermal (ID) microinjection influenza vaccine. The advantages of this vaccine, particularly its convenience and ease of administration, should help improve the coverage rate in Europe. This new vaccine for seasonal influenza is marketed as Intanza® or IDflu®. Intanza®/IDflu® vaccine is now approved in the 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). In 2010, sanofi pasteur submitted Fluzone® ID for regulatory approval in the U. S. Phase III data on the investigational Fluzone® Intradermal vaccine showed intradermal vaccine needed less antigen and smaller injection volume than Fluzone®, administered by the intramuscular method, to induce a comparable immune response. Sanofi Pasteur is seeking licensure of Fluzone® ID in the U.S. for adults from 18 to 64 years of age.

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 experienced a successful launch in the U.S. in 2010.

In September 2009, the FDA approved the company's supplemental Biologics License Application for its Influenza A(H1N1) 2009 Monovalent Vaccine, marking an important milestone in the pandemic fight. The U.S. licensed vaccine is an inactivated influenza virus vaccine indicated for active immunization of adults and children aged six months and older against influenza caused by the A(H1N1) 2009 virus. Sanofi Pasteur provides the only influenza vaccine licensed in the United States for populations as young as six months of age. In 2010, sanofi pasteur delivered 126 million doses of A(H1N1) vaccines worldwide.

In November 2009, Panenza® (non-adjuvanted A(H1N1) vaccine) was registered by the *Agence Française de Sécurité Sanitaire des Produits de Santé* (AFSSAPS). The vaccine was made available to the French authorities, and vaccination began in France in November 2009. Panenza® is also registered in Spain, Luxemburg, Germany, Brazil, Hong Kong, Slovakia, Thailand, Tunisia and Turkey. In February 2010, the EMA granted marketing authorization for Humenza®, an adjuvanted A(H1N1) monovalent influenza vaccine for the active immunization of persons aged over 6 months against influenza infections caused by the 2009 A(H1N1) pandemic virus.

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

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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. In October 2010, sanofi pasteur released positive results. The Phase II clinical trial showed the QIV was immunologically non-inferior to trivalent vaccines with just one of the B strains, and their safety profiles did not materially differ. Our candidate vaccine entered phase III in October 2010.

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### **Adult and Adolescent Boosters**

The incidence of pertussis (whooping cough) is on the rise globally, affecting children, adolescents and adults (source: WHO publication WER 2005). Its 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<sup>®</sup>, 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<sup>®</sup> 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<sup>®</sup> is now registered in more than 50 countries.

Quadracel<sup>®</sup>, a quadrivalent booster vaccine (fifth dose) including diphtheria, tetanus, acellular pertussis and IPV is being developed for the U.S. market. It will allow a child to complete the entire childhood series with the fewest doses possible. A Phase III clinical trial is scheduled to start during the first half of 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<sup>®</sup>, the first conjugate quadrivalent vaccine against meningococcal meningitis, arguably the deadliest form of meningitis in the world. In 2009, sales of Menactra<sup>®</sup> continued to grow in the United States following implementation of the recommendations of the Advisory Committee on Immunization Practices (ACIP) for routine vaccination of pre-adolescents (11-12 years old), adolescents at high school entry (15 years old), and college freshmen living in dormitories. In October 2007, the FDA granted sanofi pasteur a license to expand the indication of Menactra<sup>®</sup> to children two years through 10 years of age. Menactra<sup>®</sup> is now indicated for people aged 2-55 years in the United States and in Canada. An Infant/Toddler (age 9/12 months) biological license application was submitted for Menactra<sup>®</sup> for regulatory approval in the United States in 2010. This project is aimed at covering a lower age group with a two-dose only schedule. Three pivotal clinical studies have been completed to support the 9-12 month indication. No safety concerns were identified and the vaccine was immunogenic for the four serotypes (A, C, Y, W-135). In 2010, sanofi pasteur also launched Menactra<sup>®</sup> in the Middle East and Latin America.

**Meningitis A, C, Y, W-135 conj. Second Generation** This project targets a second generation meningococcal vaccine that uses an alternative conjugation technology. In 2009, an Investigational New Drug application was submitted to the FDA in order to conduct the Phase II clinical trial in the United States. This trial started in December 2009, and enrollment was completed in 2010.

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's Travel/Endemics vaccines provide the widest range of traveler vaccines in the industry, and include hepatitis A, typhoid, rabies, yellow fever, cholera, Japanese encephalitis, measles, mumps, rubella (MMR) and anti-venoms. These vaccines are used in endemics settings in the developing world and are the basis for important partnerships with governments and organizations such as UNICEF. These vaccines 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.

Japanese encephalitis is endemic in Southeast Asia. Replacement of the currently available vaccines with a single-dose product is expected to provide a strong competitive advantage and facilitate expansion of vaccination programs. 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.

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The Vero serum-free improvement of our current Verorab<sup>®</sup> rabies vaccine (VRVg) would provide a worldwide, single rabies vaccine as a follow-up to our current rabies vaccine offerings. Results from the 2009 Phase I clinical trial demonstrated non-inferiority of VRVg versus Verorab<sup>®</sup>. A regulatory submission to AFSSAPS in France occurred in October 2010.

In December 2009, Shantha launched ShanChol<sup>™</sup>, India's first oral vaccine to protect against cholera in children and adults.

### **Animal Health: Merial**

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 (source: Vetnosis September 2010). Its net sales for 2010 amounted to 1,983 million (Merial's sales are not included in our consolidated net sales; for more information see Item 5 Results of Operations Year Ended December 31, 2010 Compared with Year Ended December 31, 2009 Net Sales Animal Health ).

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<sup>®</sup>, a topical anti-parasitic flea and tick brand for dogs and cats; Ivomec<sup>®</sup>, a parasiticide for the control of internal and external parasites in livestock; Heartgard<sup>®</sup>, a parasiticide for control of heartworm in companion animals; and Eprinex<sup>®</sup>, a parasiticide for use in cattle.

The compound patent protecting fipronil, the active ingredient of Frontline<sup>®</sup>, 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<sup>®</sup> products are generally still protected through formulation patents (directed to combinations) which expire at the latest in 2017 in Europe (August 2016 in the United States). Frontline<sup>®</sup> 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: 8-year data exclusivity and 10-year market exclusivity. In the United States, there is 10-year data exclusivity for products approved by the Environmental Protection Agency and an additional 5 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 5 years is granted for a new chemical entity and 3 years for a previously-approved active ingredient. No data exclusivity exists at present for veterinary vaccines in the United States.

Merial's major markets are the United States, France, Italy, the United Kingdom, Brazil, Australia, Japan, Germany, Spain and Canada.

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**

Since early 2009, we have been engaged in a wide-ranging transformation program designed to overcome the challenges facing the pharmaceutical industry. Research and development (R&D) is the first priority of this program. Rapid developments in the scientific environment, which are bringing about a veritable revolution in biopharmaceutical research, especially in biology, have generated profound and continuous change in the pharmaceutical environment. To anticipate the consequences of these changes and to maintain our innovative capacities, 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, while remaining fully focused on patient needs. Streamlined organizational structures are designed to make R&D more flexible and entrepreneurial and hence better adapted to overcome future challenges.

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### **Organization**

The resulting structure is focused on addressing patient needs, and not on therapeutic indications per se.

The new R&D organization is composed of three different types of units:

Entrepreneurial Units: Divisions, Therapeutic Strategic Units (TSUs) and Distinct Project Units (DPUs), focused on patient needs and driving value in collaboration with the external academic and biotech communities. Three global divisions have been created Diabetes, Oncology and Ophthalmology to further strengthen our position in these three areas. Five TSUs have been formed with a focus on major pathophysiologies, pressing public health needs, or major geographic areas (Aging, Fibrosis & Wound Repair, Immuno-Inflammation, Infectious Diseases and Asia-Pacific). DPUs have been created to drive projects outside the areas covered by the Divisions and TSUs. In addition, an exploratory unit will deliver early innovation, exploring and incubating new ideas, new technologies and new methodology.

Five scientific core platforms provide expert scientific support throughout the organization and operate as internal state-of-the-art service providers to the Entrepreneurial Units.

Enabling and Support functions are being realigned to support the new structure and governance arrangements.

This new model will foster a strategy of openness with closer cooperation between our researchers and external partners, and a more reactive and flexible organization that promotes the emergence of innovation and the grouping of researchers in stronger centers of expertise (oncology, diabetes, aging, etc.). Implementation of this new structure is ongoing.

In line with this approach, a number of alliances and acquisitions were entered into during 2010 with companies including Ascenta, Regulus, Metabolex and TargeGen. See Note D.1. and Note D.21.1. to our consolidated financial statements included at Item 18 of this annual report.

### **Portfolio**

During 2010, R&D followed up the rigorous and comprehensive portfolio review 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).

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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-aventis competencies;

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

financial: predicted return on investment for the project.

A Portfolio Management & Reporting Group provides permanent support to the new operating structures in management, reporting, and other processes. Complete R&D pipeline reviews will be conducted regularly.

At the end of 2010, 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:

	<b>Phase I</b>	<b>Phase II</b>	<b>Phase III</b>
Diabetes	SAR101099	SAR260093	Lixisenatide
		SAR236553	
Oncology	SAR3419	SAR245408 (XL147)	aflibercept
	SAR103168	SAR256212 (MM-121)	ombrabulin (AVE8062)
	SAR153192		SAR240550 (BSI-201)
	SAR245409 (XL765)		
	SAR302503 (TG101348)		
	SAR566658		
	SAR650984		
Ophthalmology	RetinoStat®	FOV1101	
		FOV2302	
		FOV2304	
TSU Aging	SAR110894		
	SAR113945		
	SAR114137		
	SAR152954		
	SAR292833		
TSU Fibrosis & Wound Repair	SAR100842		
	SAR302532		
TSU Infectious Diseases	SAR97276	ferroquine	
	SAR279356		
TSU Immuno-Inflammation	SAR231893	SAR153191	
DPU	SAR104772	SSR125543	semuloparin
	SAR411298	celivarone	otamixaban
			teriflunomide

Phase I studies are the first studies performed in humans, in healthy volunteers. Their main objective is to assess the tolerability, the pharmacokinetic profile and where possible the pharmacodynamic profiles of the new drug.

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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. This section focuses on Phase I compounds entries, and lists projects that were terminated in 2010.

### **Diabetes/Other Metabolic Disorders portfolio**

**SAR101099**, a Urotensin II Receptor Antagonist, entered Phase I. The product is being developed to reduce progression of diabetic nephropathy, a severe complication of diabetes.

The novel regenerative compound **SAR288223**, also known as Pancreate™, is in the preclinical stage. This product is in-licensed from CureDM, and aims to stimulate growth of islet cells in the pancreas, resulting in restoration of glucose control in the blood.

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### Lantus®

The Lantus® European marketing authorization was renewed in May 2010, and the Lantus® Pediatric Investigational Plan was adopted in September 2009.

The partnership with Wellstat for the development of a PKC epsilon inhibitor in the treatment of type 2 diabetes has been terminated.

### Oncology portfolio

In June 2010, we announced that we had signed an agreement to acquire TargeGen Inc., whose lead compound **TG 101348 (SAR302503)** is a potent inhibitor of Janus kinase 2 (JAK-2). It is an oral agent in Phase I/II and is being developed for the treatment of patients with myeloproliferative diseases including myelofibrosis (MF) and Polycythemia Vera (PV).

Also in June 2010, we signed an exclusive global collaboration and licensing agreement with Ascenta Therapeutics for a number of compounds that could restore tumor cell apoptosis. These compounds inhibit the p53-HDM2 (Human Double Minute 2) protein-protein interaction, leading potentially to reactivation of p53 tumor suppressor functions and thereby enhancing current cancer treatments.

In September 2010, sanofi-aventis and the **Belfer Institute of Applied Cancer Science at the Dana-Farber Cancer Institute (DFCI)** announced that they had entered into a collaboration and license agreement to identify novel oncology targets for the development of new therapeutic agents directed at such targets and related biomarkers.

The following late phase projects were terminated:

The global development of **alvocidib** was halted because the regulatory path proved longer than initially planned.

The development of **larotaxel** was terminated due to a lack of sufficient efficacy.

### Ophthalmology portfolio

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

RetinoStat® (gene therapy) for the treatment of Age-related Macular Degeneration (AMD) entered Phase I in December.



**TSU Aging portfolio**

**SAR110894** (H3 receptor antagonist for the treatment of Alzheimer's dementia) completed its Phase I program and is expected to start Phase II early 2011.

Three compounds progressed into clinical development (First In Man study)

**SAR113945**, an IKK- $\beta$  kinase inhibitor for the treatment of osteoarthritis (intra-articular administration);

**SAR114137**, a cathepsin S/K inhibitor for the treatment of osteoarthritis;

**SAR152954**, an H3 receptor antagonist.

GCR15300 (**SAR292833**), a first-in-class molecule for the treatment of chronic pain in-licensed from Glenmark, entered the portfolio in Phase I.

In December 2010, FDA put on hold all the clinical trials performed with anti-NGF drugs because of side effects occurring with products developed by other companies. Consequently, the development of SAR164877 (REGN475), co-developed with Regeneron, is on clinical hold.

A key collaboration agreement was signed with La Charite Hospital, Berlin, on stroke research.

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### **TSU Infectious Diseases portfolio**

**SAR279356** (first-in-class human monoclonal antibody for the prevention and treatment of *S. aureus*, *S. epidermidis*, *E. coli*, *Y. pestis* and other serious infections) The option to acquire a license from Alopexx for the development of SAR279356 was finalized in October 2010. The phase I study program has been completed successfully and Phase II is expected in the first half of 2011.

**SAR97276** is an antimalarial drug belonging to a new chemical class with an innovative mechanism of action, being developed for the treatment of severe malaria. The optimal dosing schedule is currently being evaluated in children with uncomplicated malaria, prior to initiating the treatment of subjects with severe *Plasmodium falciparum* malaria.

### **Other Projects portfolio**

The phase I program for **SAR104772**, an oral inhibitor of thrombin-activable fibrinolysis (TAFIa) for acute ischemic stroke, is ongoing. Preclinical development of the corresponding intravenous formulation (**SAR126119**) has been initiated, and the Phase I program is expected to start in 2011.

The CHMP issued a positive opinion on **Plavix**<sup>®</sup> in addition to aspirin for patients with atrial fibrillation who are at increased risk of stroke and are not suitable for oral anticoagulant treatment. A dossier is also under review in several other countries.

Pediatric development has been completed on **clopidogrel**. At a dose of 0.2 mg/kg determined on the basis of similar pharmacodynamic activity to clopidogrel 75 mg in adults was not effective in neonates and infants with congenital heart disease palliated with a systemic to pulmonary artery shunt.

In Japanese patients receiving elective PCI, **clopidogrel** was shown to have a better safety profile than ticlopidine. A dossier for this indication is in preparation for submission in Japan in 2011.

A dossier was submitted for **Uroxatral**<sup>®</sup> based on the results of the pediatric development. While the results could not demonstrate the efficacy of alfuzosin in patients with voiding disorders, all elements of the pediatric written request were met, and exclusivity has been granted for **Uroxatral**<sup>®</sup> in the United States thereby prolonging the product patent exclusivity until July 18, 2011.

Development of **SSR411298** a fatty acid amide hydrolase (FAAH) inhibitor in major depressive disorder in elderly patients was discontinued, as the results of the Phase II dose finding study did not support progression to Phase III. Alternative development strategies are under evaluation based on analysis of the data.

**Nerispiridine** (K<sup>+</sup> and Na<sup>+</sup> Channel Blocker, symptomatic treatment for multiple sclerosis; Phase II) was terminated in symptomatic therapy for MS because it failed to meet the endpoints of the Phase II dose ranging study, as reported in April 2010

### **Other discovery/ development partnerships**

A licensing agreement was signed in May with Glenmark Pharmaceuticals for the development and commercialization of new products in chronic pain treatment. The first molecule included in this agreement entered the portfolio in Phase I (SAR292833)

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GRC15300) (see TSU Aging portfolio above).

A global strategic alliance for the discovery, development and commercialization of microRNA therapeutics was signed with Regulus in June 2010. These products are at the discovery stage.

### **Vaccines Research and Development**

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

**Table of Contents***Portfolio*

The sanofi pasteur R&D portfolio includes 15 vaccines currently in advanced development as shown in the table below. The portfolio includes 6 vaccines for novel targets and 9 vaccines which are enhancements of existing vaccine products.

<b>Phase I</b>	<b>Phase IIa</b>	<b>Phase IIb</b>	<b>Phase III</b>	<b>Submitted</b>
<b>Streptococcus pneumonia *</b>	<b>Rabies *</b>		<b>Hexaxim</b>	<b>Menactra®</b>
Meningitis & pneumonia vaccine	mAb post exposure prophylaxis		DTP-HepB-Polio-Hib vaccine <sup>(1)</sup>	Meningococcal conjugate vaccine for Infants/Toddlers at 9-12 months
<b>Tuberculosis *</b>	<b>Meningitis A,C,Y,W conj.</b>		<b>Quadracel®</b>	<b>Fluzone® ID</b>
Recombinant subunit vaccine	2 <sup>nd</sup> generation		DTP <sup>(1)</sup> IPV vaccine 4-6 years U.S.	Seasonal influenza vaccine. intradermal micro-injection U.S.
<b>Rotavirus (Shantha)</b>	Meningococcal conjugate Infant vaccine		<b>Dengue *</b>	
Live Attenuated Tetravalent Rotavirus oral vaccine	<b>Rabies VRVg</b>		Mild-to-severe dengue fever vaccine	
	Purified vero rabies vaccine			
<b>Pseudomonas aeruginosa *</b>	<b>DTP-HepB-Polio-Hib vaccine <sup>(1)</sup></b>		<b>Fluzone® QIV</b> Quadrivalent inactivated influenza vaccine	
Antibody fragment product	<b>ACAM C. diff *</b>			
Prevention of ventilator-associated pneumonia	Clostridium difficile Toxoid vaccine			

<sup>(1)</sup> D=Diphtheria, T=Tetanus, Hib=Haemophilus influenzae b, HepB=Hepatitis B, P=Pertussis.

\* New targets

**Project highlights**

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

## **Influenza**

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

## **Pediatric Combination & Adolescent/Adult Boosters**

Several pediatric vaccines are under development. Tailored for specific markets, they are aimed at protecting against five or all six of the following diseases: diphtheria, tetanus, pertussis, poliomyelitis (polio), *Haemophilus influenzae* type b infections and hepatitis B.

## **Meningitis**

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

## **Pneumococcal Vaccine**

*Streptococcus pneumoniae* bacteria is the leading etiological agent causing severe infections such as pneumonia, septicemia, meningitis and otitis media, and is responsible for over three million deaths per year worldwide, of which one million are children. Anti-microbial resistance in *Streptococcus pneumoniae* has complicated the treatment of pneumococcal disease and further emphasized the need for vaccination to prevent large-scale morbidity and mortality.

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Sanofi Pasteur is focused on the development of a multi-protein-based pneumococcal vaccine. This approach should result in a vaccine with superior serotype coverage as compared to current polysaccharide or conjugate based vaccines. The first Phase I clinical trial of a bivalent formulation was initiated in February 2010 and completed enrollment in 2010. A second Phase I clinical trial to evaluate a third antigen was initiated in June 2010.

### **Rabies Vaccine**

**Rabies mAb Post Exposure Prophylaxis** This product consists of two rabies monoclonal antibodies (MABs) that will be used in association with the rabies vaccine for post-exposure prophylaxis. It is being developed in collaboration with Crucell. A Phase II clinical trial to evaluate safety and immunogenicity will be initiated in 2011.

### **New Vaccine Targets**

**Dengue** Dengue fever has increasing epidemiological importance due to global socio-climatic changes. It is a major medical and economic burden in the endemic areas of Asia-Pacific, Latin America and Africa. It is also one of the leading causes of fever among travelers. Multiple approaches have been tested to develop a vaccine covering the four viral serotypes of dengue fever in order to prevent this disease and its severe complications (hemorrhagic fever). Results of a Phase II clinical trial in adults in the United States demonstrated proof of concept of the lead vaccine candidate based on ChimeriVax technology. Sanofi Pasteur's dengue vaccine research program includes ongoing clinical studies (adults and children) in several countries in endemic regions. The first Phase III study was initiated in October 2010 in Australia. This final stage of clinical development aims at demonstrating that production of the vaccine on an industrial scale will meet the consistency criteria required for market authorizations. The study in Australia is the first to use our dengue vaccine doses produced on an industrial scale. Further Phase III studies to evaluate efficacy will begin in 2011.

**Tuberculosis** Statens Serum Institute of Denmark (SSI) has granted sanofi pasteur a license to its technology with regard to the use of certain fusion proteins in the development of a tuberculosis vaccine. The license from SSI includes access to the Intercell IC31<sup>®</sup> adjuvant. The candidate vaccine is made up of recombinant protein units. Results from the 2008 Phase I trial found that the H4/IC31 tuberculosis vaccine candidate was safe when administered to healthy adults living in a region of high endemic tuberculosis. Rapid antigen-specific T cell responses were induced following a single dose of the investigational vaccine. A second Phase I trial was initiated in Switzerland in December 2010.

**HIV** The Phase III clinical trial in Thailand completed in 2009 provided the first concrete evidence since the discovery of the HIV virus in 1983 that a vaccine against HIV is potentially feasible. Additional work is required to develop and test a vaccine suitable for approval and worldwide use. During 2010, the Thai study partnership (the U.S. Army, the National Institute of Allergy and Infectious Diseases of the National Institutes of Health (NIH), the Ministry of Public Health of Thailand, and sanofi pasteur) continued to work together in monitoring patients infected with HIV in the Phase III trial, evaluating existing clinical samples using state-of-the-art immunological tools, and designing future studies. Sanofi Pasteur has also initiated discussions with potential industrial partners to substantiate and extend the vector prime/protein subunit boost regimen used in the Phase III trial. Public-private partnerships will be evaluated as a source of funding for future clinical trials and product development.

**ACAM-Cdiff** *Clostridium difficile* is a major public health concern in North America and Europe. In hospitals, it is the leading cause of infectious diarrhea in adults, particularly the elderly. The epidemiology of *Clostridium difficile* associated disease (CDAD) has been increasing at an alarming rate since 2003, driven primarily by the emergence of a treatment-resistant, highly virulent strain CD027. There is currently no vaccine available and the only vaccine candidate currently in development is ACAM-Cdiff. ACAM-Cdiff is a toxoid-based vaccine. Toxoids have been used as the basis of a number of highly successful licensed vaccines. This vaccine candidate has successfully completed Phase I

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clinical trials with more than 200 participants in which safety and immunogenicity were evaluated. Sanofi Pasteur received a positive response from the United States FDA's Center for Biologics Evaluation & Research (CBER) on the Fast Track Development Program submission in 2010. In November 2010, our *Clostridium difficile* vaccine started Phase II of clinical study in the U.S. This

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trial is focused on evaluating prevention of the first episode of *Clostridium difficile* infection (CDI) in at-risk individuals, which includes adults with imminent hospitalization or current or impending residence in a long-term care or rehabilitation facility.

***Pseudomonas aeruginosa*** In February 2010, sanofi pasteur entered into an agreement with KaloBios Pharmaceuticals, a U.S.-based, privately held biotech company, for the development of a Humaneered antibody fragment to both treat and prevent *Pseudomonas aeruginosa* (*Pa*) infections. Most serious *Pa* infections occur in hospitalized and critically or chronically ill patients primarily affecting the respiratory system in susceptible individuals and are a serious clinical problem due to their resistance to antibiotics. The two primary target indications for the antibody are prevention of *Pa* associated pneumonia in mechanically ventilated patients in hospitals, and prevention of relapses and potential improvement of treatment outcomes in patients with an ongoing *Pa* infection. Under the terms of the agreement, sanofi pasteur acquired worldwide rights for all disease indications related to *Pa* infections except cystic fibrosis and bronchiectasis, which sanofi pasteur has the option to obtain at a later date. KaloBios has already completed phase I clinical trials one in healthy volunteers and one in cystic fibrosis patients and a small proof of concept phase II clinical trial in mechanically ventilated patients.

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

## **Patents, Intellectual Property and Other Rights**

### **Patent Protection**

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

active ingredients;

pharmaceutical formulations;

product manufacturing processes;

intermediate chemical compounds;

therapeutic indications/methods of use;

delivery systems; and



enabling technologies, such as assays.

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

The product may additionally benefit from the protection of patents obtained during development or after the product's initial marketing approval. The protection a patent affords the related product depends upon the type of patent and its scope of coverage, and may also vary from country to country. In Europe for instance, applications for new patents may be submitted to the European Patent Office (EPO), an intergovernmental organization which centralizes filing and prosecution. As of December 2010, an EPO patent application may

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cover the 38 European Patent Convention member states, including all 27 member states of the European Union. The granted European Patent establishes corresponding national patents with uniform patent claims among the member states. However, some older patents were not approved through this centralized process, resulting in patents having claim terms for the same invention that differ by country. Additionally, a number of patents prosecuted through the EPO may pre-date the European Patent Convention accession of some current European Patent Convention member states, resulting in different treatment in those countries.

We monitor our competitors and vigorously seek to challenge patent infringement when such challenges would negatively impact our business objectives. See Note D.22.b) to the consolidated financial statements included in Item 18 of this annual report.

The expiration or loss of an active ingredient patent may result in significant competition from generic products and can result in a dramatic reduction in sales of the original branded product. See Item 3. Key Information D. Risk Factors Risks Relating to Legal Matters Generic versions of some of our products may be approved for sale in one or more of their major markets. In some cases, it is possible to continue to obtain commercial benefits from product manufacturing trade secrets or from other types of patents, such as patents on processes, intermediates, structure, formulations, methods of treatment, indications or delivery systems. Certain categories of products, such as traditional vaccines and insulin, have been historically relatively less reliant on patent protection and may in many cases have no patent coverage, although it is increasingly frequent for novel vaccines and insulins to be patent protected. See Focus on Biologics below. Patent protection is an important factor in our animal health business, but is of comparatively lesser importance to our Consumer Health Care and generics businesses, which rely principally on trademark protection.

**Regulatory Exclusivity**

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

In the United States, the FDA will not grant final marketing approval to a generic competitor for a New Chemical Entity (NCE) until the expiration of the regulatory exclusivity period (generally five years) that commences upon the first marketing authorization of the reference product. The FDA will accept the filing of an Abbreviated New Drug Application (ANDA) containing a patent challenge one year before the end of this regulatory exclusivity period (see the descriptions of ANDAs in Product Overview Challenges to Patented Products below). In addition to the regulatory exclusivity granted to NCEs, significant line extensions of existing NCEs may qualify for an additional three years of regulatory exclusivity. Also, under certain limited conditions, it is possible to extend unexpired U.S. regulatory and patent-related exclusivities by a pediatric extension. See Pediatric Extension, below.

In the European Union, regulatory exclusivity is available in two forms: data exclusivity and marketing exclusivity. Generic drug applications will not be accepted for review until eight years after the first marketing authorization (data exclusivity). This eight-year period is followed by a two-year period during which generics cannot be marketed (marketing exclusivity). The marketing exclusivity period can be extended to three years if, during the first eight-year period, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which are deemed to provide a significant clinical benefit over existing therapies. This is known as the 8+2+1 rule.

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While these exclusivities are intended to be applicable throughout the European Union, in a decentralized system, national authorities may act in ways that are inconsistent with EU regulatory exclusivity. For example, although European marketing exclusivity for clopidogrel expired in July 2008, in May 2008 the German Health authority BfArM had already registered a competitor's clopidogrel product based on a contested interpretation of the law. Furthermore, in 2006, the Polish and Bulgarian authorities registered generics of clopidogrel bisulfate based on these countries' contested position that EU marketing exclusivities need not be applied by individual countries where generics had been approved prior to their accession date.

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In Japan, the regulatory exclusivity period varies from four years (for medicinal products with new indications, formulations, dosages, or compositions with related prescriptions) to six years (for new drugs containing a medicinal composition, or requiring a new route of administration) to eight years (for drugs containing a new chemical entity) to ten years (for orphan drugs or new drugs requiring pharmaco-epidemiological study).

## **Emerging Markets**

One of the main limitations on our operations in emerging market countries is the lack of effective intellectual property protection or enforcement for our products. The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIP) has required developing countries to amend their intellectual property laws to provide patent protection for pharmaceutical products since January 1, 2005 although it provides a limited number of developing countries an extension to 2016. Additionally, these same countries frequently do not provide non-patent exclusivity for innovative products. While the situation has gradually improved, the lack of protection for intellectual property rights or the lack of robust enforcement of intellectual property rights poses difficulties in certain countries. Additionally, in recent years a number of countries faced with health crises have waived or threatened to waive intellectual property protection for specific products, for example through compulsory licensing. See Item 3. Key Information D. Risk Factors Risks Relating to Our Business The globalization of the Group's business exposes us to increased risks.

## **Pediatric Extension**

In the United States and Europe, under certain conditions, it is possible to extend a product's regulatory exclusivities for an additional period of time by providing data regarding pediatric studies.

In the United States, the FDA may ask a company for pediatric studies if it has determined that information related to the use of the drugs in the pediatric population may produce health benefits. The FDA has invited us by written request to provide additional pediatric data on several of our main products. Under the Hatch-Waxman Act, timely provision of data meeting the FDA's requirements (regardless of whether the data supports a pediatric indication) may result in the FDA extending regulatory exclusivity and patent life by six months, to the extent these protections have not already expired (the so-called pediatric exclusivity). The main products having received past FDA grants of pediatric exclusivity are Aprovel<sup>®</sup>, Lantus<sup>®</sup>, Allegra<sup>®</sup>, Ambien<sup>®</sup>/Ambien<sup>®</sup> CR, Plavix<sup>®</sup> and Taxotere<sup>®</sup>.

In Europe, a regulation on pediatric medicines came into force on January 26, 2007. This regulation was implemented in 2009, and provides for pediatric research obligations with potential associated rewards including extension of patent protection (for patented medicinal products) and regulatory exclusivity for pediatric marketing authorization (for off-patent medicinal products). For additional details, see Regulation below.

Japanese regulations do not currently offer the possibility of similar extensions in exchange for pediatric study results.

## **Product Overview**

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We summarize below the intellectual property coverage in our major markets of the marketed products described above at [Pharmaceutical Products - Main Pharmaceutical Products](#) . Concerning animal health products, Meril's intellectual property coverage is described above (see [Animal Health: Meril](#) ). In the discussion of patents below, we focus on active ingredient patents (compound patents) and any later filed improvement patents listed in the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations (the [Orange Book](#) ) or on their foreign equivalents, because these patents tend to be the most relevant in the event of an application by a competitor to produce a generic version of one of our products or the equivalent of these patents in other countries (see [Challenges to Patented Products](#) below). In some cases, products may also benefit from pending patent applications and from patents not eligible for Orange Book listing (*e.g.*, patents claiming industrial processes). In each case below, we specify whether the active ingredient is claimed by an unexpired patent. Where patent terms have been extended to compensate for regulatory delay, the extended dates are presented below. U.S. patent expirations presented below reflect U.S. Patent and Trademark Office dates, and therefore do not reflect six-month pediatric extensions to the FDA's Orange Book dates for the

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products concerned (Aprovel<sup>®</sup>, Lantus<sup>®</sup>, Stilnox<sup>®</sup>/Ambien<sup>®</sup> CR, Allegra<sup>®</sup>, Plavix<sup>®</sup> and Taxotere<sup>®</sup>). A footnote indicates those cases where the FDA's Orange Book reflects a pediatric exclusivity extended 6 months beyond the United States Patent and Trademarks Office (U.S. PTO) patent expiration date.

We do not provide later filed improvement patent information relating to formulations already available as an unlicensed generic. References below to patent protection in Europe indicate the existence of relevant patents in most major markets in the European Union. Specific situations may vary country by country, most notably with respect to older patents and to countries having only recently joined the European Union.

We additionally set out any regulatory exclusivity from which these products continue to benefit in the United States, European Union or Japan. Regulatory exclusivities presented below incorporate any pediatric extensions obtained. While EU regulatory exclusivity is intended to be applied throughout the European Union, in some cases member states have taken positions prejudicial to our exclusivity rights. See Regulatory Exclusivity above.

<p><b>U.S.</b> Compound: August 2014<sup>1</sup></p>	<p><i>Lantus<sup>®</sup> (insulin glargine)</i> <b>E.U.</b> Compound: November 2014 in most of the EU; no compound patent in force in much of Eastern Europe</p>	<p><b>Japan</b> Compound: November 2014  Regulatory exclusivity: October 2011</p>
<p><b>U.S.</b> Compound: June 2018</p>	<p><i>Apidra<sup>®</sup> (insulin glulisine)</i> <b>E.U.</b> Compound: September 2019 in most of the EU</p>	<p><b>Japan</b> Compound: May 2022</p>
<p>Later filed improvement patents: formulation March 2022 and January 2023</p>	<p>Regulatory exclusivity: September 2014</p>	<p>Later filed improvement patent: formulation July 2022  Regulatory exclusivity: April 2017</p>
<p><b>U.S.</b> Compound: expired in May 2010<sup>2</sup></p>	<p><i>Taxotere<sup>®</sup> (docetaxel)</i> <b>E.U.</b> Compound: expired in November 2010 in most of the EU</p>	<p><b>Japan</b> Compound: June 2012</p>
<p>No generic products presently on the market.</p>	<p>Later filed improvement patents: additional patent coverage (2012 to 2013)</p>	<p>Later filed improvement patents: formulation running through November 2013</p>
	<p>Genericized</p>	

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	<i>Eloxatine® (oxaliplatin)</i> <sup>3</sup>	
<b>U.S.</b>	<b>E.U.</b>	<b>Japan</b>
Compound: expired	Compound: expired	N/A
Later filed improvement patents: coverage ranging through August 2016 <sup>4</sup>	Genericized	

<sup>1</sup> pediatric exclusivity until February 2015.

<sup>2</sup> pediatric exclusivity until November 2010.

<sup>3</sup> We do not own most Eloxatine® patents but license them from Debiopharm for marketing.

<sup>4</sup> Was genericized in 2010 until settlement of litigation. Is not currently genericized and may or may not retain exclusivity until August 9, 2012, depending on outcome of settlement dispute presently in court.

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<p><b>U.S.</b> Compound: March 2016 (up to 2021 if PTE is granted)</p>	<p><i>Jevtana® (cabazitaxel)</i> <b>E.U.</b> Compound: March 2016 (patent term extension to be determined once product is approved in Europe)</p>	<p><b>Japan</b> Compound: March 2016 (patent term extension to be determined once product is approved in Japan)</p>
<p>Later filed improvement patents: coverage ranging through 2025</p>		
<p>Regulatory exclusivity: June 2015</p>		
<p><b>U.S.</b> Compound: no compound patent coverage</p>	<p><i>Lovenox® (enoxaparin sodium)</i> <b>E.U.</b> Compound: June 2011 in part of the EU; exceptions: no compound patent in force in France, Germany, Spain, Portugal, Finland, Norway, Greece and much of Eastern Europe</p>	<p><b>Japan</b> Compound: expired</p>
<p>Genericized</p>		<p>Regulatory exclusivity: 2016</p>
<p><b>U.S.</b> Compound: November 2011<sup>1</sup></p>	<p><i>Plavix® (clopidogrel bisulfate)</i> <b>E.U.</b> Genericized (other clopidogrel salts)</p>	<p><b>Japan</b> Compound: 2013 Regulatory exclusivity: 2014</p>
<p><b>U.S.</b> Compound: September 2011<sup>2</sup></p>	<p><i>Aprovel® (irbesartan)</i> <b>E.U.</b> Compound: August 2012 in most of the EU; exceptions: expires March 2011 in the Czech Republic, Hungary, Romania, Slovakia and 2013 in Lithuania and Latvia. No compound patent in force in Spain, Portugal, Finland, Norway and much of Eastern Europe</p>	<p><b>Japan</b> Compound: 2016</p>
	<p>Later filed improvement patents: formulation coverage ranging through 2016</p>	<p>Later filed improvement patent: formulation (2021)</p>
		<p>Regulatory exclusivity: 2016</p>
	<p>Generics on the market in some EU countries</p>	
<p><b>U.S.</b> N/A</p>	<p><i>Tritace® (ramipril)</i> <b>E.U.</b> Compound: expired</p>	<p><b>Japan</b> Compound: expired</p>
	<p>Genericized</p>	

<sup>1</sup> pediatric exclusivity until May 2012.

<sup>2</sup> pediatric exclusivity until March 2012.



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<p><b>U.S.</b> Compound: July 2011</p> <p>(2016 if PTE petition is granted)</p> <p>Later filed improvement patent: formulation (2018)</p> <p>Regulatory exclusivity: July 2014</p>	<p><b>Multaq® (dronedaron hydrochloride)</b> <b>E.U.</b> Compound: August 2011</p> <p>Later filed improvement patent: formulation (2018; 2023 if SPC granted)</p> <p>Regulatory exclusivity: 2019</p>	<p><b>Japan</b> Compound: August 2011</p>
<p><b>U.S.</b> Compound patent: expired</p> <p>Later filed improvement patent; Ambien® CR formulation (2019)</p> <p>Genericized</p>	<p><b>Stilnox® (zolpidem tartrate)</b> <b>E.U.</b> Compound patent: expired</p> <p>Genericized</p>	<p><b>Japan</b> Compound patent: expired</p> <p>Regulatory exclusivity: expired.</p>
<p><b>U.S.</b> N/A</p>	<p><b>Copaxone® (glatiramer acetate) <sup>1</sup></b> <b>E.U.</b> Compound: 2015</p>	<p><b>Japan</b> N/A</p>
<p><b>U.S.</b> N/A</p>	<p><b>Depakine® (sodium valproate)</b> <b>E.U.</b> Compound: expired</p> <p>Later filed improvement patent: Depakine® Chronosphere® formulation (2017)</p>	<p><b>Japan</b> Compound: expired</p> <p>Later filed improvement patent: Depakine® Chronosphere® formulation (2017)</p>
<p><b>U.S.</b> Compound: expired</p> <p>Converted to Over-the-Counter</p>	<p><b>Allegra® (fexofenadine hydrochloride)</b> <b>E.U.</b> Compound: expired</p> <p>Genericized</p>	<p><b>Japan</b> Compound: expired</p> <p>Later filed improvement patents: coverage ranging through 2016</p>
<p><b>U.S.</b> Compound: expired</p> <p>Later filed improvement patents: formulation and method of use July 2016 Generic licensed as early as 2011 <sup>2</sup></p>	<p><b>Nasacort® (triamcinolone acetonide) <sup>2</sup></b> <b>E.U.</b> Compound: expired</p> <p>Later filed improvement patent: formulation 2017</p>	<p><b>Japan</b> Compound: expired</p>

- 1. Sanofi-aventis has licensed Copaxone® from Teva, with which we co-promote the product.*
- 2. A license was granted to Barr Laboratories, Inc. in settlement of patent litigation.*

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<p><b>U.S.</b> Compound: expired <sup>3</sup></p> <p>Genericized</p>	<p><i>Xatral® (alfuzosin hydrochloride)</i></p> <p><b>E.U.</b> Compound: expired</p> <p>Genericized</p>	<p><b>Japan</b> Compound: expired</p> <p>Genericized</p>
<p><b>U.S.</b> Compound: December 2013</p> <p>Later filed improvement patents: coverage ranging through June 2018</p>	<p><i>Actonel® (risedronate sodium) <sup>4</sup></i></p> <p><b>E.U.</b> Compound: expired in December 2010 in Austria, Belgium, France, Germany, the Netherlands, the United Kingdom, Sweden, Switzerland and Italy; previously expired elsewhere</p> <p>Later filed improvement patents: coverage ranging through 2018</p>	<p><b>Japan</b> N/A</p>

3. *Pediatric exclusivity for Uroxatral® until July 2011.*

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

Patents held or licensed by the Group do not in all cases provide effective protection against a competitor's generic version of our products. For example, notwithstanding the patents listed above competitors have launched generic versions of Eloxatine® in Europe and in the United States, Allegra® in the United States (prior to the product being switched to over-the-counter status) and Plavix® in Europe.

We caution the reader that there can be no assurance that we will prevail when we assert a patent in litigation and that there may be instances in which the Group determines that it does not have a sufficient basis to assert one or more of the patents mentioned in this report, for example in cases where a competitor proposes a formulation not appearing to fall within the claims of our formulation patent, a salt or crystalline form not claimed by our composition of matter patent, or an indication not covered by our method of use patent. See Item 3. Key Information D. Risk Factors – Risks Relating to Legal Matters. Generic versions of some of our products may be approved for sale in one or more of their major markets.

As disclosed in Note D.22.b) to our consolidated financial statements included at Item 18 of this annual report, we are involved in significant litigation concerning the patent protection of a number of products.

**Challenges to Patented Products**

In the United States, companies have filed Abbreviated New Drug Applications (ANDAs), containing challenges to patents related to a number of our products. An ANDA is an application by a drug manufacturer to receive authority to market a generic version of another company's approved product, by demonstrating that the purportedly generic version has the same properties as the original approved product. ANDAs may not be filed with respect to drugs licensed as a biological. See Focus on Biologics below. An ANDA relies on the safety and other technical data of the original approved product, and does not generally require the generic manufacturer to conduct clinical trials (thus the name abbreviated new drug application), presenting a significant benefit in terms of time and cost. As a result of regulatory protection of our safety and other technical data, the ANDA may generally be filed only five years following the initial U.S. marketing authorization of the original product. See Regulatory Exclusivity above. This period can be reduced to four years if the ANDA includes a challenge to a patent listed in the FDA's Orange Book. However, in such a case if the patent holder or licensee brings suit in response to the patent challenge within the statutory window, then

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the FDA is barred from granting final approval to an ANDA during the 30 months following the patent challenge (this bar being referred to in our industry as a 30-month stay ), unless, before the end of the 30 months, a court decision or settlement has determined either that the ANDA does not infringe the listed patent or that the listed patent is invalid and/or unenforceable.

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FDA approval of an ANDA after this 30-month period does not resolve outstanding patent disputes, but it does remove the regulatory impediments to a product launch by a generic manufacturer willing to take the risk of later being ordered to pay damages to the patent holder.

Procedures comparable to the ANDA exist in other major markets.

In the European Union, a generic drug manufacturer may only reference the data of the regulatory file for the original approved product after data exclusivity has expired. However, there is no patent listing system in Europe comparable to the Orange Book, which would allow the patent holder to prevent the competent authorities from granting marketing approval by bringing patent infringement litigation prior to approval. As a result, generic products may be approved for marketing following the expiration of marketing exclusivity without regard to the patent holder's rights. Nevertheless, in most of these jurisdictions once the competing product is launched and in some jurisdictions, even prior to launch (once launch is imminent), the patent holder can seek an injunction against such marketing if it believes its patents are infringed. See Note D.22.b) to our consolidated financial statements included at Item 18 of this annual report.

The accelerated ANDA-type procedures are potentially applicable to most, but not all, of the products we manufacture. See Focus on Biologics and Regulation below. We seek to defend our patent rights vigorously in these cases. Success or failure in the assertion of a given patent against one competing product is not necessarily predictive of the future success or failure in the assertion of the same patent - or *a fortiori* the corresponding foreign patent - against a second competing product due to factors such as possible differences in the formulations of the competing products, intervening developments in law or jurisprudence, local variations in the patents and differences in national patent law and legal systems. See Item 3. Key Information D. Risk Factors Risks Relating to Legal Matters Generic versions of our products may be approved for sale in one or more of their major markets .

## **Trademarks**

Our products are sold around the world under trademarks that we consider to be of material importance in the aggregate. Our trademarks help to maintain the identity of our products and services, and protect the sustainability of our growth. It is our policy to register our trademarks with a strategy adapted to each product or service depending on their countries of commercialization: *i.e.*, on a worldwide basis for worldwide products or services, or on a regional or local basis for regional or local products or services.

Our trademarks are monitored and defended based on this policy and in order to prevent infringement and/ or unfair competition.

Our trademarks contribute to the identity of our products and services, and help support their development.

The degree of trademark protection varies country by country, as each state applies its own trademark laws to trademarks used in its territory. In most countries, trademark rights may only be obtained by registration. In some countries, trademark protection is primarily based on use. Registrations are granted for a fixed term (in most cases ten years) and are renewable indefinitely, but in some instances may be subject to the continued use of the trademark.

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When trademark protection is based on use, it covers the products and services for which the trademark is used. When trademark protection is based on registration, it covers only the products and services designated in the registration. Additionally, in certain cases, we may enter into a coexistence agreement with a third-party that owns potentially conflicting rights in order to better protect and defend our trademarks.

### **Production and Raw Materials**

Our principal manufacturing processes consist of three stages: the manufacture of active ingredients, the incorporation of those ingredients into products, and packaging.

We generally develop and manufacture the active ingredients that we use in our products. We have a general policy of producing the active ingredients for our principal products at our own plants in order to minimize our

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dependence on external manufacturers and control the product throughout the production cycle. In some cases however, we have outsourced certain production elements, especially as part of supply agreements entered into within the framework of plant divestitures, or in order to adapt to market growth in emerging markets. As a result, we outsource a portion of the production of the active ingredients used in Stilnox<sup>®</sup> and Xatral<sup>®</sup>, and certain formulations of various pharmaceutical products. Our main subcontractors are Famar, Haupt, Patheon, Catalent and Sofarimex. These subcontractors are required to follow our guidelines in terms of quality, logistics and other criteria. See Item 3. Key Information D. Risk Factors Risks Relating to 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, delay the launch of new products and adversely affect our operating results and financial condition .

Among our other key products, we also depend on third parties in connection with the manufacture of Eloxatine<sup>®</sup>. Under the terms of our license agreement with Debiopharm, we purchase the active ingredient from Debiopharm, and the production of the finished lyophilized product is outsourced to two manufacturers. The manufacturing of the liquid form of Eloxatine<sup>®</sup> is conducted at our facility in Dagenham (United Kingdom).

Under our partnership with BMS, a multi-sourcing organization and security stock are in place for Plavix<sup>®</sup>/clopidogrel bisulfate and Aprovel<sup>®</sup> / irbesartan.

We purchase the raw materials used to produce Lovenox<sup>®</sup> from a number of sources.

Our main European pharmaceutical production facilities are located in France, Germany, Italy, Spain, the United Kingdom and Hungary. In North America, we run two facilities in the United States (Kansas City and Saint Louis), supplemented recently with the acquisition of Chattem (Tennessee), and one in Canada (Laval). We have one plant in Japan (Kawagoe) and additional facilities located in many other parts of the world. To carry out the production of vaccines, sanofi pasteur uses a wide industrial operations network, with sites located in North America, France, China, Thailand, Argentina and India. A new antigen production unit in Mexico for seasonal and pandemic influenza vaccines is expected to commence commercial production in 2012, once the necessary production and marketing approvals have been obtained from Mexican officials.

All of our pharmaceutical and vaccine facilities are Good Manufacturing Practices (GMP) compliant in accordance with international guidelines. Our main facilities are also FDA approved, including our pharmaceutical facilities in Ambarès, Tours, Le Trait, Maisons-Alfort and Compiègne in France, Dagenham and Holmes Chapel in the United Kingdom, Frankfurt in Germany, Veresegyhaz in Hungary, Saint Louis in the United States and Laval in Canada, our vaccines facilities at Marcy 1 Etoile and Val de Reuil (hosting a distribution center) in France, Swiftwater in the United States and Toronto in Canada. Wherever possible we seek to have multiple plants approved for the production of key active ingredients and finished products, as in the case of Lovenox<sup>®</sup> for example.

In February 2011, we received an FDA warning letter concerning part of our Frankfurt facility following a routine FDA inspection in September 2010. The warning letter cites CGMP compliance issues in certain manufacturing processes, without referring to specific products. While we take the warning seriously and are working to address the remaining recommendations, we are also confident that none of the issues raised in the letter compromise the quality of our marketed products or our ability to continue to supply the markets with all products.

More details about our manufacturing sites are set forth below at D. Property, Plant and Equipment .

**Health, Safety and Environment (HSE)**

The manufacturing and research operations of sanofi-aventis are subject to increasingly stringent health, safety and environmental laws and regulations. These laws and regulations are complex and rapidly changing, and sanofi-aventis invests the necessary sums in order to comply with them. This investment, which aims to respect health, safety and the environment, varies from year to year and totaled approximately 113 million in 2010.

The applicable environmental laws and regulations may require sanofi-aventis to eradicate or reduce the effects of chemical substance usage and release at its various sites. The sites in question may belong to the



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

Moreover, as for a number of companies involved in the pharmaceutical, chemical and agrochemical industries, soil and groundwater contamination has occurred at some Group sites in the past, and may still occur or be discovered at others. In the Group's case, such sites are mainly located in the United States, Germany, France, Hungary, the Czech Republic, Slovakia, Brazil, Italy and the United Kingdom. As part of a program of environmental audits conducted over the last few years, detailed assessments of the risk of soil and groundwater contamination have been carried out at current and former Group sites. In cooperation with national and local authorities, the Group constantly assesses the rehabilitation work required and this work has been implemented when appropriate. Long-term rehabilitation work is in progress or planned in Rochester, Cincinnati, Mount-Pleasant, East Palo Alto, Ambler and Portland in the United States; Frankfurt in Germany; Beaucaire, Valernes, Limay, Rousset, Romainville, Neuville and Vitry in France; Dagenham in the United Kingdom; Brindisi and Garessio in Italy; Ujpest in Hungary; Hlohovec in Slovakia; Prague in the Czech Republic; and on a number of sites divested to third parties and covered by contractual environmental guarantees granted by sanofi-aventis. Sanofi-aventis may also have potential liability for investigation and cleanup at several other sites.

Provisions have been established for the sites already identified and to cover contractual guarantees for environmental liabilities for sites that have been divested. For example, in 2007 the State of New Jersey initiated a claim against Bayer CropScience seeking compensation for damages caused to natural resources (NRD) at a former Rhône-Poulenc site in the United States, resulting in indemnification claims by Bayer CropScience against the Group under contractual environmental guarantees granted at the time of Bayer's acquisition of the CropScience business. Rehabilitation studies and an NRD assessment are underway in a similar project in Portland, Oregon. Potential environmental contingencies arising from certain business divestitures are described in Note D.22.e) to the consolidated financial statements included at Item 18 of this annual report. In 2010, sanofi-aventis spent 45 million on rehabilitating sites previously contaminated by soil or groundwater pollution. During the year ended December 31, 2010, a comprehensive review was carried out relating to the legacy of environmental pollution. In light of data collected during this review, the Group adjusted the provisions to approximately 781 million as at December 31, 2010.

Because of changes in environmental regulations governing site remediation the Group's provisions for remediation obligations may not be adequate due to the multiple factors involved, such as the complexity of operational or previously operational sites, the nature of claims received, the rehabilitation techniques considered, the planned timetable for rehabilitation, and the outcome of discussions with national regulatory authorities or other potentially responsible parties, as in the case of multiparty sites. Given the long industrial history of some of our sites and the legacy obligations of Aventis arising from its past involvement in the chemical and agrochemical industries, it is impossible to quantify the future impact of these laws and regulations with precision. See Item 3.D. Risk Factors – Environmental Risks of Our Industrial Activities .

To our knowledge, the Group is not currently subject to liabilities for non-compliance with current HSE laws and regulations that could be expected to significantly jeopardize its activities, financial situation or operating income. We also believe that we are in substantial compliance with current HSE laws and regulations and that all the environmental permits required to operate our facilities have been obtained. Regular HSE audits (22 in 2010) are carried out by the Group in order to assess compliance with our standards (which implies compliance with regulations) and to initiate corrective measures. Moreover, 103 loss prevention technical visits were carried out in 2010.

Sanofi-aventis has implemented a worldwide master policy on health, safety and the environment to promote the health and well-being of the employees and contractors working on its sites and respect for the environment. We consider this master policy to be an integral part of our commitment to social responsibility. In order to implement this master policy, 77 rules (policies) have been drawn up in the key fields of HSE management, Good HSE Practices, safety in the workplace, process safety, industrial hygiene, health in the workplace and protection of the environment.



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### ***Health***

From the development of compounds to the commercial launch of new drugs, sanofi-aventis research scientists continuously assess the effect of products on human health. This expertise is made available to employees through two committees responsible for chemical and biological risk assessment. The Group's COVALIS committee classifies all chemical and pharmaceutical products handled within the Group and establishes workplace exposure limits for each of them. The Group's TRIBIO Committee is responsible for classifying all biological agents according to their degree of pathogenicity, and applies rules for their containment and the preventive measures to be respected throughout the Group. See Item 3. Key Information D. Risk Factors Environmental Risks of Our Industrial Activities Risks from the handling of hazardous materials could adversely affect our results of operations .

Appropriate Industrial Hygiene practices and programs are defined and implemented in each site. These practices consist essentially of containment measures for collective and individual protection against exposure in all workplaces where chemical substances or biological agents are handled. All personnel are monitored with an appropriate initial and routine medical program, focused on the potential occupational health risks linked to their duties.

In addition, a committee has been set up to prepare and support the implementation of the new European Union REACH regulation on Registration, Evaluation, Authorization and Restriction of Chemicals. To fully comply with the new European regulation on the labeling of chemicals (Classification Labeling Packaging), the Group has registered the relevant hazardous chemical substances with the European Chemicals Agency (ECHA).

### ***Safety***

Sanofi-aventis has rigorous policies to identify and evaluate safety risks and to develop preventive safety measures, and methods for checking their efficacy. Additionally, sanofi-aventis invests in training that is designed to instill in all employees a sense of concern for safety, regardless of their duties. These policies are implemented on a worldwide scale to ensure the safety of all employees and to protect their health. Each project, whether in research, development or manufacturing, is subject to evaluation procedures, incorporating the chemical substance and process data communicated by the COVALIS and TRIBIO committees described above. The preventive measures are designed primarily to reduce the number and seriousness of work accidents and to minimize exposures involving permanent and temporary sanofi-aventis employees as well as our sub-contractors.

The French chemical manufacturing sites in Aramon, Neuville-sur-Saône, Sisteron, Vertolaye and Vitry, as well as the plants located in the Hoechst Industry Park in Frankfurt, Germany, the Zentiva site in Hlohovec, Slovakia, and the chemical production site in Budapest, Hungary, are listed Seveso II (from the name of the European directive that deals with potentially dangerous sites through a list of activities and substances associated with classification thresholds). In accordance with French law on technological risk prevention, the French sites are also subject to heightened security inspections in light of the toxic or flammable materials stored on the sites and used in the operating processes.

Risk assessments of processes and their installations are drawn up according to standards and internal guidelines incorporating the best state-of-the-art benchmarks for the industry. These assessments are used to fulfill regulatory requirements and are regularly updated. Particular attention is paid to any risk-generating changes: process or installation changes, as well as changes in production scale and transfers between industrial or research units.

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Our laboratories that specialize in process safety testing, which are fully integrated into our chemical development activities, apply methods to obtain the physico-chemical parameters of manufactured chemical substances (intermediate chemical compounds and active ingredients) and apply models to measure the effect of potentially leachable substances in the event of a major accident. In these laboratories the parameters for qualifying hazardous reactions are also determined to define scale-up process conditions while transferring from development stage to industrial scale. All these data ensure the relevance of the risk assessments.

We believe that the safety management systems implemented at each site, the hazard studies carried out and the risk management methods implemented, as well as our third-party property insurance policies covering any third-party physical damage, are consistent with legal requirements and the best practices in the industry.

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### ***Environment***

The main objectives of our environmental policy are to implement clean manufacturing techniques, minimize the use of natural resources and reduce the environmental impact of our activities. In order to optimize and improve our environmental performance, we have a strategy of continuous improvement practiced at all our sites through the annual implementation of HSE progress plans. In addition, 49 sites are currently ISO 14001 certified. We believe that this strategy clearly expresses the commitment of both management and individuals to health, safety and the environment. In 2010, seven of our European sites were included in the scope of the European CO<sub>2</sub> Emissions Credit Trading Scheme aimed at helping to reach the targets set by the Kyoto protocol.

Our recent efforts in terms of environmental protection have mainly targeted reductions in energy consumption, greenhouse gas emissions control, improvements in the performance of water treatment installations, reduction of volatile organic compound emissions, raw material savings and recycling, and reductions in waste materials or increases in the percentage being recycled. In 2010, we reduced carbon dioxide emissions caused by our sales representation car fleet by 13% versus 2009, due to the policy of using energy efficient cars as well as a reduction in the number of cars. Since 2005, in terms of our activity level per unit produced, our direct and indirect carbon dioxide emissions have decreased by 8% and 17% respectively<sup>(1)</sup>.

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

### **Markets**

A breakdown of revenues by business segment and by geographic region for 2008, 2009 and 2010 can be found at Note D.35. to our consolidated financial statements included at Item 18 of this annual report.

The following market shares and ranking information is based on sales data from IMS Health MIDAS, retail and hospital for full year 2010, in constant euros (unless otherwise indicated). For more information on market shares and ranking, see Presentation of Financial and Other Information at the beginning of this document.

### **Marketing and Distribution**

Sanofi-aventis has a commercial presence in approximately 100 countries, and our products are available in more than 170. Our main markets in terms of net sales are, respectively:

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Western Europe represents 29.6% of our net sales; we are the leading pharmaceutical company in France where our market share is 10.1% (11.4% in 2009), and we rank third in Germany with a 5.8% market share (5.6% in 2009). In 2010, sales in Western Europe were down 8.8% due to the impact of generic competition for Plavix<sup>®</sup> and of Taxotere<sup>®</sup> and of price pressure applied by the healthcare authorities.

The United States represents 29.5% of our net sales ; we rank twelfth with a market share of 3.1% (3.4% in 2009). Sales in the U.S. were down 8.4% at constant exchange rates in 2010 reflecting the impact of generics of Lovenox<sup>®</sup> and Ambien<sup>®</sup> CR, the workdown of Eloxatine<sup>®</sup> generics inventory during the second half of 2010, and the impact of healthcare reform. Chattem's sales are included from February 2010.

Emerging Markets (see definition in B. Business Overview Strategy , above) represent 29.9% of our net sales, for the first time the largest contribution to net sales of any region. We are the leading healthcare company in emerging markets. In 2010, sales in emerging markets grew by 16.3% at constant exchange rates. This performance was due to robust organic growth (13.2% on a constant structure basis and at constant exchange

<sup>(1)</sup> The CO<sub>2</sub> emissions variations per produced unit are calculated for each business and added proportionally to their respective contribution to the total of direct and indirect CO<sub>2</sub> emissions. Each business defines a specific indicator of its activity (e.g., hours worked for vaccines, number of boxes produced for pharmaceuticals, etc.).

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rates) and the impact of targeted acquisitions (mainly Zentiva in Eastern Europe and Medley in Brazil). In 2010, Brazil, Russia and China generated substantial growth of 51.4%, 19.9% and 23.6%, respectively. In Latin America, mostly in Brazil and Mexico, growth was driven by flu vaccine sales, which virtually trebled (+189%).

Japan represents 7.3% of our net sales; our market share is 3.1% (3.0% in 2009). In 2010, sales grew by 9.1% at constant exchange rate and growth was mostly generated by the success of Plavix® (+37.1%) and by a good performance from the Vaccines activity.

A breakdown of our sales by geographic market is presented in Item 5. Operating and Financial Review and Prospects Results of Operations Year Ended December 31, 2010 Compared with Year Ended December 31, 2009.

Although specific distribution patterns vary by country, we sell prescription drugs primarily to wholesale drug distributors, independent and chain retail drug outlets, hospitals, clinics, managed care organizations and government institutions. With the exception of Consumer Health Care products, these drugs are ordinarily dispensed to patients by pharmacies upon presentation of a doctor's prescription.

We use a selection of channels to disseminate information about and promote our products among healthcare professionals and patients, ensuring that the channels not only cover our latest therapeutic advances but also our mature products, as they provide the foundation for satisfying major therapeutic needs. We regularly advertise in medical journals and exhibit at major medical congresses. In some countries, products are also marketed directly to patients by way of television, radio, newspapers and magazines, and we sometimes use new media channels (such as the internet) to market our products. National education and prevention campaigns can be used to improve patients' knowledge of conditions.

Our medical representatives, who work closely with healthcare professionals, use their expertise to promote and provide information on our drugs. They represent our values on a day-to-day basis and are required to adhere to a code of ethics. As of December 31, 2010, we had a global sales force of 32,686 representatives: 10,287 in Europe, 5,531 in the United States, and 16,868 in the rest of the world.

Although we market most of our products through our own sales forces, we have entered into and continue to form partnerships to co-promote/co-market certain products in specific geographic areas. Our major alliances are detailed at Pharmaceutical Products Main pharmaceutical products above.

Our vaccines are sold and distributed through multiple channels, including physicians, pharmacies, hospitals and distributors in the private sector, and governmental entities and non-governmental organizations in the public and international donor markets, respectively.

## **Competition**

The pharmaceutical industry is currently experiencing significant changes in its competitive environment. Innovative drugs, a broad product range, and a presence in all geographical markets are key factors in maintaining a strong competitive position.

There are four types of competition in the prescription pharmaceutical market:

competition between pharmaceutical companies to research and develop new patented products or new therapeutic indications;

competition between different patented pharmaceutical products marketed for the same therapeutic indication;

competition between original and generic products or between original biological products and biosimilars, at the end of patent protection; and

competition between generic or biosimilar products.



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We compete with other pharmaceutical companies in all major markets to develop innovative new products. We may develop new technologies and new patented products wholly in-house, but we also enter into collaborative R&D agreements in order to access new technologies. See Note D.21. to our consolidated financial statements included at Item 18 of this annual report.

Our prescription drugs compete in all major markets against patented drugs from major pharmaceutical companies like Abbott in benign prostatic hyperplasia; AstraZeneca in cardiovascular disease, hypertension and oncology; Bayer-Schering in thrombosis prevention; Boehringer-Ingelheim in atherothrombosis and benign prostatic hyperplasia; Bristol-Myers Squibb in oncology; Lilly in osteoporosis, diabetes and oncology; GlaxoSmithKline in oncology, allergies, diabetes and thrombosis; Merck in hypertension, osteoporosis, diabetes and benign prostatic hyperplasia; Novartis in hypertension and oncology; Novo Nordisk in diabetes; Pfizer in oncology, thrombosis and allergies; and Roche in oncology and osteoporosis.

In our Vaccines business, we compete primarily with multinational players backed by large healthcare groups, including Merck (outside Europe), GlaxoSmithKline, Pfizer (Wyeth) and Novartis.

In selected market segments, sanofi pasteur competes with mid-size international players (such as CSL of Australia in the influenza market for the Southern Hemisphere). Sanofi Pasteur also competes with an increasing number of manufacturers, entrenched in densely populated and economically emerging regions, which are leveraging their cost/volume advantage and raising their level of technical capability and quality standards to compete on more sophisticated antigens in their domestic markets and also in international donor markets. Multinational players are increasingly seeking alliances with manufacturers from emerging economies to secure positions in their markets of origin.

We also face competition from generic drugs that enter the market when our patent protection or regulatory exclusivity expires, or when we lose a patent infringement lawsuit (see Patents, Intellectual Property and Other Rights above). Similarly, when a competing patented drug from another pharmaceutical company faces generic competition, these generic products can also affect the competitive environment of our own patented product.

Competition from producers of generics has increased sharply in response to healthcare cost containment measures and to the increased number of products for which patents have expired.

Generics manufacturers who have received all necessary regulatory approvals for a product may decide to launch a generic version before the patent expiry date. Such launch may occur notwithstanding the fact that the owner of the original product may already have commenced patent infringement litigation against the generics manufacturer. Such launches are said to be at risk for the promoter of the generic product because it may be required to pay damages to the owner of the original product in the context of patent infringement litigation; however, these launches may also significantly impair the profitability of the pharmaceutical company whose product is challenged.

Another competitive issue drug manufacturers are facing is parallel trade, also known as reimportation. This takes place when drugs sold abroad under the same brand name as in a domestic market are imported into that domestic market by parallel traders, who may repackage or resize the original product or sell it through alternative channels such as mail order or the Internet. This situation is of particular relevance to the European Union, where these practices have been encouraged by the current regulatory framework. Parallel traders take advantage of the price differentials between markets arising from factors including sales costs, market conditions (such as intermediate trading stages), tax rates, or national regulation of prices.

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Finally, pharmaceutical companies face illegal competition from counterfeit drugs. The WHO estimates that counterfeit products account for 10% of the market worldwide, rising to as much as 30% in some countries. However, in markets where powerful regulatory controls are in place, counterfeit drugs are estimated to represent less than 1% of market value.

The WHO also estimates that 50% of sales over the Internet are of counterfeit drugs: their development has intensified in 2010.

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A medical product is counterfeit when there is a false representation in relation to its identity (e.g., name, composition, strength, etc.) or source (e.g., manufacturer, country of manufacturing/origin, marketing authorization holder, etc.) or its background (e.g., filings and documentation related to its distribution channels). Sanofi-aventis is committed to being part of any efforts made to overcome drug counterfeiting and has implemented the following actions:

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

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

## **Regulation**

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

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

The International Conference on Harmonization (ICH) consists of the regulatory agencies of the three founder members (European Union, Japan, United States), plus Health Canada and Swissmedic as observers. Product approval can vary from six months to several years from the date of application depending upon the country. Factors such as the quality of data submitted, the degree of control exercised by the regulatory authority, the review procedures, the nature of the product and the condition to be treated, play a major role in the length of time a product is under review.

In recent years, efforts have been made by the ICH participants to harmonize product development and regulatory submission requirements. An example of these efforts is the Common Technical Document (CTD), which can be used in different ICH regions for a product application review, with only local or regional adaptation. Electronic CTD is becoming the standard for worldwide product submission.

Pharmaceutical manufacturers have committed to publishing protocols and results of clinical studies performed with their products in publicly accessible registries (e.g., Clinical Trials Registry, Clinical Trial Results Registry). In addition, the various ICH and non-ICH countries often impose mandatory disclosure of clinical trials information.

The requirement of many countries, including Japan and several member states of the European Union, to negotiate selling prices or reimbursement rates for pharmaceutical products with government regulators can substantially extend the time for market entry beyond the

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initial marketing approval. While marketing authorizations for new pharmaceutical products in the European Union have been substantially centralized with the European Medicines Agency (EMA), pricing and reimbursement remain a matter of national competence.

In the European Union, there are three main procedures by which to apply for marketing authorization:

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

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

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

Post-authorization safety monitoring of pharmaceutical products is carefully regulated in Europe (Council Regulation (EEC) No 2309/93 and Council Directive -2001/83/EC describe the respective obligations of the marketing authorization holder and of the competent authorities to set up a system for pharmacovigilance in order to collect, collate and evaluate information about suspected adverse reactions), and pharmacovigilance activities also pertain to nationally approved products: pharmacovigilance obligations apply to all authorized medicinal products including those authorized before 1 January 1995.

It is possible for health authorities to withdraw products from the market for safety reasons. The responsibilities for pharmacovigilance rest with the competent authorities of all the Member States in which the authorisations are held. In accordance with the applicable legislation, each Member State has established a pharmacovigilance system for the collection and evaluation of information relevant to the benefit to risk balance of medicinal products. The competent authority continually monitors the safety profile of the products available on its territory and takes appropriate action where necessary and monitors the compliance of marketing authorisation holders with their obligations with respect to pharmacovigilance. All relevant information should be shared between the competent authorities and the marketing authorization holder, in order to allow all parties involved in pharmacovigilance activities to assume their obligations and responsibilities. The principal mandate of the CHMP's Pharmacovigilance Working Party is to provide a forum for dialogue between Member States on pharmacovigilance and to review safety issues at the request of the competent authorities, for centrally authorized products and products undergoing a referral.

Following a routine inspection of the sanofi-aventis U.S. site in Bridgewater during April and May 2010, the FDA issued a warning letter citing inadequate procedures for the surveillance, receipt, evaluation and reporting of adverse events in a timely manner, and failure to include all required postmarketing studies in NDA Annual Reports to the agency. The warning letter is specific to reporting processes and timeframes, not to safety concerns with any specific medication. Sanofi-aventis has already been working to address the observation and is fully committed to ensure compliance with all reporting requirements.

In 2010 new legislation aimed at strengthening and rationalizing the Community Pharmacovigilance System was approved, which will be enforced in July 2012. Changes include a strengthened legal basis for regulators to require post-authorization safety and efficacy studies throughout the life cycle of the medicinal product. An additional scientific committee called the Pharmacovigilance Risk Assessment Committee, with a key role in pharmacovigilance assessments (scope: all marketed drugs in the EU), is to be established at the level of the EMA. This committee, which includes a patient representative, can hold public hearings.

Implementation of this pharmacovigilance legislation will be a particular priority in light of the Mediator affair that has caused uproar in France. Given AFSSAPS' stature as a leading regulatory agency, as well as the way the European regulatory network is organized, (with national agencies that are closely entwined with the EMA through their experts' membership of the EMA's various scientific committees and groups), it is possible the affair will have EU repercussions.

AFSSAPS' failures were highlighted in the report by the French Health Ministry's General Inspectorate of Social Affairs (IGAS). The French Health Minister has outlined a radical set of proposals for AFSSAPS. More input will come from the parliamentary inquiry with a report expected in June, and from a wide consultation on the reform of the regulatory and pharmacovigilance system to be held with results expected in May.

Some of the measures identified by the French Health Minister are already being addressed in the EU legislation, while others will have broader implications:

Strengthening policy on conflicts of interest. This was actioned by the EMA in 2010. It can be expected that national agencies will have to examine their own procedures to see if they could be improved.

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Funding system of regulatory authorities. This is a key issue for national agencies but also for the EMA.

Ongoing safety monitoring and life-cycle management approach to monitoring the benefit:risk profile. In its Roadmap to 2015, the EMA calls for a continuous benefit:risk assessment throughout a product's life-cycle. It can be expected that this objective will be implemented with a high priority at the EU level. The new Pharmacovigilance legislation gives the legal basis for enforcing this life cycle approach, with the power to request Post Authorization Safety and Efficacy Studies at any time.

New products submitted for approval to be at least equivalent to a product already on the market. This idea which appears to be more radical than the others, would in reality be more in line with the current tendency of companies to conduct more active control clinical studies.

Other relevant aspects in the EU regulatory framework are the following:

The sunset clause is a provision leading to the cessation of the validity of any marketing authorization which is not followed by marketing within 3 years or not remaining on the market for a consecutive 3 year period.

Generic products are subject to a harmonized procedure in all countries of the European Union. A generic product should contain the same active medicinal substance as an originator product. Generic applications are abridged: generic manufacturers only need to submit quality data and demonstrate that the generic drug is bioequivalent to the originator product (i.e., works in the same way in the patient's body), but with no need to submit safety or efficacy data since regulatory authorities can refer to the originator product's dossier. Generic product applications can be filed and approved in the European Union only after the eight year data exclusivity period of the originator product has expired. Further, generic manufacturers can only market their generic products after a 10- or 11-year period from the date of approval of the originator product has elapsed.

The EMA has introduced a series of initiatives aimed at improving the transparency of its activities, such as the publication of the European Public Assessment Report, which contains product approvals, withdrawals and rejections. In addition, there is an increased focus on comparative effectiveness. New initiatives have been proposed with regard to the disclosure of information on marketing authorization applications; meanwhile, the EMA has become more proactive on the disclosure of documents/information throughout the product lifecycle, with an emphasis on safety related data. In addition, patients and consumers are increasingly involved in the work of the EMA's scientific committees.

A regulation in pediatric development came into force in January 2007. It is aimed at promoting the development of drugs well adapted to children and ensuring safe use in the pediatric population. Incentives are proposed such as extension of SPC (Supplementary Protection Certificate) or data protection for PUMA (Pediatric Use Marketing Authorization).

A new regulatory framework has been implemented covering Advanced Therapy Medicinal Products (ATMPs). This new legislation provides specific requirements for the approval, supervision and pharmacovigilance of ATMPs. A new scientific committee – the Committee for Advanced Therapies (CAT) – has been established within the EMA to play a central role in the scientific assessment of ATMPs.

An additional regulatory change relates to variations in marketing authorizations with a view to rendering the whole system for post-authorization activities simpler, clearer and more flexible without compromising public health.

International collaboration between regulatory authorities continues to develop with implementation of confidentiality arrangements between ICH regulatory authorities, and with non-ICH regulatory authorities. Examples include work-sharing on Good Clinical Practices (GCP) inspections between the United States and the European Union, as well as creating permanent representatives from the U.S. Food and Drug Administration (FDA) and Japanese Pharmaceutical and Medical Devices Agency (PMDA) now based in London, and a corresponding permanent representative from EMA at the FDA.

In the United States, applications for drug and biological approval are submitted for review to the FDA, which has broad regulatory powers over all pharmaceutical products that are intended for U.S. sale and marketing. To commercialize a product, a New Drug Application (NDA) under the Food, Drug and Cosmetic



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(FD&C) Act or Biological License Application (BLA) under the Public Health Service (PHS) Act is submitted to the FDA with data for filing and pre-market review. Specifically, the FDA must decide whether the product is safe and effective for its proposed use, if the benefits of the drug's use outweigh its risks, whether the drug's labeling is adequate, and if the manufacturing of the drug and the controls used for maintaining quality are adequate to preserve the drug's identity, strength, quality and purity. Based upon this review, the FDA can require post-approval commitments. Approval for a new indication of a previously approved product requires the submission of a supplemental NDA (sNDA) for a drug or supplemental BLA (sBLA) for a biological product.

In the United States, generic drug manufacturers may file an Abbreviated NDA (ANDA) under 505(j) of the FD&C Act. These applications are abbreviated because they are generally not required to include data to establish safety and effectiveness, but need only demonstrate that their product is bioequivalent (i.e., performs in humans in the same manner as the originator's product). Consequently, the length of time and cost required for development of generics can be considerably less than for the originator's drug. The ANDA pathway in the United States can only be used for NDA approved drugs under the FD&C Act and not for BLA approved biological products under the PHS Act.

In Japan, the regulatory authorities can require local development studies. They can also request bridging studies to verify that foreign clinical data are applicable to Japanese patients and require data to determine the appropriateness of the dosages for Japanese patients. These additional procedures have created a significant delay in the registration of some innovative products in Japan compared to the European Union and United States.

## **Focus on Biologics**

Products can be referred to as biologics when they are derived from plant or animal tissues, including blood products or products manufactured within living cells (e.g., antibodies). Most biologics are complex molecules or mixtures of molecules which are difficult to characterize and require physico-chemical-biological testing, and an understanding of and control over the manufacturing process.

The concept of generics is not scientifically appropriate for biologics due to their high level of complexity and therefore the concept of biosimilar products is more appropriate. A full comparison of the purity, safety and efficacy of the biosimilar product against the reference biological product should be undertaken, including assessment of physical/chemical, biological, non-clinical and clinical similarity.

In the European Union, a regulatory framework for developing and evaluating biosimilar products has been in place since November 2005. The CHMP has issued several product/disease specific guidelines for biosimilar products. In March 2009, the CHMP adopted a guideline on preclinical and clinical development of biosimilars of low molecular weight heparins. For example, in Europe a potential product candidate claiming to be biologically similar to Lovenox® must show therapeutic equivalence in terms of efficacy and safety in at least one adequately powered, randomized, double-blind, parallel group clinical trial. With respect to vaccines, the CHMP has taken the position that currently it is unlikely that these products may be characterized at the molecular level, and that each vaccine product must be evaluated on a case by case basis.

In Japan, guidelines defining the regulatory approval pathway for follow-on biologics were finalized in March 2009. These guidelines set out the requirements on preclinical and clinical data to be considered for the development of the new application category of biosimilars.

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For historical reasons in the U.S., a few complex protein-based drugs have been approved as NDAs under the Federal Food Drug and Cosmetic Act (FD&C Act). It is currently possible to submit an abbreviated application (ANDA) with respect to those particular products (e.g., Lovenox<sup>®</sup>, Lantus<sup>®</sup>). Since an ANDA is not required to contain clinical trial data other than from bioequivalence studies, the appropriateness of an ANDA with respect to these NDA approved biological products raises significant scientific issues for the FDA.

The FD&C Act provides another abbreviated option for NDA approved biological products, called the 505(b)(2) pathway. This pre-market application may refer to the FDA finding that the reference product has been found to be safe and effective by the FDA based upon the innovator's preclinical and clinical data.

Lovenox<sup>®</sup> (enoxaparin) was approved as a drug by the FDA on March 29, 1993. Lovenox<sup>®</sup> was approved under Section 505(b)(1) of the FD&C Act and not as a biologic under Section 351 of the Public Health

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Service Act, and therefore a biosimilar of the product was not possible. An abbreviated NDA (ANDA/generic) application was submitted to FDA August 2005 by Momenta/Sandoz under section 505(j) of the FDCA. This application was approved July 2010; the generic product was approved as therapeutically equivalent to Lovenox<sup>®</sup>. Two other generic applications are believed to be pending with the FDA; one submitted by Teva and the other from Amphastar, both in 2003. Teva received a Minor Deficiency letter from the FDA on January 25, 2011 and has stated that it expects to answer those deficiencies in the near future.

U.S. law now provides for a procedure for biosimilar versions of a reference product licensed as a biological under the PHS Act. Healthcare reform legislation entitled the Patient Protection and Affordable Care Act, was signed into law by the President on March 30, 2010. Title VII, Subtitle A Biologics Price Competition and Innovation, allows for the creation of a regulatory approval pathway for biosimilars and a litigation procedure for patent infringement lawsuits brought against biosimilar applicants. Previously, a biological product was defined under the PHS Act, Section 351, as a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product or analogous product or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

In the U.S., Lovenox<sup>®</sup> is approved as a drug NDA (New Drug Application) under the FD&C Act. The new U.S. Biosimilars Law currently covers products regulated as Biologics under the Public Health Services (PHS) Act and therefore does not apply to Lovenox<sup>®</sup> or other products approved as drugs.

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

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

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

## **Pricing & Reimbursement**

Rising overall healthcare costs are leading to efforts to curb drug expenditures in most markets in which sanofi-aventis operates. Increasingly these efforts result in pricing and market access controls for pharmaceuticals. The nature and impact of these controls vary from country to country, but some common themes are reference pricing, systematic price reductions, formularies, volume limitations, patient co-pay

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requirements, and generic substitution. In addition, governments and third-party payers are increasingly demanding comparative / relative effectiveness data to support their decision making process. They are also increasing their utilization of emerging healthcare information technologies such as electronic prescribing and health records to enforce transparency and tight compliance with these regulations and controls. As a result, the environment in which pharmaceutical companies must operate in order to make their products available to patients and providers who need them continues to grow more complex each year.

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Significant changes in the Pharmaceutical/Healthcare environment emerged during 2010:

In the United States, 2010 was marked by the health insurance and market reforms that are expected to lead to a large number of uninsured being covered by 2014, either through state aid or mandatory coverage, with a system of fines for non-compliance. These reforms will also see the establishment of a health insurance exchange and the eventual closure of the doughnut hole in Medicare Part D.

In Europe, several countries (including, Germany, Greece, Spain, Portugal and Ireland) have introduced emergency cost containment measures and reforms, following economic crises, that led to a reduction in the price of marketed drugs and will significantly affect the size of the pharmaceutical market. In parallel, Germany introduced a law that would effectively put an end to the free-price-setting system through systematic health technology assessments and pricing negotiations. And in the United Kingdom, the new coalition government is looking to end the current Pharmaceutical Price Regulation Scheme (PPRS 2014) with a shift towards value-based pricing with less emphasis on the Incremental Cost Effectiveness Ratio (ICER) price-setting methods currently used by the National Institute for Clinical Excellence (NICE).

In Asia, several countries have sought to increase patient access to medicines: in the Philippines, this is being achieved through direct price cuts whereas in China and Thailand, it is being achieved through healthcare expansion towards universal coverage in association with price rationalization, starting with cuts in the prices of drugs on the Essential Drug List in China.

In Russia, healthcare expansion and price rationalization have also been the subject of legislative reforms.

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

We actively engage with our key stakeholders on the value of our products to them. These stakeholders including physicians, patient groups, pharmacists, government authorities and third-party payers can have a significant impact on the market accessibility of our products.

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

Keeping in mind the importance of recognizing the value of our products and the high cost of research and development, we continue to analyze innovative pricing and access strategies that balance patient accessibility with appropriate rewards for innovation.

## **Insurance and Risk Coverage**

We are protected by four key insurance programs, relying not only on the traditional corporate insurance and reinsurance market but also on a mutual insurance company established by various pharmaceutical groups and our captive insurance company, Carraig Insurance Ltd (Carraig).

These four key programs cover Property & Business Interruption, General Liability, Stock and Transit, and Directors & Officers Liability.

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Our captive insurance company, Carraig, participates in our coverage for various lines of insurance including excess property, stock and transit and product liability. Carraig is run under the supervision of the Irish regulatory authorities, is wholly owned by sanofi-aventis, and has sufficient resources to meet the risks that it covers. It sets premiums for Group entities at market rates. Claims are assessed using the traditional models applied by insurance and reinsurance companies, and the company's reserves are regularly checked and confirmed by independent actuaries.

Our Property & Business Interruption program covers all Group entities worldwide, wherever it is possible to use a centralized program operated by our captive insurance company. This approach shares risk between

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Group entities, enabling us to set deductibles and guarantees that are appropriate to the needs of local entities. A further benefit of this program is that traditional insurance cover is supplemented by specialist cover, thanks to the involvement of an international mutual insurance company established by a number of pharmaceutical groups. It also incorporates a prevention program, including a comprehensive site visit program covering our production, storage, research and distribution facilities and standardized repair and maintenance procedures across all sites. Specialist site visits are conducted every year to address specific needs, such as testing of sprinkler systems or emergency plans to deal with flooding risks.

The Stock and Transit program protects goods of all kind owned by the Group that are in transit nationally or internationally, whatever the means of transport, and all our inventories wherever they are located. Sharing risk between Group entities means that we can set deductibles at appropriate levels, for instance differentiating between goods that require temperature controlled distribution and those that do not. We have developed a prevention program with our insurers, implementing best practices in this area at our distribution sites. This program, which is led by our captive insurance company, has substantial capacity, largely to deal with the growth in sea freight which can lead to a concentration of value in a single ship.

Our General Liability & Product Liability program has been renewed for all our subsidiaries worldwide wherever it was possible to do so, despite the increasing reluctance in the insurance and reinsurance market to cover product liability risks for large pharmaceutical groups. For several years, insurers have been reducing product liability cover because of the difficulty of insuring some products that have been subject to numerous claims. These products are excluded from the cover provided by insurers, and hence from the cover obtained by us on the insurance market. This applies to a few of our products, principally those described in Note D.22.a) to our consolidated financial statements included at Item 18 in this annual report. Because of these market conditions we have increased, year by year, the extent to which we self-insure.

The principal risk exposure for our pharmaceutical products is covered with low deductibles at the country level, the greatest level of risk being retained by our captive insurance company. The level of risk self-insured by the Group including our captive reinsurance company enables us to retain control over the management and prevention of risk. Our negotiations with third-party insurers and reinsurers are tailored to our specific risks. In particular, they allow for differential treatment of products in the development phase, for the discrepancies in risk exposure between European countries and the United States, and for specific issues arising in certain jurisdictions. Coverage is adjusted every year in order to take into account the relative weight of new product liability risks such as those emerging from healthcare products which are not subject to market approval.

Our cover for risks that are not specific to the pharmaceutical industry (general liability) is designed to address the potential impacts of our operations.

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

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

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These insurance programs are backed by best-in-class insurers and reinsurers and are designed in such a way that we can integrate most newly-acquired businesses on a continuous basis. Our cover has been designed to reflect our risk profile and the capacity available in the insurance market. By centralizing our major programs, not only do we reduce costs, but we also provide world-class coverage for the entire Group.



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Sanofi-aventis is the holding company of a consolidated group of subsidiaries. The table below sets forth our significant subsidiaries and affiliates as of December 31, 2010. For a complete list of our main consolidated subsidiaries, see Note F. to our consolidated financial statements, included in this annual report at Item 18.

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

Sanofi-aventis and its subsidiaries form a group, organized around two activities: Pharmaceutical products and Human Vaccines. The Group is also active in Animal Health through Merial.

The patents and trademarks of the pharmaceutical activity are primarily owned by the sanofi-aventis parent company, Aventis Pharma S.A. (France), Hoechst GmbH (Germany) and Sanofi-Aventis Deutschland GmbH (Germany).

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

In certain countries, sanofi-aventis carries out part of its business operations through ventures with local partners. In addition, the Group has signed worldwide alliances by which two of its products (Plavix<sup>®</sup> and Aprovel<sup>®</sup>) are marketed through an alliance with BMS (see Pharmaceutical Products – Main Pharmaceutical Products – above).

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

risks of its main subsidiaries.

***D. Property, Plant and Equipment***

Our headquarters are located in Paris, France. See [Office Space](#) below.

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

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**Breakdown of sites by use\***

Industrial	50%
Research	15%
Offices	14%
Logistics	6%
Vaccines	11%
Others	4%

\* Excludes Vaccines entities. During 2010, our Vaccines business was still treated a separate unit, with its own offices and research, production and logistics facilities. In 2011, all premises occupied by sanofi pasteur will be incorporated into the Group's global real estate portfolio, and allocated between the four uses shown in the table above.

**Breakdown of the Group's sites between owned and leased**

Leased	35%
Owned	65%

We own most of our research and development and production facilities, either freehold or under finance leases with a purchase option exercisable at expiration.

**Research and Development Sites: Pharmaceuticals segment**

Research and Development activities are housed at 22 sites:

8 operational sites in France, the largest in terms of built-on surface area in use being Vitry/Alfortville (approximately 105,000 m<sup>2</sup>), Montpellier (106,000 m<sup>2</sup>), Chilly/Longjumeau (114,000 m<sup>2</sup>) and Toulouse (60,500 m<sup>2</sup>);

5 sites in other European countries (Germany, United Kingdom, Hungary, Spain and Italy), the largest being in Frankfurt, Germany (84,000 m<sup>2</sup>);

6 sites in the United States, the largest being in Bridgewater, New Jersey (111,000 m<sup>2</sup>);

1 site in Tokyo, Japan;

2 sites in China: the principal facility in Shanghai, and a Clinical Research Unit in Beijing.

**Industrial Sites: Pharmaceuticals Segment**

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Production of chemical and pharmaceutical products is the responsibility of our Industrial Affairs function, which is also in charge of most of our logistics facilities (distribution and storage centers).

We have 75 industrial sites worldwide. The sites where the major sanofi-aventis drugs, active ingredients and medical devices are manufactured are:

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

Germany: Frankfurt (insulins, ramipril, Lantus<sup>®</sup>, Tritace<sup>®</sup>, pens, Apidra<sup>®</sup>);

Italy: Scoppito (Tritace<sup>®</sup>, Amaryl<sup>®</sup>);

United Kingdom: Dagenham (Taxotere<sup>®</sup>), Fawdon (Plavix<sup>®</sup>, Aprovel<sup>®</sup>); Holmes Chapel (Nasacort<sup>®</sup>);

Hungary: Ujpest (irbesartan), Csanyikvölgy (Lovenox<sup>®</sup>);

Japan: Kawagoe (Plavix<sup>®</sup>);

United States: Kansas City (Allegra<sup>®</sup>), Chattem (consumer health products).

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### **Sanofi Pasteur Sites**

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

In May 2009, sanofi aventis launched the construction of a new sanofi pasteur vaccine manufacturing center in Neuville-sur-Saône, France. The investment of 350 million euros, the largest ever made by sanofi-aventis, takes place on an existing sanofi-aventis site. The objective is to progressively transition the existing chemical activity to vaccine production.

In 2010, sanofi pasteur acquired VaxDesign located in Orlando, Florida. VaxDesign's Modular IMMune In-vitro Construct (MIMIC<sup>®</sup>) System is designed to capture genetic and environmental diversity and predict human immune responses. The MIMIC<sup>®</sup> platform is expected to accelerate vaccine development, reduced time to market and increased probability of success rates in pre-clinical and clinical stages.

We own most of sanofi pasteur's Research and Development and production sites, either freehold or under finance leases with a purchase option exercisable at expiration.

### **Merial Sites**

Because we intend to contribute Merial to a joint venture in 2011 and consequently lose our exclusive control (see Note D.8.1 to our consolidated financial statements included at Item 18 of this annual report) we have not included Merial sites in the discussion included at this Item 4. Information on the Company's D. Property, Plant and Equipment notwithstanding the fact that on December 31, 2010, Merial was a wholly owned subsidiary of sanofi-aventis. Merial has 16 industrial sites, 9 research and development sites and numerous administrative offices with its principal headquarters located at Lyon (France) and Duluth (United States).

### **Acquisitions, Capital Expenditures and Divestitures**

The carrying amount of our property, plant and equipment at December 31, 2010 was 8,155 million. During 2010, we invested 1,199 million (see Note D.3. to the consolidated financial statements) in increasing capacity and improving productivity at our various production and R&D sites.

The Group's principal capital expenditures and divestments for 2008, 2009 and 2010 are set out in this annual report at Item 5. Operating and Financial Review and Prospects Divestments, Acquisitions and Liquidity and Capital Resources and in the notes to the consolidated financial statements (Note D.1., Note D.2., Note D.3. and Note D.4. to our consolidated financial statements included at Item 18 of this annual report).

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Our principal investments in progress are described below:

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

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

In Emerging Markets, we currently rely on industrial sites dedicated to serving regional markets, a situation reinforced by our 2009 acquisitions (Zentiva in Eastern Europe and Medley in Brazil). In

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China, the project to extend our current manufacturing facility located at the Beijing Economic and Technological Development Area will enable us to install assembly and packaging lines for SoloSTAR<sup>®</sup>, the pre-filled injection pen used to administer Lantus<sup>®</sup> (insulin glargine). In Hangzhou (China), we are building a new manufacturing site to replace the current manufacturing facility in downtown Hangzhou. The new site is scheduled to be completed in 2012. In Russia, the Orel insulin factory, recently acquired following the deal with Bioton Vostok, is a key element of our strategy to improve and improve and accelerate our access to the fast-growing Russian market. In Latin America, we are expanding our manufacturing operations in Argentina, where we already have a factory producing vaccines with the acquisition of the Merck Schering Plough site in Mirador (Buenos Aires).

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

Other investments related mainly to Research & Development sites.

As of December 31, 2010, our firm orders related to future capital expenditure amounted to 321 million. They were mainly related to the following industrial sites: Swiftwater (United States) and Marcy l'Étoile for the vaccines activity, and Vitry (France) and Frankfurt (Germany) for the pharmaceuticals activity.

In the medium term and on a constant structure basis, we expect our yearly average capital expenditure to be in the range of 1.4 billion. We believe that our existing cash resources and unused credit facilities will be sufficient to finance these investments.

## **Office Space**

As part of the rationalization of our office sites in the Paris region of France, we have since mid-2009 been reviewing our medium-term office space master plan for the Greater Paris area. This review is expected to result in all our Corporate and Operating Division support functions being housed on a smaller number of sites (five in 2011, when phase 1 is implemented). All of these sites will meet environmental certification standards, and offer cost-effective space solutions. The first step in the master plan was the closure of our offices on the Quai de la Rapée in the 12th *arrondissement* of Paris.

We have also chosen our new corporate headquarters in the Rue La Boétie, in the 8th *arrondissement* of Paris, at the heart of the city's business district. This headquarters building will bring all our Corporate and Operating Division support functions together on a single site, symbolizing the transformation of sanofi-aventis.

All of our research and development support functions will be housed on our Chilly Mazarin site (once the existing laboratory premises have been converted for office use) and on our Vitry site.

Finally, our current corporate headquarters at 174 avenue de France in the 13th *arrondissement* of Paris will be closed at end 2011, along with the adjacent site at 182 avenue de France and our Val de Bièvre site at Gentilly.

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

**Item 4A. Unresolved Staff Comments**

N/A



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### **Item 5. Operating and Financial Review and Prospects**

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

Our consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and with IFRS adopted by the European Union as of December 31, 2010.

The following discussion contains forward-looking statements that involve inherent risks and uncertainties. Actual results may differ materially from those contained in such forward-looking statements. See [Cautionary Statement Regarding Forward-Looking Statements](#) at the beginning of this document.

#### **2010 Overview**

Throughout 2010, sanofi-aventis continued to implement its transformation and sustainable growth strategy. Despite sales erosion for some of our flagship products under pressure from generics, healthcare reforms in the United States and lower drug prices in Europe, we once again delivered a solid performance by reinforcing our growth platforms, pushing ahead with our transformation program and maintaining tight cost control.

Consolidated net sales for the year reached 30,384 million, up 3.7% compared to 2009, down 0.8% at constant exchange rates (see definition at [Presentation of Net Sales](#) below). Sales were driven by good performances from our Emerging Markets, Diabetes and Consumer Health Care growth platforms, which offset the significant impact of competition from generics. Emerging Markets is now the region with the largest contribution to consolidated net sales, edging out the United States and Western Europe. Other highlights of 2010 included the launch of the anti-cancer drug Jevtana<sup>®</sup> in the United States, the ongoing worldwide rollout of the anti-arrhythmic Multaq<sup>®</sup>, and the introduction of the Intanza<sup>®</sup> and Fluzone<sup>®</sup> High Dose influenza vaccines.

Ongoing measures to adapt our resources enabled us to reduce our research and development expenses and selling and general expenses by 6.2% and 1.2% respectively (at constant exchange rates). On a reported basis, they respectively decreased by 4.0% and increased by 3.3%. Together, these operating expenses represented 39.4% of our net sales, compared with 40.6% in 2009. Business net income was 9,215 million, 6.8% higher than in 2009 on a reported basis. This reflects sales growth and tight control over operating costs, plus an increased contribution from the Merial business and favorable trends in various currencies against the euro during the year. Business earnings per share was 7.06, up 6.8% compared to 2009 on a reported basis; on a diluted basis, business earnings per share was 7.04 (up 6.7%). Business net income and business earnings per share are non-GAAP financial measures which our management uses to monitor our operational performance, and which are defined at [Business Net Income](#) below.

Net income attributable to equity holders of sanofi-aventis totaled 5,467 million, 3.8% higher than in 2009. Basic earnings per share for 2010 was 4.19, 4.0% higher than in 2009; diluted earnings per share for 2010 was 4.18 (up 3.7%).

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Sanofi-aventis continued to set a lively pace in its targeted acquisitions and R&D alliance strategy. We successfully completed the acquisition of Chatten, Inc., one of the leading manufacturers and distributors of branded consumer health products, toiletries and dietary supplements in the United States. Further additions to our Consumer Health Care platform came with the acquisition of Nepentes S.A. in Poland, the formation of a joint venture with Minsheng Pharmaceutical Co., Ltd, and the acquisition of BMP Sunstone Corporation in China. In Generics, we set up a joint venture in Japan with Nichi-Iko Pharmaceutical Co., Ltd. In the United States, we acquired two R&D companies, TargeGen and VaxDesign Corporation. In Animal Health, we exercised our contractual right in March 2010 to combine Merial with the Intervet/Schering-Plough business to form a new joint venture equally owned by Merck and sanofi-aventis; closing of the transaction is expected in 2011. In addition, we entered into a significant number of collaboration and licensing agreements that give us access to new technologies and expand or bolster our existing research fields especially in diabetes, oncology, vaccines, pain relief and fibrosis.

While we continue our transformation process focusing on our growth platforms and cost containment, we expect erosion from generic competition to accelerate, with a negative impact on net income in 2011.

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In October 2010, sanofi-aventis initiated a tender offer to acquire all outstanding shares of common stock of Genzyme Corporation ( Genzyme ). Genzyme is a leading U.S. biotechnology company specialized in rare diseases. On February 16, 2011, sanofi-aventis and Genzyme announced they had entered into a merger agreement providing for the acquisition of Genzyme by sanofi-aventis. The agreement is described at Item 10.C. Material Contracts . On the basis of 272.5 million Genzyme shares on a diluted basis, the improved offer price values Genzyme at approximately \$20.1 billion, the majority of which will be financed through new debt. We will also issue contingent value rights, the terms of which are described at Item 10.C. Material Contracts. The acquisition remains subject to fulfillment of a number of conditions including acceptance of the offer by holders of a majority of shares of Genzyme common stock on a diluted basis.

Our operations generate significant cash flow. We recorded 9,759 million of net cash provided by operating activities in 2010 compared to 8,515 million in 2009. During the course of 2010, we paid out 3.1 billion in dividends and repaid part of our debt. With respect to our financial position, we ended 2010 with our debt, net of cash and cash equivalents (meaning the sum of short-term and long-term debt plus related interest rate and currency derivatives, minus cash and cash equivalents) at 1,577 million (2009: 4,128 million). Debt, net of cash and cash equivalents, is a non-GAAP financial measure that is used by management and investors to measure the Company's overall net indebtedness and to assess the Company's financing risk as measured by its gearing ratio (debt, net of cash and cash equivalents, to total equity). Our gearing ratio stood at 3.0% at the end of 2010 versus 8.5% at the end of 2009. See Liquidity and Capital Resources Consolidated Balance Sheet and Debt below.

### **Purchase Accounting Effects (primarily the acquisition of Aventis in 2004)**

Our results of operations and financial condition for the years ended December 31, 2010, December 31, 2009 and December 31, 2008 have been significantly affected by our August 2004 acquisition of Aventis and certain subsequent transactions.

The Aventis acquisition has given rise to significant amortization ( 3,070 million in 2010, 3,175 million in 2009 and 3,298 million in 2008) and impairment of intangible assets ( 127 million in 2010, 344 million in 2009 and 1,486 million in 2008).

In order to isolate the impact of these and certain other items, we use as an evaluation tool a non-GAAP financial measure that we refer to as business net income . For a further discussion and definition of business net income , see Business Net Income below. For consistency of application of this principle, business net income also takes into account the impact of our subsequent acquisitions.

Business net income for the years ended December 31, 2010, 2009 and 2008 is presented in Business Net Income below.

### **Sources of Revenues and Expenses**

*Revenue.* Revenue arising from the sale of goods is presented in the income statement under Net sales. Net sales comprise revenue from sales of pharmaceutical products, vaccines, and active ingredients, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities. Returns, discounts, incentives and rebates described above are recognized in the period in which the underlying sales are recognized, as a reduction of sales revenue. See Note B.14. to our consolidated financial statements included at Item 18 of this annual report. We sell pharmaceutical products and human vaccines directly, through alliances, and through licensees throughout the world. When we sell products directly, we record sales revenues as part of our consolidated net sales. When we sell products through alliances, the revenues reflected in our consolidated financial statements are based on the overall level of sales of the products and on the arrangements governing those alliances. For more information about our alliances, see Financial Presentation of Alliances below. When we sell

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products through licensees, we receive royalty income that we record in Other revenues. See Note C. to the consolidated financial statements included at Item 18 of this annual report.

*Cost of Sales.* Our cost of sales consists primarily of the cost of purchasing active ingredients and raw materials, labor and other costs relating to our manufacturing activities, packaging materials, payments made

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under licensing agreements and distribution costs. We have license agreements under which we distribute products that are patented by other companies and license agreements under which other companies distribute products that we have patented. When we pay royalties, we record them in cost of sales, and when we receive royalties, we record them in Other revenues as discussed above.

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

## **Segment Information**

### *Operating Segments*

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

The Pharmaceuticals segment includes our research, development, production and sales activities relating to pharmaceutical products, including prescription, consumer health care and generic products. This segment also includes equity affiliates and joint ventures with pharmaceutical business activities, including in particular the entities that are majority-held by BMS. See Financial Presentation of Alliances below.

The Vaccines segment includes our research, development, production and sales activities relating to human vaccines. This segment also includes our Sanofi Pasteur MSD joint venture with Merck & Co., Inc. in Western Europe.

The Other segment includes all segments that are not reportable under IFRS 8, including in particular our interest in the Yves Rocher group, our animal health business (Merial) and the impact of our retained liabilities in connection with divested businesses.

Inter-segment transactions are not material.

### *Business Operating Income of Segments*

We measure the results of operations of our operating segments on the basis of Business Operating Income, a performance measure that we adopted in accordance with IFRS 8. Our chief operating decision-maker uses Business Operating Income to evaluate the performance of our operating managers and to allocate resources.

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

amortization and impairment losses charged against intangible assets are eliminated;

restructuring costs are eliminated;

gains and losses on disposals, and litigation, are eliminated;

the share of profits/losses of associates and joint ventures is added, and net income attributable to non-controlling interests is deducted;

other acquisition-related effects (primarily, the workdown of acquired inventories remeasured at fair value at the acquisition date, and the impact of acquisitions on investments in associates and joint ventures) are eliminated; and

restructuring costs relating to associates and joint ventures are eliminated.

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

( million)	Pharmaceuticals	Vaccines	Other	Total
<b>Net sales</b>	<b>26,576</b>	<b>3,808</b>		<b>30,384</b>
Other revenues	1,623	28		1,651
Cost of sales	(7,316)	(1,371)		(8,687)
Research and development expenses	(3,884)	(517)		(4,401)
Selling and general expenses	(6,962)	(603)	(2)	(7,567)
Other operating income and expenses	177	14	(108)	83
Share of profit/loss of associates and joint ventures <sup>(1)</sup>	1,009	19	8	1,036
Net income from the held-for-exchange Merial business			418	418
Net income attributable to non-controlling interests	(258)	1		(257)
<b>Business operating income</b>	<b>10,965</b>	<b>1,379</b>	<b>316</b>	<b>12,660</b>

<sup>(1)</sup> Net of tax

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

( million)	Pharmaceuticals	Vaccines	Other	Total
<b>Net sales</b>	<b>25,823</b>	<b>3,483</b>		<b>29,306</b>
Other revenues	1,412	31		1,443
Cost of sales	(6,527)	(1,326)		(7,853)
Research and development expenses	(4,091)	(491)	(1)	(4,583)
Selling and general expenses	(6,762)	(561)	(2)	(7,325)
Other operating income and expenses	387	(3)	1	385
Share of profit/loss of associates and joint ventures <sup>(1)</sup>	792	41	8	841
Net income from the held-for-exchange Merial business			241	241
Net income attributable to non-controlling interests	(426)	(1)		(427)
<b>Business operating income</b>	<b>10,608</b>	<b>1,173</b>	<b>247</b>	<b>12,028</b>

<sup>(1)</sup> Net of tax

**Business Net Income**

In addition to net income, we use a non-GAAP financial measure that we refer to as *business net income* to evaluate our Group's performance. Business net income, which is defined below, represents the aggregate business operating income of all of our operating segments, less net financial expenses and the relevant income tax charges. We believe that this non-GAAP financial measure allows investors to understand the performance of our Group because it segregates the results of operations of our current business activities, as opposed to reflecting the impact of past transactions such as acquisitions.

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

We have also decided to report business earnings per share . Business earnings per share is a specific non-GAAP financial measure, which we define as business net income divided by the weighted average number



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of shares outstanding. Our management intends to give earnings guidance based on business earnings per share. We also present business earnings per share on a diluted basis.

Business net income is defined as Net income attributable to equity holders of sanofi-aventis, determined under IFRS, excluding (i) amortization of intangible assets; (ii) impairment of intangible assets; (iii) other impacts associated with acquisitions (including impacts of acquisitions on associates and joint ventures); (iv) restructuring costs (including restructuring costs relating to associates and joint ventures), gains and losses on disposals of non-current assets, and costs or provisions associated with litigation; (v) the tax effect related to the items listed in (i) through (iv), as well as (vi) effects of major tax disputes and (vii) the share of non-controlling interests in items (i) through (vi). The items listed in (iv) except for restructuring costs related to associates and joint ventures correspond to those reported in the line items Restructuring costs and Gains and losses on disposals, and litigation, as defined in Note B.20. to our consolidated financial statements.

The following table reconciles our business net income to Net income attributable to equity holders of sanofi-aventis for the years ended December 31, 2010, 2009 and 2008:

( million)	2010	2009	2008
<b>Business net income</b>	<b>9,215</b>	<b>8,629</b>	<b>7,314</b>
(i) Amortization of intangible assets	(3,529)	(3,528)	(3,483)
(ii) Impairment of intangible assets	(433)	(372)	(1,554)
(iii) Expenses arising from the impact of acquisitions on inventories <sup>(1)</sup>	(30)	(27)	(2)
(iv) Restructuring costs	(1,372)	(1,080)	(585)
(iii)/(iv) Other items <sup>(2)</sup>	(138)		114
(v) Tax effects of:	1,841	1,629	1,904
<i>amortization of intangible assets</i>	<i>1,181</i>	<i>1,126</i>	<i>1,189</i>
<i>impairment of intangible assets</i>	<i>143</i>	<i>136</i>	<i>537</i>
<i>expenses arising from the impact of acquisitions on inventories</i>	<i>9</i>	<i>7</i>	<i>1</i>
<i>restructuring costs</i>	<i>462</i>	<i>360</i>	<i>196</i>
<i>other items</i>	<i>46</i>		<i>(19)</i>
(iii)/(vi) Other tax items <sup>(3)</sup>		106	221
(vii) Share of items listed above attributable to non-controlling interests	3	1	
(iii) Expenses arising from the impact of the Merial acquisition <sup>(4)</sup>	(32)	(66)	(50)
(iii)/(iv) Restructuring costs of associates and joint ventures, and expenses arising from the impact of acquisitions on associates and joint ventures <sup>(5)</sup>	(58)	(27)	(28)
<b>Net income attributable to equity holders of sanofi-aventis</b>	<b>5,467</b>	<b>5,265</b>	<b>3,851</b>

<sup>(1)</sup> This line comprises the workdown of inventories remeasured at fair value at the acquisition date.

<sup>(2)</sup> Other items comprise :

<i>gain on sale of investment in Millennium</i>			38
<i>reversals of/charges to provisions for risks</i>	(138 )		76

<sup>(3)</sup> Other tax items comprise :

<i>provisions for/settlements of tax disputes</i>			221
<i>reversal of deferred taxes following ratification of the Franco-American Treaty</i>		106	

<sup>(4)</sup> This line comprises: until September 17, 2009, amortization and impairment charged against the intangible assets of Merial; and from September 18, 2009, (i) the impact of the discontinuation of depreciation of the property, plant and equipment of Merial in accordance with IFRS 5 (see Note B.7. to our consolidated financial statements) and (ii) the expense arising from the workdown of inventories remeasured at fair value at acquisition date.

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

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The most significant reconciliation items in the table above relate to the purchase accounting effect of our acquisitions, particularly the amortization and impairment of intangible assets. We believe that excluding these non-cash charges enhances an investor's understanding of our underlying economic performance because we do not consider that the excluded charges reflect the combined entity's ongoing operating performance. Rather, we believe that each of the excluded charges reflects the decision to acquire the businesses concerned.

The purchase-accounting effects on net income primarily relate to:

charges to cost of sales resulting from the workdown of acquired inventory that was written up to fair value, net of tax;

charges related to the impairment of goodwill; and

charges related to the amortization and impairment of intangible assets, net of tax and non-controlling interests.

We believe (subject to the limitations described below) that disclosing business net income enhances the comparability of our operating performance, for the following reasons:

the elimination of charges related to the purchase accounting effect of our acquisitions (particularly amortization and impairment of finite-lived intangible assets) enhances the comparability of our ongoing operating performance relative to our peers in the pharmaceutical industry that carry these intangible assets (principally patents and trademarks) at low book values either because they are the result of in-house research and development that has already been expensed in prior periods or because they were acquired through business combinations that were accounted for as poolings-of-interest;

the elimination of selected items, such as the increase in cost of sales arising from the workdown of inventories remeasured at fair value, gains and losses on disposals of non-current assets and costs and provisions associated with major litigation, improves comparability from one period to the next; and

the elimination of restructuring costs relating to the implementation of our transformation strategy enhances comparability because these costs are directly, and only, incurred in connection with transformation processes such as the rationalization of our research and development structures.

We remind investors, however, that business net income should not be considered in isolation from, or as a substitute for, net income attributable to equity holders of sanofi-aventis reported in accordance with IFRS. In addition, we strongly encourage investors and potential investors not to rely on any single financial measure but to review our financial statements, including the notes thereto, and our other publicly filed reports, carefully and in their entirety.

There are material limitations associated with the use of business net income as compared to the use of IFRS net income attributable to equity holders of sanofi-aventis in evaluating our performance, as described below:

The results presented by business net income cannot be achieved without incurring the following costs that the measure excludes:

*Amortization of intangible assets.* Business net income excludes the amortization charges related to intangible assets. Most of these amortization charges relate to intangible assets that we have acquired. Although amortization is a non-cash charge, it is important for investors to consider it because it represents an allocation in each reporting period of a portion of the purchase price that we paid for certain intangible assets that we have acquired through acquisitions. For example, in connection with our acquisition of Aventis in 2004, we paid an aggregate of \$31,279 million for these amortizable intangible assets (which, in general, were to be amortized over their useful lives, which represented an average amortization period of eight years) and \$5,007 million for in-progress research & development. A large part of our revenues could not be generated without owning acquired intangible assets.

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

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

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

In determining the level of future dividend payments, and in analyzing dividend policy on the basis of business net income, our management intends to take into account the fact that many of the adjustments reflected in business net income have no effect on the underlying amount of cash available to pay dividends. However, although the adjustments relating to the elimination of the effect of the purchase accounting treatment of the Aventis acquisition and other acquisitions represent non-cash charges, the adjustments relating to restructuring costs represent significant cash charges in the periods following the closing of the acquisition.

This Item 5 contains a discussion and analysis of business net income on the basis of consolidated financial data. Because our business net income is not a standardized measure, it may not be comparable with the non-GAAP financial measures of other companies using the same or a similar non-GAAP financial measure.

## **Presentation of Net Sales**

In the discussion below, we present our consolidated net sales for 2010, 2009 and 2008. We break down our net sales among various categories, including by business segment, product and geographic region. We refer to our consolidated net sales as "reported sales."

In addition to reported sales, we analyze non-GAAP financial measures designed to isolate the impact on our net sales of currency exchange rates and changes in group structure.

When we refer to changes in our net sales "at constant exchange rates," we exclude the effect of exchange rates by recalculating net sales for the current year using the exchange rates that were used for the previous year. See Note B.2 to our consolidated financial statements for further information relating to the manner in which we translate into euros transactions recorded in other currencies.

When we refer to our net sales on a "constant structure basis," we eliminate the effect of changes in structure by restating the net sales for the previous period as follows:

by including sales from an entity or with respect to product rights acquired in the current period for a portion of the previous period equal to the portion of the current period during which we owned them, based on sales information we receive from the party from whom we make the acquisition;

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similarly, by excluding sales for a portion of the previous period when we have sold an entity or rights to a product in the current period; and

for a change in consolidation method, by recalculating the previous period on the basis of the method used for the current period.

A reconciliation of our reported net sales to our net sales at constant exchange rates and on a constant structure basis is provided at Results of Operations Year Ended December 31, 2010 Compared with Year Ended December 31, 2009 Net Sales and at Results of Operations Year Ended December 31, 2009 Compared with Year Ended December 31, 2008 Net Sales below.

### **Financial Presentation of Alliances**

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

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The financial impact of the alliances on the Company's income statement is described in Results of Operations Year Ended December 31, 2010 Compared with Year Ended December 31, 2009 and Year Ended December 31, 2009 Compared with Year Ended December 31, 2008, in particular in Net sales, Other Revenues, Share of Profit/Loss of Associates and Joint Ventures and Net Income Attributable to Non-Controlling Interests.

### ***Alliance Arrangements with Bristol-Myers Squibb***

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

There are three principal marketing arrangements that are used:

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

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

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

The alliance arrangements include two royalty streams that are applied on a worldwide basis (excluding Japan and other opt out countries), regardless of the marketing system and regardless of which company has majority ownership and operational management:

*Discovery Royalty.* As inventor of the two molecules, we earn an adjustable discovery royalty on all Aprovel® / Avapro® / Karvea® / Avalide® and Plavix® / Iscover® sold in alliance countries regardless of the marketing system. The discovery royalty earned in territories under operational management of BMS is reflected in our consolidated income statement in Other revenues.

*Development Royalty.* In addition to the discovery royalty, we and BMS are each entitled to a development royalty related to certain know-how and other intellectual property in connection with sales of Aprovel® / Avapro® / Karvea® / Avalide® and Plavix® / Iscover®.

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

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

to Plavix<sup>®</sup> in Japan, which is marketed by sanofi-aventis.

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

Further to the termination of an ancillary supply agreement by Warner Chilcott, sanofi-aventis and Warner Chilcott have begun negotiations on the future of their alliance arrangements.

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### **Impact of Exchange Rates**

We report our consolidated financial statements in euros. Because we earn a significant portion of our revenues in countries where the euro is not the local currency, our results of operations can be significantly affected by exchange rate movements between the euro and other currencies, primarily the U.S. dollar and, to a lesser extent, the Japanese yen, and currencies in emerging countries. We experience these effects even though certain of these countries do not account for a large portion of our net sales. In 2010, we earned 29.5% of our net sales in the United States. A decrease in the value of the U.S. dollar against the euro has a negative impact on our revenues, which is not offset by an equal reduction in our costs and therefore negatively affects our operating income. A decrease in the value of the U.S. dollar has a particularly significant impact on our operating income, which is higher in the United States than elsewhere, and on the contribution to net income of our alliance with BMS in the United States, which is under the operational management of BMS, as described at [Financial Presentation of Alliances](#) [Alliance arrangements with Bristol-Myers Squibb](#) above.

For a description of positions entered into to manage operational foreign exchange risks as well as our hedging policy, see [Item 11. Quantitative and Qualitative Disclosures about Market Risk](#), and [Item 3. Key Information D. Risk Factors](#) [Risks Related to Financial Markets](#) [Fluctuations in currency exchange rates could adversely affect our results of operations and financial condition](#).

### **Divestments**

There were no material divestments in 2010, 2009 or 2008.

### **Acquisitions**

The principal acquisitions during 2010 are described below:

In February 2010, sanofi-aventis acquired the U.S.-based company Chattem, Inc. (Chattem) by successfully completing a cash tender offer. Chattem is a major consumer health player in the United States, producing and distributing branded consumer health products, toiletries and dietary supplementes across various market segments. Chattem will manage the Allegra<sup>®</sup> brand, and act as the platform for sanofi-aventis over-the-counter and consumer health products in the United States. As of December 31, 2010, sanofi-aventis held 100% of Chattem's share capital. See Note D.1. to our consolidated financial statements included at [Item 18](#) of this annual report.

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

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

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

In July 2010, sanofi-aventis acquired 100% of the share capital of TargeGen, Inc. (TargeGen), a U.S. biopharmaceutical company developing small molecule kinase inhibitors for the treatment of certain forms of leukemia, lymphoma and other hematological malignancies and blood disorders. An upfront payment of \$75 million was made on completion of the transaction. Future milestone payments may be made at various stages in the development of TG 101348, TargeGen's principal product candidate. The total amount of payments (including the upfront payment) could reach \$560 million. See Note D.1. and Note D.18. to our consolidated financial statements included at Item 18 of this annual report.

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

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

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

In October 2010, sanofi-aventis and BMP Sunstone Corporation (BMP Sunstone) signed an agreement pursuant to which sanofi-aventis acquired 100% of the share capital of BMP Sunstone on February 24, 2011 for \$521 million.

The principal acquisitions during 2009 are described below:

On September 17, 2009, and further to the agreement signed on July 29, 2009, sanofi-aventis completed the acquisition of the interest held by Merck & Co., Inc. (Merck) in Merial Limited (Merial) for consideration of \$4 billion in cash. Founded in 1997, Merial was previously held jointly (50/50) by Merck and sanofi-aventis, and is now 100% held by sanofi-aventis. Merial is one of the world's leading animal health companies, with annual sales of \$2.6 billion in 2009 and 2010. With effect from September 17, 2009, sanofi-aventis has held 100% of the shares of Merial and has exercised exclusive control over the company. In accordance with IAS 27, Merial is accounted for by the full consolidation method in the consolidated financial statements of sanofi-aventis.

In connection with the agreement signed on July 29, 2009, sanofi-aventis also signed an option contract giving it the possibility, once the Merck/Schering-Plough merger is complete, to combine the Merck-owned Intervet/Schering-Plough Animal Health business with Merial in a joint venture to be held 50/50 by Merck and sanofi-aventis. The terms of the option contract set a value of \$8 billion for Merial. The minimum total value received by Merck and its subsidiaries in consideration for the transfer of Intervet/Schering-Plough to the combined entity would be \$9.25 billion, comprising a minimum value of \$8.5 billion for Intervet/Schering-Plough (subject to potential upward revision after valuations performed by the two parties) and additional consideration of \$750 million. An additional balancing payment of \$250 million will be made to establish 50/50 parity between Merck and sanofi-aventis in the combined entity.

Because of the high probability of the option being exercised as of year end 2009, Merial was treated as an asset held for sale or exchange pursuant to IFRS 5 as of December 31, 2009. On March 8, 2010, sanofi-aventis did in fact exercise its contractual right to combine the Intervet/Schering-Plough Animal Health business with Merial. In addition to execution of final agreements, formation of the new animal health joint venture remains subject to antitrust review in the United States, Europe and other countries, and other customary closing conditions. Due to the probable formation of the joint venture with Merck in 2011, Merial was still treated as an asset held for sale or exchange pursuant to IFRS 5 as of December 31, 2010. Detailed information about the impact of Merial on the consolidated financial statements of sanofi-aventis is provided in Note D.1. and Note D.8.1. to our consolidated financial statements included at Item 18 of this annual report.

On March 11, 2009, sanofi-aventis successfully closed its offer for Zentiva N.V. (Zentiva). As of December 31, 2009, sanofi-aventis held about 99.1% of Zentiva's share capital. Following the buyout of the remaining non-controlling interests, sanofi-aventis held 100% of Zentiva's share capital as of December 31, 2010. The purchase price was 1,200 million, including acquisition-related costs. See Note D.1. to our consolidated financial statements included at Item 18 of this annual report.

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On March 31, 2009, sanofi-aventis acquired Laboratorios Kendrick, one of Mexico's leading manufacturers of generics, with sales of approximately 26 million in 2008.

On April 27, 2009, sanofi-aventis acquired a 100% equity interest in Medley, the third largest pharmaceutical company in Brazil and a leading generics company in that country. The purchase price, based on an enterprise value of 500 million, was 348 million inclusive of acquisition-related costs. See Note D.1. to our consolidated financial statements included at Item 18 of this annual report.

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On April 27, 2009 sanofi-aventis acquired 100% of BiPar Sciences, Inc. (BiPar), a U.S. biopharmaceutical company developing novel tumor-selective approaches for the treatment of different types of cancers. BiPar is the leading company in the emerging field of DNA (deoxyribonucleic acid) repair using Poly ADP-Ribose Polymerase (PARP) inhibitors. The purchase price was contingent on the achievement (regarded as probable) of milestones related to the development of BSI-201, and could reach \$500 million. See Note D.1. and Note D.18. to our consolidated financial statements included at Item 18 of this annual report.

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

In August 2009, sanofi-aventis took control of Shantha Biotechnics (Shantha), a vaccines company based in Hyderabad (India). As of December 31, 2010, sanofi-aventis held approximately 96.4% of Shantha. The purchase price allocation led to the recognition of intangible assets (excluding goodwill) worth 374 million. See Note D.1. to our consolidated financial statements included at Item 18 of this annual report.

On October 30, 2009, sanofi-aventis acquired 100% of the share capital of Fovea Pharmaceuticals SA., a privately-held French biopharmaceutical research and development company specializing in ophthalmology. The purchase consideration was contingent on milestone payments of up to 280 million linked to the development of three clinical compounds. See Notes D.1. and D.18. to our consolidated financial statements included at Item 18 of this annual report.

On November 30, 2009, sanofi-aventis completed the acquisition of 100% of the share capital of Laboratoire Oenobiol, one of France's leading players in health and beauty dietary supplements.

The principal acquisitions during 2008 are described below:

On September 1, 2008, sanofi-aventis completed the acquisition of the Australian company Symbion CP Holdings Pty Ltd (Symbion Consumer) for AUD560 million. Symbion Consumer manufactures, markets and distributes nutraceuticals (vitamins and mineral supplements) and over-the-counter brands throughout Australia and New Zealand. Symbion Consumer has a portfolio of brands including Natures Own®, Cenovis®, Bio-organics®, Golden Glow® and Microgenics®.

On September 25, 2008, sanofi-aventis completed the acquisition of 100% of the share capital of Acambis plc (Acambis) for £285 million. Acambis became Sanofi Pasteur Holding Ltd, a wholly-owned subsidiary of Sanofi Pasteur Holding SA. This company develops novel vaccines that address unmet medical needs or substantially improve current standards of care. Sanofi Pasteur and Acambis had been developing vaccines in a successful partnership of more than a decade: Acambis was conducting major projects under exclusive collaboration agreements with sanofi pasteur, for vaccines against dengue fever and Japanese encephalitis.

**Table of Contents****Results of Operations***Year Ended December 31, 2010 Compared with Year Ended December 31, 2009*

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

(under IFRS)	as % of		as % of	
( million)	2010	net sales	2009	net sales
<b>Net sales</b>	<b>30,384</b>	<b>100.0%</b>	<b>29,306</b>	<b>100.0%</b>
Other revenues	1,651	5.4%	1,443	4.9%
Cost of sales	(8,717)	(28.7%)	(7,880)	(26.9%)
<b>Gross profit</b>	<b>23,318</b>	<b>76.7%</b>	<b>22,869</b>	<b>78.0%</b>
Research & development expenses	(4,401)	(14.5%)	(4,583)	(15.6%)
Selling & general expenses	(7,567)	(24.9%)	(7,325)	(25.0%)
Other operating income	359		866	
Other operating expenses	(276)		(481)	
Amortization of intangible assets	(3,529)		(3,528)	
Impairment of intangible assets	(433)		(372)	
Restructuring costs	(1,372)		(1,080)	
Gains and losses on disposals, and litigation	(138)			
<b>Operating income</b>	<b>5,961</b>	<b>19.6%</b>	<b>6,366</b>	<b>21.7%</b>
Financial expenses	(467)		(324)	
Financial income	105		24	
<b>Income before tax and associates and joint ventures</b>	<b>5,599</b>	<b>18.4%</b>	<b>6,066</b>	<b>20.7%</b>
Income tax expense	(1,242)		(1,364)	
Share of profit/loss of associates and joint ventures	978		814	
<b>Net income excluding the held-for-exchange Merial business <sup>(1)</sup></b>	<b>5,335</b>	<b>17.6%</b>	<b>5,516</b>	<b>18.8%</b>
Net income from the held-for-exchange Merial business <sup>(1)</sup>	386		175	
<b>Net income</b>	<b>5,721</b>	<b>18.8%</b>	<b>5,691</b>	<b>19.4%</b>
Net income attributable to non-controlling interests	254		426	
<b>Net income attributable to equity holders of sanofi-aventis</b>	<b>5,467</b>	<b>18.0%</b>	<b>5,265</b>	<b>18.0%</b>
Average number of shares outstanding (million)	1,305.3		1,305.9	
Average number of shares outstanding after dilution (million)	1,308.2		1,307.4	
Basic earnings per share (in euros)	4.19		4.03	
Diluted earnings per share (in euros)	4.18		4.03	

<sup>(1)</sup> Reported separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations). For the other disclosures required under IFRS 5, refer to Note D.8. to our consolidated financial statements included at Item 18 of this annual report.

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*Net Sales*

Net sales for the year ended December 31, 2010 were 30,384 million, up 3.7% on 2009. Exchange rate movements principally the appreciation of the U.S. dollar and the yen against the euro had a favorable effect of 4.5 points. At constant exchange rates, and after taking account of changes in structure (mainly the consolidation of Zentiva from the second quarter of 2009, and of Chatterm from the first quarter of 2010), net sales fell by 0.8% year-on-year. On a constant structure basis and at constant exchange rates, organic net sales were down 2.7%.

The following table sets forth a reconciliation of our reported net sales for the years ended December 31, 2010 and December 31, 2009 to our net sales at constant exchange rates and net sales on a constant structure basis.

	Change		
( million)	2010	2009	(%)
<b>Net sales</b>	<b>30,384</b>	<b>29,306</b>	<b>+3.7%</b>
Effect of exchange rates	(1,319)		
<b>Net sales at constant exchange rates</b>	<b>29,065</b>	<b>29,306</b>	<b>-0.8%</b>
Effect of changes in structure		561	
<b>Net sales on a constant structure basis and at constant exchange rates</b>	<b>29,065</b>	<b>29,867</b>	<b>-2.7%</b>

Our net sales are generated by our two principal operating segments: Pharmaceuticals and Human Vaccines (Vaccines). We do not consolidate net sales from our Animal Health business; instead, Merial's contribution to net income is reported separately on the line Net income from the held-for-exchange Merial business, in accordance with IFRS 5 (see Note D.8. to our consolidated financial statements included at Item 18 of this annual report).

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

			Change on a	Change at	Change on a
( million)	2010	2009	reported basis	constant exchange rates	constant structure basis and at constant exchange rates
	Reported	Reported	(%)	(%)	(%)
Pharmaceuticals	26,576	25,823	+2.9%	-1.6%	-3.6%
Vaccines	3,808	3,483	+9.3%	+4.8%	+3.8%
<b>Total</b>	<b>30,384</b>	<b>29,306</b>	<b>+3.7%</b>	<b>-0.8%</b>	<b>-2.7%</b>

*Net Sales by Product - Pharmaceuticals*

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



*Flagship Products*

Our flagship products (Lantus<sup>®</sup> and other Diabetes division products, Lovenox<sup>®</sup>, Plavix<sup>®</sup>, Taxotere<sup>®</sup>, Aprovel<sup>®</sup>/CoAprovel<sup>®</sup>, Eloxatine<sup>®</sup>, Multaq<sup>®</sup> and Jevtana<sup>®</sup>) are discussed below. Sales of Plavix<sup>®</sup> and Aprovel<sup>®</sup> are discussed further below under [Worldwide Presence of Plavix<sup>®</sup> and Aprovel<sup>®</sup>](#).

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

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

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

**Lovenox**<sup>®</sup>, the leading anti-thrombotic in the United States, Germany, France, Italy, Spain and the United Kingdom (source: IMS 2010 sales), saw net sales fall by 10.5% at constant exchange rates in 2010 to 2,806 million. In the United States, sales fell by 22.7% to 1,439 million following the introduction of a generic version of enoxaparin at the end of July 2010. As of the date of this document, we are aware of only one U.S. generic approved by the FDA although other ANDAs have been submitted. Excluding the United States, net sales were up 7.8% at constant exchange rates at 1,367 million (representing 48.7% of worldwide 2010 sales of Lovenox<sup>®</sup>), with good performances in Western Europe (up 7.3%) and Eastern Europe (up 14.0%).

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

Net sales of **Eloxatine**<sup>®</sup> fell by 58.8% at constant exchange rates in 2010 to 427 million, hit by competition from generics. Following a court ruling, generics manufacturers have been under order to stop selling their unauthorized Eloxatin<sup>®</sup> generics in the U.S. market since June 30, 2010. Sun Pharmaceuticals has appealed this decision (see Note D.22.b) to our consolidated financial statements included at Item 18 of this annual report). The workdown of existing inventories of generics impaired our Eloxatine<sup>®</sup> sales performance in the second half of 2010.

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

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

Our other major products are described below.

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

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

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

The **Consumer Health Care** business posted year-on-year growth of 45.7% at constant exchange rates to 2,217 million, driven by Emerging Markets where net sales rose by 44.4% at constant exchange rates to 1,050 million. These figures consolidate the consumer health products of Zentiva from April 2009, Oenobiol from December 2009, Chatterem from February 2010, and Nepentes from August 2010. On a constant structure basis and at constant exchange rates, the division achieved sales growth of 6.9%, driven by Emerging Markets.

The **Generics** business reported 2010 net sales of 1,534 million, up 41.5% at constant exchange rates. Growth was driven by Emerging Markets, due to the acquisition and consolidation of Zentiva and Kendrick (from April 2009) and Medley (from May 2009), and by the United States, following the launch of our generic version of Ambien<sup>®</sup>CR. On a constant structure basis and at constant exchange rates, the Generics division advanced by 18.5%, driven by Emerging Markets.

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Net sales of the other products in the portfolio were flat year-on-year at 6,064 million (up 0.3% on a constant structure basis and at constant exchange rates). For a description of our other pharmaceutical products, see Item 4. Information on the Company B. Business Overview Pharmaceutical Products.

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

( million)	Product	Indication	2010 Reported	2009 Reported	Change on a reported basis (%)	Change at	Change on a
						constant	constant structure
						exchange	basis and at
						rates (%)	constant exchange
							rates (%)
	Lantus®	Diabetes	3,510	3,080	+14.0%	+9.1%	+9.1%
	Apidra®	Diabetes	177	137	+29.2%	+24.1%	+24.1%
	Amaryl®	Diabetes	478	416	+14.9%	+7.7%	+7.7%
	Insuman®	Diabetes	133	131	+1.5%	+1.5%	+1.5%
	<b>Sub-total: Diabetes</b>		<b>4,298</b>	<b>3,764</b>	<b>+14.2%</b>	<b>+9.2%</b>	<b>+9.2%</b>
	Lovenox®	Thrombosis	2,806	3,043	-7.8%	-10.5%	-10.5%
	Plavix®	Atherothrombosis	2,083	2,623	-20.6%	-24.6%	-24.6%
	Taxotere®	Breast, lung, prostate, stomach, and head & neck cancer	2,122	2,177	-2.5%	-6.4%	-6.4%
	Aprovel®/CoAprovel®	Hypertension	1,327	1,236	+7.4%	+4.2%	+4.2%
	Eloxatine®	Colorectal cancer	427	957	-55.4%	-58.8%	-58.8%
	Multaq®	Atrial fibrillation	172	25	+588.0%	+560.0%	+560.0%
	Jevtana®	Prostate cancer	82				
	Stilnox®/Ambien® /Myslec®	Sleep disorders	819	873	-6.2%	-10.9%	-10.8%
	Allegra®	Allergic rhinitis, urticaria	607	731	-17.0%	-22.4%	-18.5%
	Copaxone®	Multiple sclerosis	513	467	+9.9%	+8.4%	+11.0%
	Tritace®	Hypertension	410	429	-4.4%	-7.2%	-5.2%
	Dépakine®	Epilepsy	372	329	+13.1%	+7.6%	+7.6%
	Xatral®	Benign prostatic hypertrophy	296	296	0.0%	-3.4%	-3.1%
	Actonel®	Osteoporosis, Paget s disease	238	264	-9.8%	-16.3%	-16.3%
	Nasacort®	Allergic rhinitis	189	220	-14.1%	-16.8%	-16.8%
	<b>Other products</b>		<b>6,064</b>	<b>5,947</b>	<b>+2.0%</b>	<b>-1.9%</b>	<b>+0.3%</b>
	<b>Consumer Health Care</b>		<b>2,217</b>	<b>1,430</b>	<b>+55.0%</b>	<b>+45.7%</b>	<b>+6.9%</b>
	<b>Generics</b>		<b>1,534</b>	<b>1,012</b>	<b>+51.6%</b>	<b>+41.5%</b>	<b>+18.5%</b>
	<b>Total pharmaceuticals</b>		<b>26,576</b>	<b>25,823</b>	<b>+2.9%</b>	<b>-1.6%</b>	<b>-3.6%</b>

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

( million)	Change at		Change at		Change at		Change at	
	Western	exchange	United	exchange	Emerging	exchange	Other	exchange
Product	Europe*	rates	States	rates	Markets**	rates	countries***	rates
Lantus <sup>®</sup>	684	+5.3%	2,134	+7.4%	508	+18.2%	184	+25.2%
Apidra <sup>®</sup>	68	+21.8%	62	+11.1%	35	+37.5%	12	+150.0%
Amaryl <sup>®</sup>	42	-17.6%	6	-33.3%	222	+21.7%	208	+3.3%
Insuman <sup>®</sup>	108	-0.9%			25	+19.0%		-100.0%
<b>Sub-total: Diabetes</b>	<b>902</b>	<b>+4.2%</b>	<b>2,202</b>	<b>+7.4%</b>	<b>790</b>	<b>+20.0%</b>	<b>404</b>	<b>+13.7%</b>
Lovenox <sup>®</sup>	782	+7.3%	1,439	-22.7%	499	+6.9%	86	+19.4%
Plavix <sup>®</sup>	641	-53.9%	213 <sup>a</sup>	-4.1%	648	+0.7%	581	+25.4%
Taxotere <sup>®</sup>	709	-10.6%	786	-8.0%	394	+1.4%	233	+2.5%
Aprovel <sup>®</sup> /CoAprovel <sup>®</sup>	825	-5.0%	39 <sup>a</sup>	+457.1%	358	+8.3%	105	+67.3%
Eloxatine <sup>®</sup>	46	-42.9%	172	-76.4%	150	-9.8%	59	+4.0%
Multaq <sup>®</sup>	39		128		2		3	
Jevtana <sup>®</sup>			82					
Stilnox <sup>®</sup> /Ambien <sup>®</sup> /Myslee <sup>®</sup>	55	-8.3%	443	-21.6%	68	+5.0%	253	+13.6%
Allegra <sup>®</sup>	16	-5.9%	147	-53.6%	88	+17.4%	356	-3.2%
Copaxone <sup>®</sup>	482	+9.1%			13	-13.3%	18	+7.7%
Tritace <sup>®</sup>	189	-4.1%			191	-2.6%	30	-41.9%
Depakine <sup>®</sup>	148	+2.1%			209	+12.0%	15	+9.1%
Xatral <sup>®</sup>	66	-14.3%	155	+2.7%	70	+0.0%	5	-50.0%
Actonel <sup>®</sup>	104	-23.5%			93	-12.4%	41	+3.2%
Nasacort <sup>®</sup>	28	-3.4%	130	-20.3%	26	-10.7%	5	-20.0%
<b>Other products</b>	<b>2,649</b>	<b>-2.3%</b>	<b>652</b>	<b>+3.3%</b>	<b>2,052</b>	<b>+0.4%</b>	<b>711</b>	<b>-10.9%</b>
<b>Consumer Health Care</b>	<b>630</b>	<b>+1.1%</b>	<b>320</b>		<b>1,050</b>	<b>+44.4%</b>	<b>217</b>	<b>+31.3%</b>
<b>Generics</b>	<b>404</b>	<b>+11.1%</b>	<b>102</b>		<b>988</b>	<b>+42.8%</b>	<b>40</b>	<b>+61.9%</b>
<b>Total pharmaceuticals</b>	<b>8,715</b>	<b>-8.5%</b>	<b>7,010</b>	<b>-7.5%</b>	<b>7,689</b>	<b>+11.9%</b>	<b>3,162</b>	<b>+6.9%</b>

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

\*\* World excluding United States, Canada, Western Europe, Japan, Australia and New Zealand.

\*\*\* Japan, Canada, Australia and New Zealand.

<sup>a</sup> Sales of active ingredient to the entity majority-owned by BMS in the United States.

#### Net Sales Human Vaccines (Vaccines)

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

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



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

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

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

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

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

The following table presents the 2010 sales of our Vaccines activity by range of products:

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

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

	Change at		Change at		Change at		Change at	
	Western	constant	United	constant	Emerging	constant	Other	constant
	Europe*	exchange	States	exchange	Markets**	exchange	countries***	exchange
( million)	Reported	rates	Reported	rates	Reported	rates	Reported	rates
Influenza Vaccines <sup>a</sup>								
(inc. Vaxigrip <sup>®</sup> and Fluzone <sup>®</sup> )	128	-7.9 %	528	-20.2%	618	+116.4%	23	+5.6%
Polio/Pertussis.Hib Vaccines								
(inc. Pentacel <sup>®</sup> and Pentaxim <sup>®</sup> )	61	-16.2 %	470	-14.6%	384	+11.4%	69	+56.4%
Meningitis/Pneumonia Vaccines								
(inc. Menactra <sup>®</sup> )	5	-54.5 %	407	-11.4%	101	+25.6%	14	+0.0%
Adult Booster Vaccines								
(inc. Adacel <sup>®</sup> )	54	-3.6 %	345	+5.2%	33	+32.0%	17	-20.0%
Travel and Other Endemics Vaccines	18	+20.0 %	80	+11.6%	235	+15.8%	49	+21.2%
Other Vaccines	16	-63.2 %	128	-10.4%	15	+0.0%	10	+22.2%
<b>Total Vaccines</b>	<b>282</b>	<b>-15.6 %</b>	<b>1,958</b>	<b>-11.5%</b>	<b>1,386</b>	<b>+46.2%</b>	<b>182</b>	<b>+23.0%</b>

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

\*\* World excluding United States, Canada, Western Europe, Japan, Australia and New Zealand.

\*\*\* Japan, Canada, Australia and New Zealand.

<sup>a</sup> Seasonal and pandemic influenza vaccines.

In addition to the Vaccines activity reflected in our consolidated net sales, sales at Sanofi Pasteur MSD, our joint venture with Merck & Co., Inc. in Western Europe, amounted to 918 million, down 18.9% on a reported basis. Sales of Gardasil, a vaccine that prevents papillomavirus infections (a cause of cervical cancer), totaled 263 million in 2010, compared with 395 million in 2009. This fall of 33.5% was mainly due to a reduction in catch-up vaccination programs.

Sales generated by Sanofi Pasteur MSD are not included in our consolidated net sales.

#### Net Sales Animal Health

The Animal Health business is conducted through Merial, which has been a wholly-owned subsidiary of sanofi-aventis since September 18, 2009. In March 2010, we exercised our option to combine Merial and Intervet/Schering-Plough in a new 50/50 joint venture with Merck in 2011. Consequently, Merial's profit contribution is reported on the line Net income from the held-for-exchange Merial business, in accordance with IFRS 5 (see Note D.8. to our consolidated financial statements included at Item 18 of this annual report), and Merial's net sales are not



consolidated by sanofi-aventis.

Meril generated net sales of \$2,635 million in 2010, up 2.6% at constant exchange rates and 3.2% on a reported basis. Net sales for the companion animals franchise increased by 1.4% at constant exchange rates (1.7% on a reported basis) to \$1,707 million, as growth for the Frontline® range in the United States more than offset the impact of generics of Frontline® in Europe. The production animals franchise performed well, growing by 5.0% at constant exchange rates (6.1% on a reported basis) to \$928 million.

	2010	2009	Change at constant
(\$ million)	Reported	Reported	exchange rates
Frontline® and other fipronil-based products	1,027	996	+2.4%
Vaccines	837	794	+5.5%
Avermectin	473	475	-2.8%
Other	298	289	+4.8%
<b>Total</b>	<b>2,635</b>	<b>2,554</b>	<b>+2.6%</b>

**Table of Contents***Net Sales by Geographic Region*

We divide our sales geographically into four regions: Western Europe, the United States, Emerging Markets and other countries. The following table breaks down our 2010 and 2009 net sales by region:

	2010	2009	Change on a	Change at constant
( million)	Reported	Reported	Reported basis	exchange rates
Western Europe*	8,997	9,793	-8.1%	-8.8%
United States	8,968	9,426	-4.9%	-8.4%
Emerging Markets**	9,075	7,356	+23.4%	+16.3%
Of which Eastern Europe and Turkey	2,612	2,266	+15.3%	+10.0%
Of which Asia (excl. Pacific region***)	1,983	1,610	+23.2%	+14.2%
Of which Latin America	2,735	1,913	+43.0%	+32.4%
Of which Africa	846	775	+9.2%	+4.0%
Of which Middle East	789	647	+21.9%	+19.6%
Other Countries****	3,344	2,731	+22.4%	+7.7%
Of which Japan	2,225	1,844	+20.7%	+9.1%
<b>Total</b>	<b>30,384</b>	<b>29,306</b>	<b>+3.7%</b>	<b>-0.8%</b>

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

\*\* World excluding United States, Canada, Western Europe, Japan, Australia and New Zealand.

\*\*\* Japan, Australia and New Zealand.

\*\*\*\* Japan, Canada, Australia and New Zealand.

Western Europe saw net sales fall by 8.8% at constant exchange rates in 2010 to 8,997 million, hit by competition from generics of Plavix® and Taxotere®, and by price pressure from the healthcare authorities.

In the United States, net sales were 8.4% lower at constant exchange rates at 8,968 million (11.1% lower on a constant structure basis and at constant exchange rates), reflecting the arrival of generic competition for Lovenox® and Ambien® CR, plus the workdown of inventories of generic versions of Eloxatine® during the second half of 2010 and the effects of healthcare reform. These figures include net sales generated by Chattem from February 2010.

Emerging Markets net sales were 9,075 million, representing robust growth of 16.3% at constant exchange rates. This performance reflected solid organic growth (13.2% on a constant structure basis and at constant exchange rates), and the impact of acquisitions (primarily Zentiva in Eastern Europe and Medley in Brazil). Emerging Markets accounted for 29.9% of total consolidated net sales in 2010. The main growth drivers were Latin America, Russia and China, which achieved growth at constant exchange rates of 32.4% (to 2,735 million), 19.9% (to 654 million) and 23.6% (to 667 million), respectively. In Latin America (primarily Brazil and Mexico), growth was fueled by sales of influenza vaccines, which virtually trebled (189% growth).

In the Other Countries region, net sales rose by 7.7% at constant exchange rates to 3,344 million. Net sales in Japan reached 2,225 million, up 9.1% at constant exchange rates, thanks largely to the success of Plavix® and the performance of the Vaccines business.

*Worldwide Presence of Plavix® and Aprovel®*

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

Worldwide sales of these two products are an important indicator because they facilitate a financial statement user s understanding and analysis of our consolidated income statement, particularly in terms of

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understanding our overall profitability in relation to consolidated revenues, and also facilitate a user's ability to understand and assess the effectiveness of our research and development efforts.

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

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

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

(1) Plavix® is marketed under the trademarks Plavix® and Iscover®.

(2) Net sales of Plavix® consolidated by sanofi-aventis, excluding sales to BMS ( 273 million in 2010 and 311 million in 2009).

(3) Translated into euros by sanofi-aventis using the method described in Note B.2. Foreign currency translation to our consolidated financial statements included at Item 18 in this annual report.

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

(5) Net sales of Aprovel® consolidated by sanofi-aventis, excluding sales to BMS ( 129 million in 2010 and 113 million in 2009).

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

Worldwide sales of Aprovel®/Avapro®/Karvea®/Avalide® were 2,056 million in 2010, down 1.5% at constant exchange rates. The performance in the Other Countries region, lifted by sales of active ingredient to our alliance partners in Japan, partially offset the drop in sales in the United States and Europe, where net sales fell by 10.4% and 4.4% respectively at constant exchange rates. At the end of 2010, sales were impacted by a

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voluntary recall of certain lots of Avalide® (irbesartan-hydrochlorothiazide) by Bristol-Myers Squibb and sanofi-aventis from the U.S., Puerto Rican, Canadian, Mexican and Argentinean markets.

### *Other Revenues*

Other revenues, which mainly comprise royalty income under licensing agreements contracted in connection with ongoing operations, totaled 1,651 million in 2010, 14.4% higher than the 2009 figure of 1,443 million.

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

### *Gross Profit*

Gross profit for the year ended December 31, 2010 came to 23,318 million (76.7% of net sales), 2.0% up on the 2009 figure of 22,869 million (78.0% of net sales).

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

Nevertheless, the 2010 gross margin ratio for the Pharmaceuticals segment remained healthy at 78.6%.

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

Consolidated gross profit was also dented by a 30 million charge (0.1 of a point) arising from the workdown during 2010 of inventories remeasured at fair value in connection with acquisitions (principally Chattem).

### *Research and Development Expenses*

Research and development expenses amounted to 4,401 million in 2010 (14.5% of net sales), compared with 4,583 million in 2009 (15.6% of net sales). This represents a year-on-year reduction of 4.0% on a reported basis and 6.2% at constant exchange rates.

The Pharmaceuticals segment generated savings of 7.1% at constant exchange rates as a result of the reorganization initiated in 2009, which has helped reorient some in-house resources towards third-party collaborations. These savings also reflect a rationalization of R&D projects following a full, objective review of the portfolio.

Research and development expenses in the Vaccines segment rose by 26 million year-on-year, an increase of 1.8% at constant exchange rates.

### *Selling and General Expenses*

Selling and general expenses amounted to 7,567 million (24.9% of net sales), an increase of 3.3% on the prior-year figure of 7,325 million (25.0% of net sales). At constant exchange rates, selling and general expenses fell by 1.2%, despite the first-time consolidation of companies acquired in 2010 (primarily Chattem) and the impact of the Jevtana<sup>®</sup> and Multaq<sup>®</sup> launches. This reduction reflects the transformation program initiated in 2009, and was mainly driven by savings in marketing costs in the United States and Europe, and in general expenses.

*Other Operating Income and Expenses*

Other operating income amounted to 359 million in 2010 (2009: 866 million), and other operating expenses totaled 276 million (2009: 481 million).

Overall, other operating income and expenses represented net income of 83 million in 2010, compared with 385 million in 2009. The year-on-year fall of 302 million was mainly due to the discontinuation of royalty payments from Teva on North American sales of Copaxone<sup>®</sup> from the second quarter of 2010.

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In addition, sanofi-aventis recorded a net operational foreign exchange loss of 141 million due to highly volatile currency markets; this compares with a net gain of 40 million in 2009.

### *Amortization of Intangible Assets*

Amortization charged against intangible assets in the year ended December 31, 2010 amounted to 3,529 million, compared with 3,528 million in the previous year. An increase in amortization expense in North America, related to trends in the U.S. dollar/euro exchange rate and the Chatterm acquisition, was offset by a reduction in Europe as some intangible assets reached the end of their useful lives.

This line item mainly comprises amortization charged against intangible assets remeasured at fair value on the acquisitions of Aventis (3,070 million in 2010, versus 3,175 million in 2009) and of Zentiva (130 million in 2010, versus 98 million in 2009).

### *Impairment of Intangibles Assets*

This line recorded impairment losses of 433 million in 2010, compared with 372 million in 2009. The losses booked in 2010 related mainly to (i) Actonel<sup>®</sup>, due to contemplated amendments to the terms of the collaboration agreement with Warner Chilcott; (ii) the pentavalent vaccine Shan5<sup>®</sup>, for which sales projections were revised to take account of the need to file a new application for WHO pre-qualification following a flocculation problem in some batches; (iii) the BSI-201 project, for which the development plan was revised following the announcement of the initial results from a Phase III trial in triple-negative metastatic breast cancer; and (iv) some of Zentiva's generics and consumer health products, whose sales projections in Eastern Europe were adjusted downwards.

The net impairment loss of 372 million recognized in 2009 related mainly to Actonel<sup>®</sup>, Benzaclin<sup>®</sup> and Nasacort<sup>®</sup>, and reflected the changing competitive environment and the approval dates of generics.

### *Restructuring Costs*

Restructuring costs amounted to 1,372 million in 2010, compared with 1,080 million in 2009.

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

In 2009, restructuring costs related mainly to measures aimed at transforming R&D operations to encourage innovation, and adapting central support functions to streamline the organizational structure. They mainly comprised employee-related expenses, in the form of early retirement benefits and termination benefits under voluntary redundancy plans. To a lesser extent, they reflected ongoing measures to adapt our industrial facilities in Europe and adjust our sales forces.



*Gains and Losses on Disposals, and Litigation*

In 2010, this line item reported an expense of 138 million, relating to an adjustment to vendor's guarantee provisions in connection with past divestments.

We made no material divestments in 2010 or 2009.

*Operating Income*

Operating income for 2010 was 5,961 million, versus 6,366 million for 2009, a drop of 6.4%.

*Financial Income and Expenses*

Net financial expenses were 362 million in 2010, compared with 300 million in 2009, an increase of 20.7%.

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Financial expenses directly related to net debt (defined as short-term and long-term debt, plus related interest rate and currency derivatives, minus cash and cash equivalents) were 397 million in 2010, versus 230 million in 2009. This year-on-year rise reflected the following factors:

an increase in the average interest rate (due to a longer average maturity), charged on a higher level of average consolidated debt;

a reduction in interest income, reflecting a lower average rate of return; and

the 34 million of financial expenses incurred on the acquisition credit facilities contracted in October 2010 in connection with the launch of the public tender offer for Genzyme (see Item 8.B. Significant changes ).

Gains on disposals amounted to 61 million, mainly on the sale of the equity interest in Novexel.

Net foreign exchange losses on financial items totaled 20 million in 2010 (2009: 67 million).

### *Income before Tax and Associates and Joint Ventures*

Income before tax and associates and joint ventures was 5,599 million in 2010, versus 6,066 million in 2009, a fall of 7.7%.

### *Income Tax Expense*

Income tax expense totaled 1,242 million in 2010, compared with 1,364 million in 2009.

The effective tax rate is calculated on the basis of business operating income minus net financial expenses and before the share of profit/loss of associates and joint ventures, net income from the held-for-exchange Merial business, and net income attributable to non-controlling interests. The effective tax rate was 27.8% in 2010, versus 28.0% in 2009. The difference relative to the standard income tax rate applicable in France (34%) was mainly due to royalty income being taxed at a reduced rate in France.

This line item also includes tax effects of amortization of intangible assets ( 1,181 million in 2010, 1,126 million in 2009) and of restructuring costs ( 462 million in 2010, 360 million in 2009).

### *Share of Profit/Loss of Associates and Joint Ventures*

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Our share of profits and losses from associates and joint ventures was 978 million in 2010, compared with 814 million in 2009. This line mainly includes our share of after-tax profits from territories managed by BMS under the Plavix® and Avapro® alliance, which rose by 24.8% from 785 million in 2009 to 980 million in 2010. This year-on-year increase was mainly related to stronger sales of Plavix® in the United States (up 10.8% at constant exchange rates) and to the appreciation of the U.S. dollar against the euro (positive impact of 3.7%).

### *Net Income from the Held-for-Exchange Merial Business*

With effect from September 18, 2009, the date on which we obtained exclusive control over Merial, the operations of this company have been accounted for using the full consolidation method. In accordance with IFRS 5, the results of Merial's operations are reported separately in the line item Net income from the held-for-exchange Merial business (see Note D.8.1. to our consolidated financial statements included at Item 18 of this annual report).

Net income from the held-for-exchange Merial business amounted to 386 million, compared with 175 million in 2009. The increase mainly reflects the fact that since September 18, 2009, this line has included 100% of Merial's net income, against 50% previously. The figure reported also includes the impact of the workdown of inventories remeasured at fair value in September 2009.

### *Net Income*

Net income for the year was 5,721 million in 2010, compared with 5,691 million in 2009.

**Table of Contents***Net Income Attributable to Non-Controlling Interests*

Net income attributable to non-controlling interests amounted to 254 million in 2010, compared with 426 million in 2009. This line mainly comprises the share of pre-tax profits paid to BMS from territories managed by sanofi-aventis (238 million, versus 405 million in 2009). The decrease in Net income attributable to non-controlling interests in 2010 was directly related to increased competition from generics of clopidogrel (Plavix®) in Europe.

*Net Income Attributable to Equity Holders of Sanofi-Aventis*

Net income attributable to equity holders of sanofi-aventis totaled 5,467 million in 2010, against 5,265 million in 2009.

Basic earnings per share for 2010 was 4.19, 4.0% higher than the 2009 figure of 4.03, based on an average number of shares outstanding of 1,305.3 million in 2010 and 1,305.9 million in 2009. Diluted earnings per share was 4.18 in 2010 compared with 4.03 in 2009, based on an average number of shares outstanding after dilution of 1,308.2 million in 2010 and 1,307.4 million in 2009.

*Business Operating Income*

Business operating income for 2010 was 12,660 million, compared to 12,028 million in 2009. The table below shows trends in business operating income by business segment for 2010 and 2009:

<i>( million)</i>	<b>2010</b>	<b>2009</b>
Pharmaceuticals	10,965	10,608
Vaccines	1,379	1,173
Other	316	247
<b>Business operating income</b>	<b>12,660</b>	<b>12,028</b>

*Business Net Income*

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

Business net income for 2010 was 9,215 million, an improvement of 6.8% on the 2009 figure of 8,629 million, and represented 30.3% of net sales compared with 29.4% in 2009. The increase was mainly due to our good operating performance, reflected in the increase in gross profit (23,318 million in 2010 versus 22,869 million in 2009).



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<i>( million)</i>	<b>2010</b>	<b>2009</b>
<b>Business net income</b>	<b>9,215</b>	<b>8,629</b>
(i) Amortization of intangible assets	(3,529)	(3,528)
(ii) Impairment of intangible assets	(433)	(372)
(iii) Expenses arising from the impact of acquisitions on inventories <sup>(1)</sup>	(30)	(27)
(iv) Restructuring costs	(1,372)	(1,080)
(iii)/(iv) Other items <sup>(2)</sup>	(138)	
(v) Tax effects of:	1,841	1,629
<i>amortization of intangible assets</i>	1,181	1,126
<i>impairment of intangible assets</i>	143	136
<i>expenses arising from the impact of acquisitions on inventories</i>	9	7
<i>restructuring costs</i>	462	360
<i>other items</i>	46	
(iii)/(vi) Other tax items <sup>(3)</sup>		106
(vii) Share of items listed above attributable to non-controlling interests	3	1
(iii) Expenses arising from the impact of the Merial acquisition <sup>(4)</sup>	(32)	(66)
(iii)/(iv) Restructuring costs of associates and joint ventures, and expenses arising from the impact of acquisitions on associates and joint ventures <sup>(5)</sup>	(58)	(27)
<b>Net income attributable to equity holders of sanofi-aventis</b>	<b>5,467</b>	<b>5,265</b>

<sup>(1)</sup> This line comprises the workdown of inventories remeasured at fair value at the acquisition date.

<sup>(2)</sup> Other items comprise:

*reversals of charges to provisions for risks*

(138)

<sup>(3)</sup> Other tax items comprise:

*reversal of deferred taxes following ratification of the Franco-American Treaty*

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<sup>(4)</sup> This line item comprises: until September 17, 2009, amortization and impairment charged against the intangible assets of Merial; and from September 18, 2009, (i) the impact of discontinuation of depreciation of the property, plant and equipment of Merial in accordance with IFRS 5 (see Note B.7. to the consolidated financial statements) and (ii) the expense arising from the workdown of inventories remeasured at fair value at the acquisition date.

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

**Business Earnings Per Share**

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

Business earnings per share for 2010 were 7.06, up 6.8% on the 2009 business earnings per share figure of 6.61. The weighted average number of shares outstanding was 1,305.3 million in 2010 and 1,305.9 million in 2009. Diluted business earnings per share for 2010 were 7.04, up 6.7% on the 2009 diluted business earnings per share figure of 6.60. On a diluted basis, the weighted average number of shares outstanding was 1,308.2 million in 2010 and 1,307.4 million in 2009.

**Table of Contents****Year Ended December 31, 2009 Compared with Year Ended December 31, 2008**

The consolidated income statements for the years ended December 31, 2009 and December 31, 2008 break down as follows:

(under IFRS)	as % of		as % of	
( million)	2009	net sales	2008	net sales
<b>Net sales</b>	<b>29,306</b>	<b>100.0%</b>	<b>27,568</b>	<b>100.0%</b>
Other revenues	1,443	4.9%	1,249	4.5%
Cost of sales	(7,880)	(26.9%)	(7,337)	(26.6%)
<b>Gross profit</b>	<b>22,869</b>	<b>78.0%</b>	<b>21,480</b>	<b>77.9%</b>
Research & development expenses	(4,583)	(15.6%)	(4,575)	(16.6%)
Selling & general expenses	(7,325)	(25.0%)	(7,168)	(26.0%)
Other operating income	866		556	
Other operating expenses	(481)		(353)	
Amortization of intangible assets	(3,528)		(3,483)	
Impairment of intangible assets	(372)		(1,554)	
Restructuring costs	(1,080)		(585)	
Gains and losses on disposals, and litigation			76	
<b>Operating income</b>	<b>6,366</b>	<b>21.7%</b>	<b>4,394</b>	<b>15.9%</b>
Financial expenses	(324)		(335)	
Financial income	24		103	
<b>Income before tax and associates and joint ventures</b>	<b>6,066</b>	<b>20.7%</b>	<b>4,162</b>	<b>15.1%</b>
Income tax expense	(1,364)		(682)	
Share of profit/loss of associates and joint ventures	814		692	
<b>Net income excluding the held-for-exchange Merial business <sup>(1)</sup></b>	<b>5,516</b>	<b>18.8%</b>	<b>4,172</b>	<b>15.1%</b>
Net income from the held-for-exchange Merial business <sup>(1)</sup>	175		120	
<b>Net income</b>	<b>5,691</b>	<b>19.4%</b>	<b>4,292</b>	<b>15.6%</b>
Net income attributable to non-controlling interests	426		441	
<b>Net income attributable to equity holders of sanofi-aventis</b>	<b>5,265</b>	<b>18.0%</b>	<b>3,851</b>	<b>14.0%</b>
Average number of shares outstanding (million)	1,305.9		1,309.3	
Average number of shares outstanding after dilution (million)	1,307.4		1,310.9	
Basic earnings per share (in euros)	4.03		2.94	
Diluted earnings per share (in euros)	4.03		2.94	

<sup>(1)</sup> Reported separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations). For the other disclosures required under IFRS 5, refer to Note D.8. to our consolidated financial statements included at Item 18 of this annual report.

*Net Sales*

Net sales for the year ended December 31, 2009 amounted to 29,306 million, an increase of 6.3% versus 2008. Exchange rate movements had a favorable effect of 1.0 point, mainly reflecting the appreciation in the U.S. dollar against the euro. At constant exchange rates and after taking account of changes in structure (mainly the consolidation of Zentiva and Medley from the second quarter of 2009, and the reversion of Copaxone® to Teva in North America effective April 1, 2008), net sales rose by 5.3%. Excluding changes in structure and at constant exchange rates, organic net sales growth was 4.0%.

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The following table sets forth a reconciliation of our reported net sales for the years ended December 31, 2009 and December 31, 2008 to our net sales at constant exchange rates and net sales on a constant structure basis.

	Change		
( million)	2009	2008	(%)
<b>Reported net sales</b>	<b>29,306</b>	<b>27,568</b>	<b>+6.3%</b>
Effect of exchange rates	(274)		
<b>Net sales at constant exchange rates</b>	<b>29,032</b>	<b>27,568</b>	<b>+5.3%</b>
Effect of changes in structure	339		
<b>Net sales on a constant structure basis and at constant exchange rates</b>	<b>29,032</b>	<b>27,907</b>	<b>+4.0%</b>

Our net sales comprise the net sales generated by our Pharmaceuticals business and net sales generated by our Human Vaccines (Vaccines) business. Net sales from the animal health business are not consolidated, the profit contribution from Merial being reported on the line Net income from the held-for-exchange Merial business in accordance with IFRS 5 (see Note D.8. to our consolidated financial statements included at Item 18 of this annual report). The following table breaks down our 2009 and 2008 net sales by business segment:

			Change on a	Change at	Change on a
( million)	2009	2008	reported basis	constant exchange rates	basis and at constant exchange rates (%)
	Reported	Reported	(%)	(%)	(%)
Pharmaceuticals	25,823	24,707	+4.5%	+3.7%	+2.3%
Vaccines	3,483	2,861	+21.7%	+19.2%	+18.9%
<b>Total</b>	<b>29,306</b>	<b>27,568</b>	<b>+6.3%</b>	<b>+5.3%</b>	<b>+4.0%</b>

*Net Sales by Product - Pharmaceuticals*

Net sales generated by our Pharmaceuticals business in 2009 were 25,823 million, an increase of 3.7% at constant exchange rates and of 4.5% on a reported basis.

Net sales of our flagship products (see table below) were adversely affected by competition from generics of Eloxatine® in the United States and Europe; without this effect, growth in Pharmaceuticals net sales would have been 2.2 points higher in 2009 (at constant exchange rates).

Net sales of the other products in our portfolio fell by 6.0% at constant exchange rates to 6,078 million, compared with 6,484 million in 2008. At constant exchange rates, net sales of these products were down 9.7% in Europe, at 3,283 million; up 1.2% in the United States, at 610 million; and down 1.5% in the Other Countries region, at 2,185 million.



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For a description of our other pharmaceutical products, see Item 4. Information on the Company B. Business Overview Pharmaceutical Products.

Our Consumer Health Care business achieved net sales growth of 26.8% in 2009 at constant exchange rates, to 1,430 million. This includes the consolidation of Symbion Consumer (now sanofi-aventis Healthcare Holdings Pty Limited), with effect from September 1, 2008; of Zentiva's consumer health care products, with effect from April 1, 2009; and of Oenobiol, with effect from December 1, 2009. On a constant structure basis and at constant exchange rates, the growth rate was 8.1%.

In 2009, net sales for our Generics business increased almost threefold (by 198% at constant exchange rates) to 1,012 million, boosted by the consolidation of Zentiva and Kendrick (each from April 1) and Medley (from May 1). On a constant structure basis and at constant exchange rates, the growth rate was 8.7%.

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The following table breaks down our 2009 and 2008 net sales for the Pharmaceuticals business by product:

( million)	Product	Indication	2009 Reported	2008 Reported	Change on a reported basis (%)	Change at	Change on a constant structure basis and at constant exchange rates (%)
						constant exchange rates (%)	
	Lantus®	Diabetes	3,080	2,450	+25.7%	+22.5%	+22.5%
	Apidra®	Diabetes	137	98	+39.8%	+38.8%	+38.8%
	Amaryl®	Diabetes	416	379	+9.8%	+4.2%	+4.2%
	Insuman®	Diabetes	131	143	-8.4%	-7.0%	-7.0%
	<b>Sub-total: Diabetes</b>		<b>3,764</b>	<b>3,070</b>	<b>+22.6%</b>	<b>+19.4%</b>	<b>+19.4%</b>
	Lovenox®	Thrombosis	3,043	2,738	+11.1%	+8.8%	+8.8%
	Taxotere®	Breast, lung, prostate, stomach, and head & neck cancer	2,177	2,033	+7.1%	+6.1%	+6.1%
	Plavix®	Atherothrombosis	2,623	2,609	+0.5%	+0.2%	+0.2%
	Aprovel®/CoAprovel®	Hypertension	1,236	1,202	+2.8%	+4.7%	+4.7%
	Eloxatine®	Colorectal cancer	957	1,345	-28.8%	-34.7%	-34.7%
	Multaq®	Atrial fibrillation	25				
	Stilnox®/Ambien® /Myslee®	Sleep disorders	873	822	+6.2%	-1.3%	-1.3%
	Allegra®	Allergic rhinitis, urticaria	731	666	+9.8%	-2.6%	-2.6%
	Copaxone®	Multiple sclerosis	467	622	-24.9%	-23.8%	+20.6%
	Tritace®	Hypertension	429	491	-12.6%	-9.2%	-9.2%
	Dépakine®	Epilepsy	329	322	+2.2%	+7.1%	+7.1%
	Xatral®	Benign prostatic hypertrophy	296	319	-7.2%	-8.5%	-8.5%
	Actonel®	Osteoporosis, Paget's disease	264	330	-20.0%	-17.6%	-7.5%
	Nasacort®	Allergic rhinitis	220	240	-8.3%	-11.7%	-11.7%
	<b>Other products</b>		<b>5,947</b>	<b>6,341</b>	<b>-6.2%</b>	<b>-5.9%</b>	<b>-2.4%</b>
	<b>Consumer Health Care</b>		<b>1,430</b>	<b>1,203</b>	<b>+18.9%</b>	<b>+26.8%</b>	<b>+8.1%</b>
	<b>Generics</b>		<b>1,012</b>	<b>354</b>	<b>+185.9%</b>	<b>+198.0%</b>	<b>+8.7%</b>
	<b>Total pharmaceuticals</b>		<b>25,823</b>	<b>24,707</b>	<b>+4.5%</b>	<b>+3.7%</b>	<b>+2.3%</b>

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The table below breaks down net sales of our Pharmaceuticals business products by geographical region in 2009:

( million)	Change at		Change at		Change at		Change at	
	Western	exchange	United	exchange	Emerging	exchange	Other	exchange
Product	Europe*	rates	States	rates	Markets**	rates	countries***	rates
Lantus®	643	+10.2%	1,909	+23.6%	401	+34.1%	127	+48.1%
Apidra®	55	+34.1%	54	+27.5%	24	+68.8%	4	+200.0%
Amaryl®	51	-15.0%	9	+33.3%	175	+7.7%	181	+6.9%
Insuman®	109	-9.1%			21	+4.3%	1	
<b>Sub-total: Diabetes</b>	<b>858</b>	<b>+6.7%</b>	<b>1,972</b>	<b>+23.8%</b>	<b>621</b>	<b>+25.4%</b>	<b>313</b>	<b>+22.7%</b>
Lovenox®	725	+11.4%	1,822	+5.3%	434	+17.4%	62	+21.2%
Taxotere®	786	+6.5%	827	+5.3%	364	+6.1%	200	+7.1%
Plavix®	1,383	-11.6%	222 <sup>a</sup>	+28.5%	608	+4.9%	410	+44.4%
Aprovel®/CoAprovel®	861	+2.5%	7 <sup>a</sup>		313	+11.4%	55	-8.2%
Eloxatine®	77	-55.0%	677	-37.2%	153	-12.4%	50	+4.2%
Multaq®			25					
Stilnox®/Ambien®/Myslee®	60	-4.8%	555	-4.8%	60	-6.1%	198	+15.1%
Allegra®	17	-15.0%	306	-15.9%	69	+4.3%	339	+14.8%
Copaxone®	439	+21.6%			15	-5.6%	13	-55.2%
Tritace®	197	-12.4%			189	-6.0%	43	-8.3%
Depakine®	143	+2.1%			175	+12.1%	11	+0.0%
Xatral®	77	-32.2%	147	+16.0%	66	-6.7%	6	-40.0%
Actonel®	136	-26.7%			97	-8.0%	31	+3.3%
Nasacort®	29	-9.1%	158	-15.4%	28	+7.1%	5	+0.0%
<b>Other products</b>	<b>2,696</b>	<b>-11.1%</b>	<b>610</b>	<b>+1.2%</b>	<b>1,927</b>	<b>+0.4%</b>	<b>714</b>	<b>-7.6%</b>
<b>Consumer Health Care</b>	<b>622</b>	<b>+5.6%</b>			<b>674</b>	<b>+38.1%</b>	<b>134</b>	<b>+129.5%</b>
<b>Generics</b>	<b>360</b>	<b>+23.2%</b>			<b>631</b>		<b>21</b>	<b>+0.0%</b>
<b>Total pharmaceuticals</b>	<b>9,466</b>	<b>-3.6%</b>	<b>7,328</b>	<b>-1.2%</b>	<b>6,424</b>	<b>+19.4%</b>	<b>2,605</b>	<b>+11.5%</b>

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

\*\* World excluding United States, Canada, Western Europe, Japan, Australia and New Zealand.

\*\*\* Japan, Canada, Australia and New Zealand.

<sup>a</sup> Sales of active ingredient to the entity majority-owned by BMS in the United States.

*Flagship Products <sup>(1)</sup>*

Net sales of **Lantus®**, the world's leading insulin brand (source: IMS 2009 sales), rose by 22.5% (at constant exchange rates) to 3,080 million in 2009, driven largely by the SoloSTAR® injection pen. Growth was strong across all three geographic regions at 23.6% in the United States, 12.2% in Europe and 42.8% in the Other Countries region (all at constant exchange rates). In the Other Countries region, the performance of Lantus® is particularly high in China, Japan and Mexico, with respective growth rates at constant exchange rates of 113.7%, 81.6% and 48.2%.

Net sales of the rapid-acting analog of human insulin **Apidra®** were 137 million, up 38.8% (at constant exchange rates), boosted by the launch of Apidra® SoloSTAR® in the United States.

(1) Sales of Plavix® and Aprovei® are discussed below under Worldwide Presence of Plavix® and Aprovei® .

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**Lovenox**<sup>®</sup>, the leader in anti-thrombotics in the United States, Germany, France, Italy, Spain, and the United Kingdom (source: IMS 2009 sales), achieved net sales growth of 8.8% in 2009 (at constant exchange rates) to 3,043 million, driven by double-digit growth in Europe (up 13.7% at constant exchange rates, at 890 million) and in the Other Countries region (up 14.8% at constant exchange rates, at 331 million). In the United States, net sales increased by 5.3% to 1,822 million.

**Taxotere**<sup>®</sup> posted growth of 6.1% in 2009 at constant exchange rates to 2,177 million, driven by its use in adjuvant breast cancer treatment and in prostate cancer. Growth was good across all three geographic regions at 7.1% in Europe, 5.3% in the United States and 5.1% in the Other Countries region (all at constant exchange rates). In Japan, the product made further advances, with net sales rising by 9.5% to 129 million, in particular due to the prostate cancer indication approved in the second half of 2008.

**Eloxatine**<sup>®</sup> saw net sales fall by 34.7% at constant exchange rates in 2009 to 957 million, due to ongoing genericization in Europe and competition from a number of generics in the United States during the second half of the year.

Net sales of the hypnotic **Stilnox**<sup>®</sup>/**Ambien**<sup>®</sup>/**Myslee**<sup>®</sup> fell by 1.3% at constant exchange rates. In the United States, Ambien<sup>®</sup> CR reported growth of 0.9% at constant exchange rates, to 497 million. In Japan, net sales of Myslee<sup>®</sup>, the leading hypnotic on the market (source: IMS 2009 sales), totaled 194 million, an increase of 15.2% at constant exchange rates.

**Allegra**<sup>®</sup> saw net sales fall by 2.6% at constant exchange rates in 2009 to 731 million, reflecting the arrival of Allegra<sup>®</sup> D 12 generics in the United States in the fourth quarter of 2009 (which follows the settlement of the U.S. patent infringement suit related to Barr's proposed generic version) and ongoing genericization in Europe. In 2009, sales decreased respectively by 15.9% and 20% (at constant exchange rates) in the United States and Europe. The product recorded further growth in Japan, with sales up 15.2% at constant exchange rates, at 334 million.

The end of commercialization of **Copaxone**<sup>®</sup> by sanofi-aventis in North America effective April 1, 2008 resulted in a 23.8% drop in consolidated net sales of this product in 2009 (at constant exchange rates), to 467 million.

**Multaq**<sup>®</sup> was launched in the United States during the third quarter of 2009. Sales of the product in 2009 amounted to 25 million.

#### *Net Sales - Human Vaccines (Vaccines)*

In 2009, our Vaccines business generated consolidated net sales of 3,483 million, up 19.2% at constant exchange rates and 21.7% on a reported basis. The main growth drivers were Pentacel<sup>®</sup> and A(H1N1) influenza vaccines. Growth at constant exchange rates was robust across all three geographic regions, at 19.1% in the United States (to 2,098 million), 15.9% in Europe (to 448 million) and 20.8% in the Other Countries region (to 937 million). Excluding the impact of sales of pandemic influenza vaccines (A(H1N1) and H5N1), net sales growth was 7.1% (at constant exchange rates).

Polio/Pertussis/Hib vaccines achieved growth of 22.8% at constant exchange rates to 968 million, reflecting the success of **Pentacel**<sup>®</sup> (the first 5-in-1 pediatric combination vaccine against diphtheria, tetanus, pertussis, polio and *haemophilus influenzae* type b licensed in the United States

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in June 2008), which posted net sales of 343 million in 2009 versus 84 million in 2008.

Net sales of **influenza vaccines** rose by 46.7% at constant exchange rates to 1,062 million, mainly due to the shipment during 2009 of batches of vaccines against the A(H1N1) influenza virus for a total amount of 440 million, including 301 million in the United States.

Meningitis/pneumonia vaccines achieved net sales of 538 million, up 6.1% at constant exchange rates, largely as a result of good growth in sales of vaccines against pneumococcal infections. Net sales of **Menactra**<sup>®</sup> (quadrivalent meningococcal meningitis vaccine) increased by 1.1% at constant exchange rates to 445 million.

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Net sales of adult booster vaccines fell by 3.0% at constant exchange rates to 406 million. Net sales of **Adacel**® (adult and adolescent tetanus/diphtheria/pertussis booster vaccine) were 267 million, down 1.2% at constant exchange rates.

Shantha, consolidated from September 1, 2009, contributed net sales of 17 million in 2009.

The following table presents the 2009 sales of our Vaccines activity by range of products:

	2009	2008	Change on a reported	Change at constant exchange
( million)	Reported	Reported	basis (%)	rates (%)
Influenza Vaccines (including Vaxigrip® and Fluzone®)	1,062	736	+44.3%	+46.6%
of which seasonal influenza vaccines	597	610	-2.1%	-1.7%
of which pandemic influenza vaccines	465	126		
Polio/Pertussis/Hib Vaccines (including Pentacel® and Pentaxim®)	968	768	+26.0%	+22.8%
Meningitis/Pneumonia Vaccines (including Menactra®)	538	472	+14.0%	+6.1%
Adult Booster Vaccines (including Adacel®)	406	399	+1.8%	-3.0%
Travel and Other Endemics Vaccines	313	309	+1.3%	0.0%
Other Vaccines	196	177	+10.7%	+6.8%
<b>Total Vaccines</b>	<b>3,483</b>	<b>2,861</b>	<b>+21.7%</b>	<b>+19.2%</b>

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

	Change at		Change at		Change at		Change at	
( million)	Western	constant	United	constant	Emerging	constant	Other	constant
	Europe*	exchange	States	exchange	Markets**	exchange	countries***	exchange
	Reported	rates	Reported	rates	Reported	rates	Reported	rates
Influenza Vaccines <sup>a</sup>								
(inc. Vaxigrip® and Fluzone®)	139	+113.8%	618	+36.2%	287	+53.6%	18	0.0%
Polio/Pertussis.Hib Vaccines								
(inc. Pentacel® and Pentaxim®)	68	+7.7%	529	+56.8%	332	-5.4%	39	+29.0%
Meningitis/Pneumonia Vaccines								
(inc. Menactra®)	11	+120.0%	437	0.0%	78	+32.2%	12	+50.0%
Adult Booster Vaccines								
(inc. Adacel®)	56	+9.8%	310	-8.5%	25	+47.1%	15	+14.3%
Travel and Other Endemics Vaccines	15	-16.7%	69	-15.8%	196	+9.5%	33	-5.6%

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Other Vaccines	38	-9.3%	135	+13.2%	14	+16.7%	9	0.0%
<b>Total Vaccines</b>	<b>327</b>	<b>+33.6%</b>	<b>2,098</b>	<b>+19.1%</b>	<b>932</b>	<b>+16.0%</b>	<b>126</b>	<b>+11.1%</b>

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

\*\* *World excluding United States, Canada, Western Europe, Japan, Australia and New Zealand.*

\*\*\* *Japan, Canada, Australia and New Zealand.*

<sup>a</sup> *Seasonal and pandemic influenza vaccines.*

In addition to the Vaccines activity reflected in our consolidated net sales, sales at Sanofi Pasteur MSD, our joint venture with Merck & Co. in Western Europe, reached 1,132 million, a fall of 11.0% on a reported basis.



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Full-year net sales of Gardasil<sup>®</sup>, a vaccine that prevents papillomavirus infections (a cause of cervical cancer), amounted to 395 million, compared with 584 million in 2008. This 32.4% decrease reflects extensive catch-up vaccination campaigns in 2008.

Sales generated by Sanofi Pasteur MSD are not included in our consolidated net sales.

*Net Sales by Geographic Region*

We divide our sales geographically into four regions: Western Europe, the United States, Emerging Markets and Other Countries. The following table breaks down our 2009 and 2008 net sales by region:

( million)	2009 Reported	2008 Reported	Change on a reported basis	Change at constant exchange rates
Western Europe*	9,793	10,189	-3.9%	-2.7%
United States	9,426	8,609	+9.5%	+2.8%
Emerging Markets**	7,356	6,540	+12.5%	+19.0%
<i>Of which Eastern Europe and Turkey</i>	<i>2,266</i>	<i>1,907</i>	<i>+18.8%</i>	<i>+34.9%</i>
<i>Of which Asia (excl. Pacific region***)</i>	<i>1,610</i>	<i>1,486</i>	<i>+8.3%</i>	<i>+9.0%</i>
<i>Of which Latin America</i>	<i>1,913</i>	<i>1,739</i>	<i>+10.0%</i>	<i>+15.7%</i>
<i>Of which Africa</i>	<i>775</i>	<i>725</i>	<i>+6.8%</i>	<i>+8.6%</i>
<i>Of which Middle East</i>	<i>647</i>	<i>556</i>	<i>+16.2%</i>	<i>+16.4%</i>
Other Countries****	2,731	2,230	+22.5%	+11.5%
<i>Of which Japan</i>	<i>1,844</i>	<i>1,408</i>	<i>+30.9%</i>	<i>+10.7%</i>
<b>Total</b>	<b>29,306</b>	<b>27,568</b>	<b>+6.3%</b>	<b>+5.3%</b>

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

\*\* World excluding United States, Canada, Western Europe, Japan, Australia and New Zealand.

\*\*\* Japan, Australia and New Zealand.

\*\*\*\* Japan, Canada, Australia and New Zealand.

In 2009, net sales in Western Europe decreased by 2.7% at constant exchange rates, reflecting the effect of the ongoing genericization of Eloxatine<sup>®</sup> and Plavix<sup>®</sup>.

In the United States, the end of commercialization of Copaxone<sup>®</sup> by sanofi-aventis effective April 1, 2008 and the genericization of Eloxatine<sup>®</sup> during the second half of 2009 slowed the pace of net sales growth to 2.8% (at constant exchange rates). Lantus<sup>®</sup> and Lovenox<sup>®</sup>, with net sales growth of 23.6% and 5.3% respectively (at constant exchange rates) were the principal growth drivers in Pharmaceuticals. Growth for the Vaccines business was boosted by sales of pandemic influenza vaccines (A(H1N1) and H5N1).

In Emerging Markets, net sales were 7,356 million, an increase of 19.0% at constant exchange rates, due largely to strong growth in Eastern Europe (34.9% growth at constant exchange rates) where Zentiva's sales were consolidated from April 1, 2009, and to the dynamism of Latin America (up 15.7% at constant exchange rates), the Middle East (up 16.4% at constant exchange rates), China (up 28.8% at constant exchange rates) and Russia (up 59.8% at constant exchange rates). Net sales in Latin America (1,913 million) were underpinned by good organic growth

and by the acquisition of Medley in the second quarter of 2009.

Net sales in Japan reached 1,844 million (up 10.7% at constant exchange rates), driven by the performances of Plavi<sup>®</sup>, Myslee<sup>®</sup> and Allegra<sup>®</sup>.

**Table of Contents***Worldwide Presence of Plavix® and Aprovel®*

The table below sets forth the worldwide sales of Plavix® and Aprovel® in 2009 and 2008, by geographic region:

( million)	2009			2008			Change on a reported basis	Change at constant exchange rates
	sanofi-aventis <sup>(2)</sup>	BMS <sup>(3)</sup>	Total	sanofi-aventis <sup>(2)</sup>	BMS <sup>(3)</sup>	Total		
Plavix®/Iscover® <sup>(1)</sup>								
Europe	1,443	161	1,604	1,622	211	1,833	-12.5%	-10.3%
United States		4,026	4,026		3,351	3,351	+20.1%	+12.8%
Other countries	897	255	1,152	711	248	959	+20.1%	+14.4%
<b>Total</b>	<b>2,340</b>	<b>4,442</b>	<b>6,782</b>	<b>2,333</b>	<b>3,810</b>	<b>6,143</b>	<b>+10.4%</b>	<b>+6.2%</b>

( million)	2009			2008			Change on a reported basis	Change at constant exchange rates
	sanofi-aventis <sup>(5)</sup>	BMS <sup>(3)</sup>	Total	sanofi-aventis <sup>(5)</sup>	BMS <sup>(3)</sup>	Total		
Aprovel®/Avapro®								
/Karvea®/Avalide® <sup>(4)</sup>								
Europe	810	172	982	816	176	992	-1.0%	+0.8%
United States		524	524		499	499	+5.0%	-1.6%
Other countries	314	192	506	291	184	475	+6.5%	+7.2%
<b>Total</b>	<b>1,124</b>	<b>888</b>	<b>2,012</b>	<b>1,107</b>	<b>859</b>	<b>1,966</b>	<b>+2.3%</b>	<b>+1.7%</b>

<sup>(1)</sup> Plavix® is marketed under the trademarks Plavix® and Iscover®.

<sup>(2)</sup> Net sales of Plavix® consolidated by sanofi-aventis, excluding sales to BMS ( 311 million in 2009 and 282 million in 2008).

<sup>(3)</sup> Translated into euros by sanofi-aventis using the method described in Note B.2. Foreign currency translation to our consolidated financial statements included at Item 18 in this annual report.

<sup>(4)</sup> Aprovel® is marketed under the trademarks Aprovel®, Avapro®, Karvea® and Avalide®.

<sup>(5)</sup> Net sales of Aprovel® consolidated by sanofi-aventis, excluding sales to BMS ( 113 million in 2009 and 94 million in 2008).

In the United States, sales of Plavix®/Iscover® (consolidated by BMS) reported strong growth of 12.8% at constant exchange rates in 2009, reaching 4,026 million. In Europe, net sales of Plavix® were down 10.3% at constant exchange rates at 1,604 million due to the marketing of generics using alternative salts of clopidogrel, especially in the United Kingdom, Germany and France (where we launched our own generic version, Clopidogrel Winthrop®, in the fourth quarter of 2009). In Japan, Plavix® continued its success, with sales up 58.9% at constant exchange rates to 339 million.

In a competitive environment, 2009 worldwide sales of Aprovel®/Avapro®/Karvea®/Avalide® were 2,012 million, an increase of 1.7% at constant exchange rates. In Europe, the product faced competition from generics in the monotherapy segment in Spain and Portugal, and recorded sales growth of 0.8% at constant exchange rates.

*Other Revenues*

Other revenues, which mainly comprise royalty income under licensing agreements contracted in connection with ongoing operations, amounted to 1,443 million in 2009 compared with 1,249 million in 2008.

Licensing revenues under the worldwide alliance with BMS on Plavix<sup>®</sup> and Aprovei<sup>®</sup> totaled 1,155 million in 2009, compared with 985 million in 2008 (up 17.3% on a reported basis), boosted by strong growth in sales of Plavix<sup>®</sup> in the United States and the favorable impact of trends in the exchange rate of the U.S. dollar against the euro.

*Gross Profit*

Gross profit for 2009 was 22,869 million (78.0% of net sales), versus 21,480 million in 2008 (77.9% of net sales).

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The gross margin ratio for the Pharmaceuticals segment improved by 0.5 of a point, reflecting the rise in royalty income (impact: +0.6 of a point) and an unfavorable trend in the ratio of cost of sales to net sales (impact: -0.1 of a point). This trend was the net result of:

the favorable effect on net sales and other revenues of movements in the exchange rates of various currencies against the euro (mainly the rise in the U.S. dollar), which largely feeds through into gross profit because our cost of sales is largely incurred in the euro zone;

the favorable effect of the end of commercialization of Copaxone® by sanofi-aventis in North America, effective April 1, 2008;

a less favorable product mix due to the impact of acquisitions of companies that generate lower gross margins than we do (primarily on generics).

The gross margin ratio for the Vaccines segment was unchanged, with the effect of lower royalty income (impact: -0.5 of a point) offset by an improvement in the ratio of cost of sales to net sales (impact: +0.5 of a point) that was largely due to the appreciation of various currencies against the euro.

Consolidated gross profit was also impacted by the expense arising from the workdown during 2009 of inventories remeasured at fair value on completion of acquisitions (mainly Zentiva, impact 27 million or 0.1 of a point).

### *Research and Development Expenses*

Research and development expenses were 4,583 million (versus 4,575 million in 2008), representing 15.6% of net sales (versus 16.6% in 2008); they were down 1.4% year-on-year at constant exchange rates, but up 0.2% on a reported basis.

Cost savings were achieved in the Pharmaceuticals segment due to tight cost control and a reduction in clinical trial costs, reflecting the discontinuation of some projects following the portfolio review.

In the Vaccines segment, research and development expenses increased by 66 million, up 15.5%, in particular due to the consolidation of Acambis from October 1, 2008 and to clinical trials related to influenza vaccines in the light of the pandemic.

### *Selling and General Expenses*

Selling and general expenses totaled 7,325 million, compared with 7,168 million in the previous year, an increase of 2.2% (or 1.1% at constant exchange rates). The ratio of selling and general expenses to net sales improved from 26.0% in 2008 to 25.0%, mainly because of savings in marketing expenses (in particular, due to the transfer of commercialization of Copaxone® to Teva in North America in April 2008) and cost savings in Europe. The 2009 figure includes the expenses of companies consolidated for the first time during the year.

Selling and general expenses for the Vaccines segment rose by 7.9%. This increase was due primarily to the influenza pandemic, and to the consolidation of Acambis with effect from October 1, 2008.

*Other Operating Income and Expenses*

Other operating income for 2009 came to 866 million (versus 556 million in 2008), and other operating expenses amounted to 481 million (versus 353 million in 2008).

The balance of other operating income and expenses represented net income of 385 million for 2009, compared with net income of 203 million for 2008. The 182 million increase was mainly due to the transfer of commercialization of Copaxone® to Teva in North America effective April 1, 2008. We were entitled to receive a 25% royalty of North American sales of Copaxone® over a two-year period from that date, and recognized this royalty income in Other operating income in 2008 and 2009.

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We also recognized gains on disposals relating to our ordinary operations of 56 million (compared with 24 million in 2008), and a net operating foreign exchange gain of 40 million (compared with a net foreign exchange loss of 94 million in 2008).

### *Amortization of Intangible Assets*

Amortization charged against intangible assets in 2009 amounted to 3,528 million, versus 3,483 million in the previous year. The increase was due mainly to trends in the exchange rate of the U.S. dollar against the euro and the acquisition of Zentiva.

These charges mainly relate to the amortization of intangible assets remeasured at fair value at the time of the Aventis acquisition (3,175 million in 2009, versus 3,298 million in 2008).

### *Impairment of Intangible Assets*

Net impairment losses charged against intangible assets amounted to 372 million in 2009, and related primarily to the impact of changes in the competitive environment and of generic approval dates on our products Benzaclin<sup>®</sup>, Nasacort<sup>®</sup> and Actonel<sup>®</sup>. This item also includes impairment losses of 28 million arising from the decision to discontinue the development of TroVa<sup>®</sup>, and from the withdrawal of our product Di-Antalvic<sup>®</sup> from the market in response to a decision by the European Medicines Agency (EMA). With the exception of Trovax<sup>®</sup>, all of these products were recognized as assets in 2004 upon the acquisition of Aventis.

In 2008, this line item showed impairment losses of 1,554 million charged against intangible assets due to the discontinuation of some research projects and to the genericization of some products marketed by the Group, originating mainly from Aventis. The main discontinued research projects were those relating to larotaxel and cabazitaxel (new taxane derivatives developed in breast cancer, 1,175 million) and the antihypertensive ilepatril (57 million), both of which were recognized as assets on the acquisition of Aventis; and the oral anti-cancer agent S-1, following termination of the agreement with Taiho Pharmaceutical for the development and commercialization of this product. In addition, an impairment loss of 114 million was charged in respect of Nasacort<sup>®</sup> (also recognized as an asset on the acquisition of Aventis in 2004) following the settlement agreement with Barr in the United States.

### *Restructuring Costs*

Restructuring costs amounted to 1,080 million in 2009, compared with 585 million in 2008. In 2009, our restructuring costs related primarily to measures taken to improve innovation by transforming our Research & Development operations, and to streamline our organizational structures by adapting central support functions. These costs consist mainly of employee-related charges, arising from early retirement benefits and termination benefits under the announced voluntary redundancy plans. The 2009 charge also reflects, though to a lesser extent, ongoing measures to adapt our industrial facilities in Europe and to adjust our sales forces.

The restructuring costs recognized in 2008 related primarily to the adaptation of industrial facilities in France and to measures taken in response to the changing economic environment in various European countries, principally France and Spain.

*Gains and Losses on Disposals, and Litigation*

Sanofi-aventis did not make any major disposals in either 2009 or 2008.

In 2008, this item included 76 million of reversal of litigation provisions.

*Operating Income*

Operating income for 2009 was 6,366 million, 44.9% higher than the 2008 figure of 4,394 million.

*Financial Income and Expenses*

Net financial expense for 2009 was 300 million, compared to 232 million in 2008, an increase of 68 million.



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Interest expense directly related to our net debt (short-term and long-term debt, net of cash and cash equivalents) amounted to 222 million, versus 183 million in 2008. Although the average level of net debt was lower in 2009 than in 2008, sanofi-aventis was adversely affected by lower interest rates on its cash deposits (which averaged 5.0 billion in 2009, compared with 2.4 billion in 2008).

In 2008, we tendered our shares in Millennium Pharmaceuticals, Inc (Millennium) to the public tender offer for Millennium by Takeda Pharmaceuticals Company Ltd. This transaction generated a 38 million gain.

Net financial foreign exchange losses for the year were 67 million, compared with 74 million in 2008.

### *Income before Tax and Associates and Joint Ventures*

Net income before tax and associates and joint ventures for 2009 was 6,066 million, 45.7% higher than the 2008 figure of 4,162 million.

### *Income Tax Expense*

The effective tax rate is calculated on the basis of business operating income minus net financial expenses and before the share of profit/loss of associates and joint ventures, net income from the held-for-exchange Merial business, and net income attributable to non-controlling interests

The effective tax rate was 28.0% in 2009, compared to 29.0% in 2008, the reduction resulting directly from the entry into force in 2009 of a protocol to the tax treaty between France and the United States that abolished withholding tax between the two countries subject to certain conditions. During 2009, this protocol resulted in the reversal through the consolidated income statement of 106 million in deferred tax liabilities relating to the tax cost of distributions made out of the reserves of Group subsidiaries as of January 1, 2009. The difference between the effective tax rate and the standard corporate income tax rate applicable in France for 2009 (34%) was mainly due to the impact of the reduced rate of income tax on royalties in France.

In 2008, this line item included a gain through the consolidated income statement of 221 million on reversals of tax provisions related to the settlement of tax audits.

### *Share of Profit/Loss of Associates and Joint Ventures*

Our share of the profits of associates and joint ventures was 814 million in 2009, versus 692 million in 2008. This item mainly comprises our share of after-tax profits from the territories managed by BMS under the Plavix® and Avapro® alliance, which increased by 26.0% year-on-year from 623 million in 2008 to 785 million in 2009. This increase was a direct result of the growth in sales of Plavix in the United States (up 12.8% at constant exchange rates) and of the appreciation of the U.S. dollar against the euro (up 7.0%).

*Net Income from the Held-for-Exchange Merial Business*

With effect from September 18, 2009, the date on which sanofi-aventis obtained exclusive control over Merial, the operations of this company have been accounted for using the full consolidation method. As of December 31, 2009, the results of Merial's operations were reported in the line item "Net income from the held-for-exchange Merial business", in accordance with IFRS 5 (refer to Note D.8. to our consolidated financial statements). The net income of the Merial business for the year ended December 31, 2009 was \$175 million, compared with \$120 million in the previous year.

This growth was attributable to a strong operating performance by Merial and to the appreciation of the U.S. dollar against the euro. The figures cited above include 100% of the net income of Merial with effect from September 18, 2009, compared with 50% prior to that date. The 2009 figure also includes a net expense of \$46 million relating to the workdown of inventories remeasured at fair value, as part of the provisional purchase price allocation on the acquisition of the 50% interest in Merial acquired in 2009.

**Table of Contents***Net Income*

Net income (before non-controlling interests) totaled 5,691 million in 2009, compared with 4,292 million in 2008.

*Net Income Attributable to Non-Controlling Interests*

Net income attributable to non-controlling interests for the year ended December 31, 2009 was 426 million, against 441 million for the previous year. This item includes the share of pre-tax income paid over to BMS from territories managed by sanofi-aventis (405 million in 2009, versus 422 million in 2008).

*Net Income Attributable to Equity Holders of Sanofi-Aventis*

Net income attributable to equity holders of sanofi-aventis amounted to 5,265 million in 2009, versus 3,851 million in 2008. Basic earnings per share (EPS) for 2009 were 4.03, up 37.1% on the 2008 figure of 2.94, based on an average number of shares outstanding of 1,305.9 million in 2009 and 1,309.3 million in 2008.

Diluted earnings per share for 2009 were 4.03, up 37.1% on the 2008 figure of 2.94, based on an average number of shares after dilution of 1,307.4 million in 2009 and 1,310.9 million in 2008.

*Business Operating Income*

Business operating income for 2009 was 12,028 million, compared to 10,391 million in 2008. The table below shows trends in business operating income by business segment for 2009 and 2008:

<i>( million)</i>	<b>2009</b>	<b>2008</b>
Pharmaceuticals	10,608	9,399
Vaccines	1,173	882
Other	247	110
<b>Business operating income</b>	<b>12,028</b>	<b>10,391</b>

*Business Net Income*

Business net income is a non-GAAP financial measure that we use to evaluate our Group's performance (see Business Net Income above).

Business net income for 2009 was 8,629 million, versus 7,314 million in 2008, representing growth of 18.0%.

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( million)	2009	2008
<b>Business net income</b>	<b>8,629</b>	<b>7,314</b>
(i) Amortization of intangible assets	(3,528)	(3,483)
(ii) Impairment of intangible assets	(372)	(1,554)
(iii) Expenses arising from the impact of acquisitions on inventories <sup>(1)</sup>	(27)	(2)
(iv) Restructuring costs	(1,080)	(585)
(iii)/(iv) Other items <sup>(2)</sup>		114
(v) Tax effects of:	1,629	1,904
- amortization of intangible assets	1,126	1,189
- impairment of intangible assets	136	537
- expenses arising from the impact of acquisitions on inventories	7	1
- restructuring costs	360	196
- other items		(19)
(iii)/(vi) Other tax items <sup>(3)</sup>	106	221
(vii) Share of items listed above attributable to non-controlling interests	1	
(iii) Expenses arising from the impact of the Merial acquisition <sup>(4)</sup>	(66)	(50)
(iii)/(iv) Restructuring costs of associates and joint ventures, and expenses arising from		
the impact of acquisitions on associates and joint ventures <sup>(5)</sup>	(27)	(28)
<b>Net income attributable to equity holders of sanofi-aventis</b>	<b>5,265</b>	<b>3,851</b>

<sup>(1)</sup> This line comprises the workdown of inventories remeasured at fair value at the acquisition date.

<sup>(2)</sup> Other items comprise :

- gain on sale of investment in Millennium	38
- reversals of/charges to provisions for risks	76

<sup>(3)</sup> Other tax items comprise :

- provisions for/settlements of tax disputes	221
- reversal of deferred taxes following ratification of the Franco-American Treaty	106

<sup>(4)</sup> This line comprises: until September 17, 2009, amortization and impairment charged against the intangible assets of Merial; and from September 18, 2009, (i) the impact of the discontinuation of depreciation of the property, plant and equipment of Merial in accordance with IFRS 5 (see Note B.7. to our consolidated financial statements) and (ii) the expense arising from the workdown of inventories remeasured at fair value at acquisition date.

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

Business net income for 2009 was 8,629 million, an increase of 18.0% on the 2008 figure of 7,314 million, and represented 29.4% of net sales compared with 26.5% in 2008. The increase was mainly due to our good operating performance, reflected in the increase in gross profit ( 22,869 million in 2009 versus 21,480 million in 2008).

**Business Earnings Per Share**

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

Business earnings per share for 2009 were 6.61, up 18.2% on the 2008 business earnings per share figure of 5.59. The weighted average number of shares outstanding was 1,305.9 million in 2009 and 1,309.3 million in 2008. Diluted business earnings per share for 2009 were 6.60, up 18.3% on the 2008 diluted business earnings per share figure of 5.58. On a diluted basis, the weighted average number of shares outstanding was 1,307.4 million in 2009 and 1,310.9 million in 2008.

**Table of Contents****Liquidity and Capital Resources**

Our operations generate significant positive cash flows. We fund our investments primarily with operating cash flow, and pay regular dividends on our shares. In 2010, we also reduced our net debt. As of December 31, 2010, our debt, net of cash and cash equivalents, stood at 1,577 million (3.0% of our net equity) versus 4,128 million as of December 31, 2009 (8.5% of our net equity) and 1,802 million as of December 31, 2008. See Note D.17. to our consolidated financial statements included at Item 18 of this annual report. We expect to significantly increase our net debt in 2011 in connection with our proposed acquisition of Genzyme.

***Consolidated Statement of Cash Flows***

The table below shows our summarized cash flows for the years ended December 31, 2010, 2009 and 2008:

<i>( million)</i>	<b>2010</b>	<b>2009</b>	<b>2008</b>
Net cash provided by / (used in) operating activities	9,759	8,515	8,523
Net cash provided by / (used in) investing activities	(3,383)	(7,287)	(2,154)
Net cash provided by / (used in) financing activities	(4,647)	(787)	(3,809)
Impact of exchange rates on cash and cash equivalents	44	25	(45)
<b>Net change in cash and cash equivalents (decrease) / increase</b>	<b>1,773</b>	<b>466</b>	<b>2,515</b>

Generally, factors that affect our earnings for example, pricing, volume, costs and exchange rates flow through to cash from operations. The most significant source of cash from operations is sales of our branded pharmaceutical products and human vaccines. Receipts of royalty payments also contribute to cash from operations.

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

**Net cash provided by operating activities** amounted to 9,759 million in 2010, compared with 8,515 million in 2009. Operating cash flow before changes in working capital was 10,036 million, versus 9,362 million in 2009, reflecting our operating performance.

Our operating cash flow before changes in working capital is generally affected by the same factors that affect Operating income, which is discussed in detail above under Results of Operations Year Ended December 31, 2010 Compared with Year Ended December 31, 2009 and Results of Operations Year Ended December 31, 2009 Compared with Year Ended December 31, 2008. The principal difference is that operating cash flow before changes in working capital reflects our share of the profits and losses of associates and joint ventures, net of dividend and similar income received.

Working capital requirements rose by 277 million in 2010, compared with an 847 million increase in 2009. The main factor in 2010 was a 378 million rise in inventories, partly offset by the discontinuation of royalty payments from Teva on North American sales of Copaxon® (impact: 126 million).

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**Net cash used in investing activities** totaled 3,383 million in 2010, versus 7,287 million in 2009.

Acquisitions of property, plant and equipment and intangible assets amounted to 1,573 million (2009: 1,785 million), comprising 1,261 million of investments in industrial and research facilities and 312 million of contractual payments for intangible rights under license agreements.

Acquisitions of investments during 2010 totaled 1,733 million, net of acquired cash; after including assumed liabilities and commitments, these acquisitions were valued at 2,130 million. Our main investments during 2010 were the equity interests in Chattem (1,640 million) and Nepentes (104 million). In 2009, acquisitions of investments were 5,568 million, net of acquired cash; after including assumed liabilities and commitments, these acquisitions were valued at 6,334 million. Our main investments in 2009 were the equity interests in Merial (2,829 million), Zentiva (1,752 million), Shantha, Medley, and BiPar.

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After-tax proceeds from disposals amounted to 131 million, arising mainly on the divestment of the equity interest in Novexel ( 48 million) and on the disposal of various items of property, plant and equipment ( 55 million). In 2009, after-tax proceeds from disposals were 85 million, mainly on disposals of intangible assets, some of which were required as conditions for clearance of our acquisition of Zentiva.

**Net cash used in financing activities** amounted to 4,647 million in 2010, versus 787 million in 2009.

The 2010 figure includes our dividend payout of 3,131 million (2009: 2,872 million), plus net repayments of debt (net change in short-term and long-term debt) of 1,166 million (versus a net 1,923 million of new debt contracted in 2009). It also includes the acquisition of 5.9 million of our own shares for 321 million.

After the impact of exchange rates, the net change in cash and cash equivalents during 2010 was an increase of 1,773 million, compared with an increase of 466 million in 2009.

### *Year Ended December 31, 2009 Compared with Year Ended December 31, 2008*

**Net cash provided by operating activities** totaled 8,515 million in 2009, compared with 8,523 million in 2008. Operating cash flow before changes in working capital was 9,362 million (versus 8,524 million in 2008), reflecting our good operating performance.

Our working capital requirements increased by 847 million in 2009, having been stable in 2008. This increase was due to the growth in our operations during 2009, reflected in higher levels of inventories (up 489 million) and trade receivables (up 429 million).

**Net cash used in investing activities** was 7,287 million in 2009, versus 2,154 million in 2008.

Acquisitions of property, plant and equipment and intangible assets totaled 1,785 million (compared with 1,606 million in 2008), and mainly comprised investments in industrial facilities and research sites, plus contractual payments for intangible rights ( 325 million in 2009, mainly related to licensing agreements).

Acquisitions of investments during 2009 totaled 5,568 million, net of cash acquired. These investments, valued at a total of 6,334 million inclusive of assumed liabilities and commitments, mainly comprised acquisitions of shares in Merial ( 2,829 million), Zentiva ( 1,752 million), Shantha, Medley and BiPar. In 2008, acquisitions of investments net of cash acquired totaled 667 million, mainly comprising the acquisitions of the entire share capital of the U.K. company Acambis Plc ( 332 million) and of the Australian company Symbion CP Holdings Pty Ltd, now sanofi-aventis Healthcare Holdings Pty Limited ( 329 million).

After-tax proceeds from disposals ( 85 million in 2009) related mainly to disposals of intangible assets, some of which were required as conditions for clearance of our acquisition of Zentiva. In 2008, after-tax proceeds from disposals were 123 million, mostly arising from the May



2008 disposal of our shares in Millennium.

**Net cash used in financing activities** amounted to 787 million, against 3,809 million in 2008. The 2009 figure includes a dividend payout of 2,872 million (versus 2,702 million in 2008), and additional external financing (net increase in short-term and long-term debt) of 1,923 million (versus 69 million in 2008). During 2009, we placed five bond issues for a total amount of 4.7 billion. In 2008, we acquired 23.9 million of our own shares at a cost of 1,227 million under our share repurchase programs.

After the impact of exchange rates, the net change in cash and equivalents during 2009 was an increase of 466 million, compared with an increase of 2,515 million in 2008.

#### ***Consolidated Balance Sheet and Debt***

Total assets stood at 85,264 million as of December 31, 2010, compared with 80,251 million as of December 31, 2009, an increase of 5,013 million. Total assets as of December 31, 2009 have been adjusted to reflect adjustments to the values of certain identifiable assets and liabilities of Merial (see Note D.1. to our consolidated financial statements included at Item 18 of this annual report).

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Our **debt, net of cash and cash equivalents** was 1,577 million as of December 31, 2010, versus 4,128 million as of December 31, 2009. We define debt, net of cash and cash equivalents as short-term and long-term debt, plus related interest rate and currency derivatives, minus cash and cash equivalents.

The table below shows our financial position for the years ended December 31, 2010, 2009 and 2008:

( million)	2010	2009	2008
Long-term debt	6,695	5,961	4,173
Short-term debt and current portion of long-term debt	1,565	2,866	1,833
Related interest rate and currency derivatives	(218)	(7)	22
Cash and cash equivalents	(6,465)	(4,692)	(4,226)
<b>Debt, net of cash and cash equivalents</b>	<b>1,577</b>	<b>4,128</b>	<b>1,802</b>

The gearing ratio (debt, net of cash and cash equivalents as a proportion of total equity) fell from 8.5% to 3.0%. For an analysis of our debt by type, maturity, interest rate and currency as of December 31, 2010 and December 31, 2009, refer to Note D.17. to our consolidated financial statements.

The financing arrangements in place as of December 31, 2010 at the sanofi-aventis parent company level are not subject to covenants regarding financial ratios and do not contain any clauses linking credit spreads or fees to our credit rating. Under the Bridge Facility, the margin above LIBOR and mandatory costs may vary under Facility B as a function of our credit rating (see Item 10.C. hereof for further information.).

Other key movements in balance sheet items are described below.

Total equity stood at 53,288 million as of December 31, 2010, compared with 48,580 million a year earlier. The main factors underlying this net increase were as follows:

increases: net income for the year ended December 31, 2010 ( 5,721 million), and the change in cumulative translation differences due to the depreciation of the euro against other currencies ( 2,655 million, mainly on the U.S. dollar); and

reductions: the dividend payout of 3,131 million made to our shareholders in 2010.

As of December 31, 2010, sanofi-aventis held 6.1 million of its own shares, representing 0.5% of the share capital and recorded as a deduction from equity.

Goodwill and other intangible assets ( 44,411 million) increased by 931 million compared to a year earlier, mainly as a result of the following factors:

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increases: acquisitions of companies ( 1,017 million of goodwill, and 1,557 million of other intangible assets) plus acquisitions of intangible assets ( 388 million);

reductions: amortization and impairment losses charged during the year ( 4,011 million); and

the translation into euros of assets denominated in other currencies (positive impact of 1,979 million, mainly on the U.S. dollar).

Provisions and other non-current liabilities ( 9,326 million) were 1,090 million higher than at the previous year-end, due largely to a sharp increase of 731 million in restructuring provisions.

Net deferred tax liabilities ( 757 million) were 1,264 million lower year-on-year, mainly as a result of reversals of deferred tax liabilities relating to amortization and impairment of acquired intangible assets (impact: 1,324 million).

Liabilities related to business combinations and to non-controlling interests (current and non-current) rose by 335 million to 486 million, due mainly to contingent consideration relating to acquisitions (primarily Fovea and TargeGen) and to put options granted to non-controlling interests (see Note D.18. to our consolidated financial statements).

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Assets held for sale or exchange, net of related liabilities rose by 321 million to 5,364 million during the year, and mainly comprise the net assets of Merial which are reported separately in accordance with IFRS 5 (see Note D.8. to our consolidated financial statements).

### *Liquidity*

We expect that our existing cash resources and cash from operations will be sufficient to finance our foreseeable working capital requirements. At year end 2010, we held cash and cash equivalents amounting to 6,465 million, substantially all of which was held in euros (see Note D.13. to our consolidated financial statements). As at December 31, 2010, 436 million of our cash and cash equivalents was held by our captive insurance and reinsurance companies in accordance with insurance regulations.

At year end 2010, we had a firm commitment of approximately \$18.5 billion towards the shareholders of Genzyme Corporation (Genzyme), based on the tender offer made on October 4, 2010 for all outstanding shares of common stock at \$69.00 per share, net to the seller in cash, without interest and less any required withholding taxes. On February 16, 2011, sanofi-aventis and Genzyme announced they had entered into a merger agreement providing for the acquisition of Genzyme by sanofi-aventis. The agreement is described at Item 10.C. Material Contracts and any acquisition remains subject to fulfillment of a number of conditions including acceptance by holders of a majority of shares of Genzyme common stock on a diluted basis. The cash consideration (excluding any future payments on the contingent value rights that we propose to issue in connection with the acquisition) of the agreed offer represents a commitment of approximately \$20.1 billion on the basis of an estimated 272.5 million Genzyme shares on a diluted basis.

At year end 2010, we had a firm commitment of \$1 billion towards Merck & Co., Inc. relating to the future combination of Merial with the Intervet/Schering-Plough business to form a new joint venture equally owned by Merck and sanofi-aventis, as well as a firm commitment of \$521 million towards the shareholders of BMP Sunstone Corporation (BMP Sunstone). See Acquisitions above for further details.

At year end 2010, other than the preceeding commitments relating to Genzyme, Merial and BMP Sunstone, we had no commitments for capital expenditures that we consider to be material to our consolidated financial position.

Undrawn confirmed credit facilities amounted to a total of 12.2 billion at December 31, 2010. Moreover, in connection with the Genzyme acquisition, we signed two acquisition facilities in October 2010 for a total value of 11.2 billion (\$15 billion) that can be drawn until December 31, 2011 (see Item 10. Additional Information C. Material Contracts ). In order to have sufficient cash on hand to pay for the contemplated acquisition of 100% of the shares of Genzyme common stock, we intend to either draw on these facilities in whole or in part and/or issue new debt upon closing of the acquisition, depending on market conditions. For a discussion of our treasury policies, see Item 11. Quantitative and Qualitative Disclosures about Market Risk.

We expect that cash from the combined operations of sanofi-aventis and Genzyme would be sufficient to repay our debt, including the new debt that we expect to contract in 2011 (including refinancing of any drawings under the Acquisition Facility) in order to finance the contemplated Genzyme acquisition. For a discussion of our liquidity risks, see Item 11. Quantitative and Qualitative Disclosures about Market Risk.

### **Off-Balance Sheet Arrangements / Contractual Obligations and Other Commercial Commitments**

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We have various contractual obligations and other commercial commitments arising from our operations. Our contractual obligations and our other commercial commitments as of December 31, 2010 are shown in Notes D.3., D.17., D.18. and D.21. to our consolidated financial statements included at Item 18 of this annual report. Note D.21. to our consolidated financial statements included at Item 18 discloses details of commitments under our principal research and development collaboration agreements, as well as the financial commitments related to Merial, Genzyme and BMP Sunstone. For a description of the principal contingencies arising from certain business divestitures, refer to Note D.22.e) to our 2010 consolidated financial statements.

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The Group's contractual obligations and other commercial commitments (excluding those of Meril, see Note D.8.1. to our consolidated financial statements) are set forth in the table below:

December 31, 2010	Total	Payments due by period			
		Under 1 year	From 1 to 3 years	From 3 to 5 years	Over 5 years
( million)					
Future contractual cash-flows relating to debt and debt hedging instrument <sup>(1)</sup>	9,125	1,694	3,161	1,736	2,534
Operating lease obligations	1,291	260	337	217	477
Finance lease obligation <sup>(2)</sup>	28	7	13	6	2
Irrevocable purchase commitments <sup>(3)</sup>					
given	2,658	1,566	498	207	387
received	(176)	(74)	(35)	(16)	(51)
Research & development license agreements					
- Future service commitments <sup>(4)</sup>	1,073	199	312	252	310
- Potential milestone payments <sup>(5)</sup>	2,015	101	378	238	1,298
Obligations relating to business combinations <sup>(6)</sup>	739	87	79	438	135
<b>Total contractual obligations and other commitments</b>	<b>16,753</b>	<b>3,840</b>	<b>4,743</b>	<b>3,078</b>	<b>5,092</b>
Undrawn general-purpose credit facilities	12,238	245	5,755	6,238	
Genzyme acquisition facilities	11,226	11,226			
<b>Total undrawn credit facilities</b>	<b>23,464</b>	<b>11,471</b>	<b>5,755</b>	<b>6,238</b>	

<sup>(1)</sup> See Note D.17. to our consolidated financial statements included at Item 18 of this annual report.

<sup>(2)</sup> See Note D.3. to our consolidated financial statements included at Item 18 of this annual report.

<sup>(3)</sup> These comprise irrevocable commitments to suppliers of (i) property, plant and equipment, net of down payments (see Note D.3. to our consolidated financial statements included at Item 18 of this annual report) and (ii) goods and services.

<sup>(4)</sup> Future service commitments relating to research & development license agreements mainly comprise research financing commitments, but also include consideration for access to technologies.

<sup>(5)</sup> This line includes all potential milestone payments on projects regarded as reasonably possible, i.e., on projects in the development phase. Payments contingent upon the attainment of sales targets once a product is on the market are excluded.

<sup>(6)</sup> See Note D.18. to our consolidated financial statements included at Item 18 of this annual report.

We may have payments due to our current or former research and development partners under collaborative agreements. These agreements typically cover multiple products, and give us the option to participate in development on a product-by-product basis. When we exercise our option with respect to a product, we pay our collaboration partner a fee and receive intellectual property rights to the product in exchange. We also are generally required to fund some or all of the development costs for the products that we select, and to make payments to our partners when those products reach development milestones.

We have entered into collaboration agreements under which we have rights to acquire products or technology from third parties through the acquisition of shares, loans, license agreements, joint development, co-marketing and other contractual arrangements. In addition to upfront payments on signature of the agreement, our contracts frequently require us to make payments contingent upon the completion of development milestones by our alliance partner or upon the granting of approvals or licenses.

Because of the uncertain nature of development work, it is impossible to predict (i) whether sanofi-aventis will exercise further options for products, or (ii) whether the expected milestones will be achieved, or (iii) the number of compounds that will reach the relevant milestones. It is therefore impossible to estimate the maximum aggregate amount that sanofi-aventis will actually pay in the future under existing collaboration agreements.

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Given the nature of its business, it is highly unlikely that sanofi-aventis will exercise all options for all products or that all milestones will be achieved.

The main collaboration agreements relating to development projects in the Pharmaceuticals segment are described below. Potential milestone payments relating to development projects under these agreements amounted to 1.4 billion in 2010.

In June 2010, sanofi-aventis and Metabolex signed a global license agreement for MBX-2982, an oral agent for the treatment of type 2 diabetes.

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In May 2010, sanofi-aventis signed a license agreement with Glenmark Pharmaceuticals S.A., a wholly-owned subsidiary of Glenmark Pharmaceuticals Limited India.

In April 2010, sanofi-aventis signed a global license agreement with CureDM Group Holdings, LLC for Pancreate , a novel human peptide which could restore a patient s ability to produce insulin and other pancreatic hormones in both type 1 and 2 diabetes.

In December 2009, sanofi-aventis and the U.S. biotechnology company Alopexx Pharmaceuticals LLC simultaneously signed (i) a collaboration agreement, and (ii) an option for a license on an antibody for the prevention and treatment of infections originating in the bacterium that causes plague and other serious infections.

At end September 2009, sanofi-aventis and Merrimack Pharmaceuticals Inc. signed an exclusive global licensing and collaboration agreement covering the MM-121 molecule for the management of solid malignancies.

In May 2009, sanofi-aventis signed a global license agreement in oncology with the biotechnology company Exelixis, Inc. for XL147 and XL765, and simultaneously signed an exclusive research collaboration agreement for the discovery of inhibitors of Phosphoinositide-3 Kinase (PI3K) for the management of malignant tumors.

In September 2003, sanofi-aventis signed a collaboration agreement in oncology with Regeneron Pharmaceuticals Inc. (Regeneron) to develop the Vascular Endothelial Growth Factor (VEGF) Trap program. Under the terms of the agreement, sanofi-aventis will pay 100% of the development costs of the VEGF Trap. Once a VEGF Trap product starts to be marketed, Regeneron will repay 50% of the development costs (originally paid by sanofi-aventis) in accordance with a formula based on Regeneron s share of the profits.

In November 2007, sanofi-aventis signed another collaboration agreement with Regeneron to discover, develop and commercialize fully-human therapeutic antibodies. This agreement was broadened, and its term extended; on November 10, 2009. Under the terms of the development agreement, sanofi-aventis committed to fund 100% of the development costs of Regeneron s antibody research program until 2017. Once a product begins to be marketed, Regeneron will repay out of its profits (provided they are sufficient) half of the development costs borne by sanofi-aventis.

Sanofi-aventis has also entered into the following major agreements, which are currently in a less advanced research phase:

December 2010: a global licensing and patent transfer agreement with Ascendis Pharma (Ascendis) on the proprietary Transcon Linker and Hydrogel Carrier technology developed by Ascendis for precise, time-controlled release of therapeutic active ingredients into the body. The agreement will enable sanofi-aventis to develop, manufacture and commercialize products combining this technology with active molecules for the treatment of diabetes and related disorders.

December 2010: alliance with Avila Therapeutics Inc. (Avila) to discover target covalent drugs for the treatment of cancers, directed towards six signaling proteins that are critical in tumor cells. Under the terms of the agreement, sanofi-aventis will have access to Avila s proprietary Avilomic<sup>SM</sup> platform offering protein silencing for these pathogenic proteins.

December 2010: an exclusive global licensing option with Oxford BioTherapeutics for three existing antibodies, plus a research and collaboration agreement to discover and validate new targets in oncology.

September 2010: alliance with the Belfer Institute of Applied Cancer Science at the Dana-Farber Cancer Institute (DFCI) to identify novel targets in oncology for the development of new therapeutic agents directed towards these targets and their associated biomarkers. Under the terms of the agreement, sanofi-aventis will have access to the Belfer Institute s anticancer target identification



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and validation platform and to its translational medicine resources. Sanofi-aventis also has an option over an exclusive license to develop, manufacture and commercialize novel molecules directed towards the targets identified and validated under this research collaboration.

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June 2010: alliance with Regulus Therapeutics Inc. to discover, develop and commercialize novel micro-RNA therapeutics, initially in fibrosis. Sanofi-aventis also received an option, which if exercised, would provide access to the technology to develop and commercialize other micro-RNA based therapeutics, beyond the first four targets.

June 2010: exclusive global collaboration and license agreement with Ascenta Therapeutics, a U.S. biopharmaceutical company, on a number of molecules that could restore apoptosis (cell death) in tumor cells.

October 2009: agreement with Micromet, Inc. to develop a BiTE<sup>®</sup> antibody against a tumor antigen present at the surface of carcinoma cells.

May 2009: collaboration and licensing agreement with Kyowa Hakko Kirin Co., Ltd., under which sanofi-aventis obtained the worldwide rights to the anti-LIGHT fully human monoclonal antibody. This anti-LIGHT antibody is presently at preclinical development stage, and is expected to be first-in-class in the treatment of ulcerative colitis and Crohn's disease.

In the Vaccines segment, sanofi pasteur has entered into a number of collaboration agreements. Milestone payments relating to development projects under those agreements amounted to 0.3 billion in 2010.

In December 2009, sanofi pasteur signed a donation letter to the World Health Organization (WHO). The terms of the agreement committed sanofi pasteur to donate 10% of its future output of vaccines against A(H1N1), A(H5N1) or any other influenza strain with pandemic potential, up to a maximum of 100 million doses. Since this agreement was put in place, sanofi pasteur has already donated to the WHO some of the doses covered by the commitment.

### **Critical accounting and reporting policies**

Our consolidated financial statements are affected by the accounting and reporting policies that we use. Certain of our accounting and reporting policies are critical to an understanding of our results of operations and financial condition, and in some cases the application of these critical policies can be significantly affected by the estimates, judgments and assumptions made by management during the preparation of our consolidated financial statements. The accounting and reporting policies that we have identified as fundamental to a full understanding of our results of operations and financial condition are the following:

**Revenue recognition.** Our policies with respect to revenue recognition are discussed in Note B.14. to our consolidated financial statements included at Item 18 of this annual report. Revenue arising from the sale of goods is presented in the income statement under Net sales. Net sales comprise revenue from sales of pharmaceutical products, vaccines, and active ingredients, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities. Revenue is recognized when all of the following conditions have been met: the risks and rewards of ownership have been transferred to the customer; the Group no longer has effective control over the goods sold; the amount of revenue and costs associated with the transaction can be measured reliably; and it is probable that the economic benefits associated with the transaction will flow to the Group.

We offer various types of price reductions on our products. In particular, products sold in the United States are covered by various programs (such as Medicare and Medicaid) under which products are sold at a discount. Rebates are granted to healthcare authorities, and under contractual arrangements with certain customers. Some wholesalers are entitled to chargeback incentives based on the selling price to the end customer, under specific contractual arrangements. Cash discounts may also be granted for prompt payment. The discounts, incentives and rebates described above are estimated on the basis of specific contractual arrangements with our customers or of specific terms of the relevant

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regulations and/or agreements applicable for transactions with healthcare authorities, and of assumptions of the attainment of sales targets. They are recognized in the period in which the underlying sales are recognized, as a reduction of sales revenue. We also estimate the amount of product returns, on the basis of contractual sales terms and reliable historical data; the same recognition principles apply to sales returns. For additional details regarding the financial impact of discounts, rebates and sales returns, see Note D.23. to our consolidated financial statements included at Item 18 of this annual report.

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Non-product revenues, mainly comprising royalty income from license arrangements that constitute ongoing operations of the Group, are presented in Other revenues .

**Business combinations.** As discussed in Note B.3. Business combinations and transactions with non-controlling interests to our consolidated financial statements included at Item 18 of this annual report, business combinations are accounted for by the acquisition method. The acquiree's identifiable assets, liabilities and contingent liabilities that satisfy the recognition criteria of IFRS 3 Business combinations are measured initially at their fair values as at the acquisition date, except for non-current assets classified as held for sale, which are measured at fair value less costs to sell. Business combinations completed on or after January 1, 2010 are accounted for in accordance with the revised IFRS 3 and the revised IAS 27, Consolidated and individual financial statements . In particular, contingent consideration to former owners agreed in a business combination, e.g. in the form of milestone payments upon the achievement of certain R&D milestones, is recognized as a liability at fair value as of the acquisition date. Any subsequent changes in amounts recorded as a liability are recognized in the consolidated income statement.

**Goodwill impairment and intangible assets.** As discussed in Note B.6. Impairment of property, plant and equipment, intangible assets, and investments in associates and joint ventures and in Note D.5. Impairment of intangible assets and property, plant and equipment to our consolidated financial statements included at Item 18 of this annual report, we test our intangible assets periodically for impairment. The most significant intangible assets that we test for impairment are those resulting from the business combination of Sanofi-Synthelabo and Aventis in 2004. We test for impairment on the basis of the same objective criteria that were used for the initial valuation. Our initial valuation and ongoing tests are based on the relationship of the value of our projected future cash flows associated with the asset to either the purchase price of the asset (for its initial valuation) or the carrying amount of the asset (for ongoing tests). The determination of the underlying assumptions relating to the recoverability of intangible assets is subjective and requires the exercise of considerable judgment. Key assumptions relating to goodwill impairment and intangible assets are the perpetual growth rate and the post-tax discount rate. Any changes in key assumptions could result in an impairment charge. A sensitivity analysis to the key assumptions is performed and disclosed in Note D.5. Impairment of intangible assets and property, plant and equipment to our consolidated financial statements included at Item 18 of this annual report.

**Pensions and post-retirement benefits.** As described in Note B.23. Employee benefit obligations to our consolidated financial statements included at Item 18 of this annual report, we recognize our pension and retirement benefit commitments as liabilities on the basis of an actuarial estimate of the potential rights vested in employees and retirees as of the balance sheet date, net of the valuation of funds to meet these obligations. We prepare this estimate at least on an annual basis, taking into account actuarial assumptions, including life expectancy, staff turnover, salary growth, long-term return on plan assets, retirement and discounting of amounts payable. Pensions and post-retirement benefits key assumptions are the discount rate and the expected long term rate of return on plan assets.

Depending on the discount rate used, the pension and post-retirement benefit expense could vary within a range of outcomes and have a material effect on equity because in applying IAS 19 (Employee Benefits), we have elected to recognize all actuarial gains and losses (including the impact of a change in discount rate) immediately through equity. A sensitivity analysis to discount rate is performed in Note D.19.1. Provisions for pensions and other benefits to our consolidated financial statements included at Item 18 of this annual report.

Depending on the expected long term rate of return on plan assets used, the pension and post-retirement benefit expense could vary within a range of outcomes and have a material effect on reported earnings. A sensitivity analysis to expected long term rate of return is performed in Note D.19.1. Provisions for pensions and other benefits to our consolidated financial statements included at Item 18 of this annual report.

**Deferred taxes.** As discussed in Note B.22. Income tax expense to our consolidated financial statements included at Item 18 of this annual report, we account for deferred taxes using the liability method, whereby deferred income taxes are recognized on tax loss carry-forwards, and on the difference between the tax base and carrying amount of assets and liabilities. We calculate our deferred tax assets



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and liabilities using enacted tax rates applicable for the years during which we estimate that the temporary differences are expected to reverse. We do not recognize deferred tax assets when it is more likely than not that the deferred tax assets will not be realized. The estimates of recognized deferred tax assets are based on our assumptions regarding future profits and the timing of reversal of temporary differences. These assumptions are regularly reviewed; however, final deferred income tax could differ from those estimates.

**Provisions for risks.** Sanofi-aventis and its subsidiaries and affiliates may be involved in litigation, arbitration or other legal proceedings. These proceedings typically are related to product liability claims, intellectual property rights, compliance and trade practices, commercial claims, employment and wrongful discharge claims, tax assessment claims, waste disposal and pollution claims, and claims under warranties or indemnification arrangements relating to business divestitures. As discussed in Note B.12. Provisions for risks at Item 18 of this annual report, we record a provision where we have a present obligation, whether legal or constructive, as a result of a past event; when it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation; and when a reliable estimate can be made of the amount of the outflow of resources. For additional details regarding the financial impact of provisions for risks see Notes D.19.3. Other provisions and D.22. Legal and Arbitral Proceedings to our consolidated financial statements included at Item 18 of this annual report.

Provisions are estimated on the basis of events and circumstances related to present obligations at the balance sheet date, of past experience, and to the best of management's knowledge at the date of preparation of the financial statements. The assessment of provisions can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions. Given the inherent uncertainties related to these estimates and assumptions, the actual outflows resulting from the realization of those risks could differ from our estimates.

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### **Item 6. Directors, Senior Management and Employees**

#### **A. Directors and Senior Management**

On December 16, 2009, the Board of Directors declared its intent to appoint Serge Weinberg as non- executive Chairman of the Board of Directors to replace Jean-François Dehecq, who was approaching the age limit set in the Company's articles of association. This appointment took place on May 17, 2010, and was consistent with the decision of the Board of Directors to separate the office of Chairman from the office of Chief Executive Officer, effective from January 1, 2007.

The **Chairman** represents the Board of Directors. He organizes and directs the work of the Board, and is accountable for this to the Shareholders General Meeting. He is also responsible for ensuring that the corporate decision-making bodies chaired by him (Board of Directors and Shareholders' General Meeting) operate properly.

Because the offices of Chairman and Chief Executive Officer are separated, the Chairman may remain in office until the Ordinary General Meeting called to approve the financial statements and held during the calendar year in which he reaches the age of 70.

The **Chief Executive Officer** is responsible for the management of the Company, and represents it in dealings with third parties. He has the broadest powers to act in the name of the Company.

The Chief Executive Officer must be no more than 65 years old.

#### ***Limits placed by the Board on the powers of the Chief Executive Officer***

The Board of Directors Meeting of July 28, 2009 set limits on the powers of the Chief Executive Officer. The prior authorization of the Board of Directors is required to commit sanofi-aventis to investments, acquisitions and divestments in the following cases:

- a 500 million cap for each undertaking pertaining to a previously approved strategy; and
- a 150 million cap for each undertaking not pertaining to a previously approved strategy.

When the consideration payable to the contracting parties for such undertakings includes potential installment payments subject to the achievement of future results or objectives, such as the registration of one or more products, the caps are calculated by adding the various payments due from signature of the contract until (and including) filing of the first application for marketing authorization in the United States or in Europe.

***Board of Directors***

Sanofi-aventis is administered by a Board of Directors with fourteen members.

Since May 14, 2008, the terms of office of these directors have been staggered, such that in each year from 2010 to 2012 approximately one-third of the Board will be required to seek re-election each year.

During its meeting on February 24, 2011, the Board discussed the issue of director independence. Out of the fourteen directors, half were regarded as independent: Uwe Bicker, Lord Douro, Jean-René Fourtou, Claudie Haigneré, Carole Piwnica, Klaus Pohle and Gérard Van Kemmel.

A director is regarded as independent if he or she has no relationship of any kind with the Company, the Group or its management that is liable to impair his or her judgment. It is the responsibility of the Board, acting upon the recommendation of the Appointments and Governance Committee, to assess the independence of its members.

No more than one-third of the serving members of our Board of Directors may be over 70 years of age.



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Subject to the authority expressly reserved by law to Shareholders' General Meetings and within the scope of the corporate objects, the Board of Directors deals with and takes decisions upon all issues relating to the proper management of the Company and other matters concerning the Board.

**Composition of the Board of Directors as of December 31, 2010**

<b>Serge Weinberg</b>	Date of birth	<i>February 10, 1951</i>
Chairman of the Board	Nationality	<i>French</i>
	First elected	<i>December 2009</i>
	Term expires	<i>2011</i>
1,500 shares		

**Other current directorships and appointments**

Chairman of the Appointments and Governance Committee and of the Strategy Committee of sanofi-aventis  
 Chairman of Weinberg Capital Partners, Financière Piasa, Piasa Holding and Corum (Switzerland)  
 Director of Piasa, Team Partners Group and VL Holding  
 Manager of Alret and Maremma  
 Member of the Supervisory Committee of Amplitude Group and Financière BFSA  
 Vice Chairman and Director of Financière Poinsetia and Financière Sasa  
 Member of the Supervisory Board of Schneider Electric  
 Weinberg Capital Partners' representative on the Board of Alliance Industrie and Sasa Industrie

**Education and business experience**

Graduate in law  
 Degree from the *Institut d'Etudes Politiques*  
 Studies at the *ENA (Ecole Nationale d'Administration)*  
 1976-1982 *Sous-Préfet* and then Chief of Staff of the French Budget Minister (1981)  
 1982-1987 Deputy General Manager of FR3 (the French Television Channel) and then Chief Executive Officer of Havas  
 Tourisme  
 1987-1990 Chief Executive Officer of Pallas Finance  
 1990-2005 Various positions at PPR group including Chairman of the Management Board for 10 years

**Past directorships held since 2006**

Chairman of the Board of Accor (2006-2009)  
 Director of Alliance Industrie (2006-2008), of Road Holding (2007-2008) and of Rasec (2006-2010)  
 Member of the Board of Pharma Omnium International (2006-2010)  
 Member of the Supervisory Board of Rothschild & Cie (until 2010)  
 Member of the Supervisory Board of Gucci Group (Netherlands, until 2010)

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Director of Fnac (until 2010) and of Rothschild Concordia (until 2010)

<b>Christopher Viehbacher</b>	Date of birth	<i>March 26, 1960</i>
Chief Executive Officer	Nationalities	<i>German and Canadian</i>
Director	First elected	<i>December 2008</i>
	Term as director expires	<i>2014</i>
10,000 shares		

### Other current directorships and appointments

Chairman of the Executive Committee and the Management Committee of sanofi-aventis  
Member of the Strategy Committee of sanofi-aventis  
Chairman of the Board of Directors of PhRMA (United States)  
Vice Chairman of EFPIA (Belgium)  
Member of the Board of Directors of Research America (United States) and Burroughs Wellcome Fund (United States)  
Member of the Board of Visitors of Fuqua School of Business, Duke University (United States)  
Member of the Board of Business Roundtable (United States)

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Education and business experience

Graduate in Commerce of Queens University (Ontario-Canada); certified public accountant

Began his career at PricewaterhouseCoopers Audit

1998-2008                Various positions at the GSK group, including President Pharmaceutical Operations for North America

Past directorships held since 2006

Director of GlaxoSmithkline plc until November 2008 (United Kingdom)

Member of the Board of Triangle United Way (United States, 2003-2008), of Cardinal Club (United States, 2004-2008) and GlaxoSmithKline NC Foundation (United States, 2003-2008)

Vice Chairman of Portfolio Management Board of GSK plc (United Kingdom, 2007-2008)

Member of Advisory Council of Center for Healthcare Transformation (United States, until 2010)

<b>Uwe Bicker</b>	Date of birth	<i>June 14, 1945</i>
Independent Director	Nationality	<i>German</i>
	First elected	<i>May 2008</i>
	Term expires	<i>2012</i>
600 shares		

Other current directorships and appointments

Member of the Strategy Committee of sanofi-aventis

Chairman of the Supervisory Board of Siemens Healthcare Diagnostics Holding GmbH (Germany)

Vice Chairman of the Supervisory Board of Epigenomics AG (Germany)

Member of the Supervisory Board of Future Capital AG (Germany) and Definiens AG (Germany)

Director of Fondation Aventis (Foundation, Germany)

Chairman of the Board of Marburg University (Germany)

Member of the Board of Trustees of Bertelsmann Stiftung (Bertelsmann Foundation, Germany)

Member of the Advisory Board of Morgan Stanley (Germany)

Education and business experience

Doctorate in chemistry and in medicine

Honorary Doctorate, Klausenburg University

Honorary Senator, Heidelberg University

1975-1994                Various positions at Boehringer Mannheim GmbH (later Roche AG)

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1994-2004	Various positions at Hoechst group
Since 1983	Professor at the Medical Faculty of Heidelberg

### Past directorships held since 2006

N/A

#### **Robert Castaigne**

Director

Date of birth  
Nationality  
First elected  
Last reappointment  
Term expires

*April 27, 1946*  
*French*  
*February 2000*  
*May 2008*  
*2014*

500 shares

### Other current directorships and appointments

Member of the Audit Committee of sanofi-aventis  
Director of Vinci, Société Générale and Compagnie Nationale à Portefeuille (Belgium)  
Member of the Audit Committee of Compagnie Nationale à Portefeuille (Belgium)  
Member of the Audit, Internal control and Risk Committee of Société Générale  
Member of the Financial Statements Committee of Vinci

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Degree from the *Ecole Centrale de Lille* and the *Ecole Nationale Supérieure du Pétrole et des Moteurs*  
 Doctorate in economic sciences

1972-2008      Various positions at the Total Group, including Chief Financial Officer and member of the Executive Committee (June 1994 - May 2008)

**Past directorships held since 2006**

Chairman and Chief Executive Officer of Total Chimie (1996-2008) and of Total Nucléaire (1992-2008)  
 Director of Elf Aquitaine (2000-2008), of Hutchinson (1995-2008), of Total Gestion Filiales (1994-2008),  
 of Omnium Insurance & Reinsurance Company Ltd (Bermuda, 1996-2008), of Petrofina (Belgium, 1999-  
 2008), of Total Upstream UK Ltd (United-Kingdom, 2005-2008), Total Gabon (2003-2008), of Arkema  
 (2000-2006) and of Alphega (Bermuda, 2000-2006)

<b>Thierry Desmarest</b>	Date of birth	<i>December 18, 1945</i>
Director	Nationality	<i>French</i>
	First elected	<i>February 2000</i>
	Last reappointment	<i>May 2008</i>
500 shares	Term expires	<i>2011</i>

**Other current directorships and appointments**

Member of the Compensation Committee, the Appointments and Governance Committee and the Strategy Committee of sanofi-aventis  
 Director and Honorary President of Total SA  
 Director of L'Air Liquide, Renault SA, Renault SAS  
 Chairman of the Nominating and Governance Committee of Total S.A.  
 Member of the Compensation Committee of Total S.A.  
 Chairman of Fondation Total and l'Ecole Polytechnique (Foundations)  
 Member of the Appointments and Governance Committee and the Compensation Committee of L'Air Liquide  
 Chairman of the International Strategy Committee, member of the Remuneration Committee and member of the Industrial Strategy  
 Committee of Renault SA  
 Director, member of the Appointments and Governance Committee, member of the Human Resources and Compensation Committee of  
 Bombardier Inc. (Canada)  
 Member of the Board of Directors of l'Ecole Polytechnique  
 Director of Musée du Louvre

Education and business experience

Degree from L *Ecole Polytechnique* and L *Ecole Nationale Supérieure des Mines de Paris*

Since 1981                      Various positions at the Total group including Chairman and Chief Executive Officer (1995-2007). Chairman of the Board of Directors (February 2007-May 2010); since May 21, 2010. Honorary President of Total SA and Member of the Board of Directors as well as the Chairman of the Total foundation.

Past directorships held since 2006

Chairman and Chief Executive Officer of Elf Aquitaine (2000-2007)

Chairman and Chief Executive Officer of Total S.A. (1995-2007)

Chairman of the Board of Directors of Total (2007-2010)

Member of the Supervisory Board of Areva (2001-2010)

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<b>Lord Douro</b>	Date of birth	<i>August 19, 1945</i>
Independent Director	Nationality	<i>British</i>
	First elected	<i>May 2002</i>
	Last reappointment	<i>May 2006</i>
	Term expires	<i>2014</i>
1,000 shares		

**Other current directorships and appointments**

Member of the Appointments and Governance Committee and of the Strategy Committee of sanofi-aventis

Chairman of Richemont Holdings UK Ltd and Kings College London (United Kingdom)

Director of Pernod Ricard, Compagnie Financière Richemont AG (Switzerland), Abengoa Bioenergy (Spain) and GAM Worldwide (United Kingdom)

Advisor of Crédit Agricole (United Kingdom)

Member of the Appointments Committee and of the Compensation Committee of Compagnie Financière Richemont AG (Switzerland)

Director of RIT Capital (United Kingdom)

Chairman of the Remuneration Committee and the Conflicts Committee of RIT Capital (United Kingdom)

Member of the Nominations Committee of RIT Capital (United Kingdom)

**Education and business experience**

Degree from Oxford University

1979-1989	Member of the European Parliament
1995-2000	Chairman of Sun Life & Provincial Holdings Plc
2003-2007	Commissioner of English Heritage (United Kingdom)