SANOFI-AVENTIS
Form 20-F
March 12, 2010
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

(Mark One)

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

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2009

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)

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

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

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

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, 2009 was:

Ordinary shares: 1,318,479,052

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

YES x NO ¨.

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

YES ¨ NO x.

Note Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

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

requirements for the past 90 days.

Yes x No ¨

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

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

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

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

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

Item 17 ¨ Item 18 ¨

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

YES ¨ NO x.

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PRESENTATION OF FINANCIAL AND OTHER INFORMATION

The consolidated financial statements contained in this annual report on Form 20-F have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and with IFRS as adopted by the European Union, as of December 31, 2009.

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 Actonel®, Optinate® and Acrel®, trademarks of Warner Chilcott, Copaxone®, a trademark of Teva Pharmaceutical Industries, Mutagrip®, a trademark of Institut Pasteur, TroVax®, a trademark of Oxford BioMedica, Gardasil® a trademark of Merck & Co., Inc., BiTE®, a trademark of Micromet AG, and Xyzal®, a trademark shared by UCB and GlaxoSmithKline;

- trademarks sold by sanofi-aventis and/or its affiliates to a third party, such as Altace®, a trademark of King Pharmaceuticals in the United States, StarLink®, Liberty Link® and Liberty® trademarks of Bayer AG; and

- other third party trademarks such as Cipro® in the United States and Aspirin®, trademarks of Bayer AG, Avastin®, a trademark of Genentech Inc., LentiVector®, a trademark of Oxford BioMedica Plc, 21 Super-Vital®, a trademark of Hangzhou Minsheng Pharmaceutical Co., Ltd., IC31®, a trademark of Intercell AG, and Repevax® and Revaxis® trademarks of Sanofi Pasteur MSD.

The data relative to market shares and ranking information 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 2009, 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;

(iv) IMS sales of Medley which we recognize in our consolidated net sales but which are not attributed to us in the reports published by IMS; and

(v) 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.

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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;
- statements about our future economic performance or that of France, the United States or any other countries in which we operate; and
- statements of assumptions underlying such statements.

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

Forward-looking statements involve inherent risks and uncertainties. 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.

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, 2009, 2008 and 2007 are included in Item 18 of this annual report.

The consolidated financial statements of sanofi-aventis for the years ended December 31, 2009, 2008 and 2007 have been prepared in compliance with IFRS issued by the International Accounting Standards Board (IASB) and with IFRS adopted by the European Union. 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).

Sanofi-aventis reports its financial results in euros.

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SELECTED CONDENSED FINANCIAL INFORMATION

(million, except per share data)	As of and for the year ended December 31, 2009	2008	2007	2006	2005
IFRS Income statement data					
Net sales	29,306	27,568	28,052	28,373	27,311
Gross profit	22,869	21,480	21,636	21,902	20,947
Operating income	6,366	4,394	5,911	4,828	2,888
Net income excluding the held-for-exchange Merial business attributable to equity holders of the Company [(a)]	5,090	3,731	5,112	3,918	2,198
Net income attributable to equity holders of the Company	5,265	3,851	5,263	4,006	2,258
Basic earnings per share ( )[(b)]:					
Net income excluding the held-for-exchange Merial business attributable to equity holders of the Company [(a)]	3.90	2.85	3.80	2.91	1.64
Net income attributable to equity holders of the Company	4.03	2.94	3.91	2.97	1.69
Diluted earnings per share ( )[(c)]:					
Net income excluding the held-for-exchange Merial business attributable to equity holders of the Company [(a)]	3.90	2.85	3.78	2.88	1.63
Net income attributable to equity holders of the Company	4.03	2.94	3.89	2.95	1.68
IFRS Balance sheet data					
Intangible assets and goodwill	43,480	43,423	46,381	52,210	60,463
Total assets	80,049	71,987	71,914	77,763	86,945
Outstanding share capital	2,618	2,611	2,657	2,701	2,686
Equity attributable to equity holders of the Company	48,188	44,866	44,542	45,600	46,128
Long term debt	5,961	4,173	3,734	4,499	4,750
Cash dividend paid per share ( )[(d)]	2.40[(e)]	2.20	2.07	1.75	1.52
Cash dividend paid per share ($) [(d)(f)]	3.46[(e)]	3.06	3.02	2.31	1.80

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

(b) Based on the weighted average number of shares outstanding in each period used to compute basic earnings per share, equal to 1,305.9 million shares in 2009, 1,309.3 million shares in 2008, 1,346.9 million shares in 2007, 1,346.8 million shares in 2006, and 1,336.5 million shares in 2005.

(c) Based on the weighted average in each period of the number of shares outstanding plus stock options and restricted shares with a potentially dilutive effect; *i.e.*, 1,307.4 million shares in 2009, 1,310.9 million shares in 2008, 1,353.9 million shares in 2007, 1,358.8 million shares in 2006, and 1,346.5 million shares in 2005.

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

(e) Dividends for 2009 will be proposed for approval at the annual general meeting scheduled for May 17, 2010.

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

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SELECTED EXCHANGE RATE INFORMATION

The following table sets forth, for the periods and dates indicated, certain information concerning the exchange rates for the euro from 2005 through February 2010 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.

	Period-end Rate	Average Rate [1]	High	Low
	(U.S. dollar per euro)			
2005	1.18	1.24	1.35	1.17
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
Last 6 months				
2009				
September	1.46	1.46	1.48	1.42
October	1.48	1.48	1.50	1.45
November	1.50	1.49	1.51	1.47
December	1.43	1.46	1.51	1.42
2010				
January	1.39	1.43	1.45	1.39
February	1.37	1.37	1.40	1.35
March [2]	1.36	1.36	1.37	1.35

(1) The average of the Noon Buying Rates on the last business day of each month during the relevant period for the full year average, and on each business day of the month for the monthly average. The latest available Noon Buying Rate being March 8, 2010, we have used European Central Bank Rates for March 9 and 10, 2010.

(2) In each case, measured through March 10, 2010.

On March 10, 2010 the European Central Bank Rate was 1.3610 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, 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, including to maintain product exclusivity. Furthermore 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, 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.

A number of the Group s products are already subject to aggressive generic competition (in particular, in the United States where legislative initiatives to further facilitate the introduction of generic drugs or comparable biologic products through accelerated approval procedures may

create further challenges) and additional products of the Group could become subject to generic competition in the future. A few particularly significant products sold by the Group that may face the risk of generic competition in a major market as early as 2010 are described below:

Lovenox® may face generic competition in the United States following a final decision by the U.S. courts that our patent is unenforceable. We are not aware of any Food and Drug Administration (FDA) decision to approve any of the related Abbreviated New Drug Applications (ANDAs) filed to date.

Ambien® CR may face generic competition in the United States following the expiration of data protection in March 2009. Several ANDAs have been filed in respect of different generic formulations of this product, but we have not asserted patent infringement suits against all of these.

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If we do not obtain pediatric exclusivity, Taxotere® may face generic competition in the United States starting in May 2010 (upon expiration of the patent protecting the active ingredient). Furthermore, even though we have secondary formulation patents with later expiration dates, it is not certain that we would be successful in asserting them against a competing product (see Note D.22.b) to the consolidated financial statements included at Item 18 of this annual report).

Product liability claims could adversely affect our business, results of operations and financial condition.

Product liability is a significant business risk for us, notably in the United States where product liability claims can be particularly costly. The Group s recent acquisitions may increase product liability exposure (see The diversification of the Group s business exposes us to additional risks below). Substantial damage awards have been made in certain jurisdictions against pharmaceutical companies based upon claims for injuries allegedly caused by the use of their products. Not all possible side effects of a product can be anticipated based on preapproval clinical studies involving only several hundred to several thousand patients. Routine review and analysis of the continually growing body of post-marketing safety surveillance and clinical trials provide additional information for example, potential evidence of rare, population-specific or long-term adverse reactions or of drug interactions that were not observed in preapproval clinical studies and may cause product labeling to evolve, restriction of therapeutic indications and potentially even the suspension or withdrawal of a product. See Item 19. Exhibits 99.1 Report of the Chairman of the Board of Directors for 2009 for further discussion of these issues. Several pharmaceutical companies have recalled or 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 these claims or will not face additional claims in the future.

Although we continue to insure part of our product liability, 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 risk of our pharmaceutical and vaccines businesses. The availability of insurance capacity may also suffer from the possible effects of the global financial crisis on insurers that remain active in this market. 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 and may harm our reputation and 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 marketing practices and competition law 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.

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

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

Unfavorable outcomes in these matters 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.

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 competition to existing products through new regulatory proposals intended to or resulting in, within the major markets, changes to the scope of patent rights or data exclusivity rules.

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 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 more 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 the making of acquisitions or 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 2009, we spent 4,583 million on research and development, amounting to approximately 15.6% 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 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). 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. Furthermore each regulatory authority may 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.

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As a complement to its portfolio of products, sanofi-aventis pursues 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 possibly placed on the market without any assurance that such investments will ultimately become profitable in the long term. Because of the active competition among pharmaceutical groups for such business development opportunities, there can be no assurance of our success in completing these transactions when such opportunities are identified.

A substantial share of the revenue and income of sanofi-aventis depends on the performance of certain flagship products

Sanofi-aventis generates a substantial share of its revenues from the sale of certain key products (see Item 5. Operating and Financial Review and Prospects Results of Operations Net Sales by Product Pharmaceuticals), which represented 45.3% of the Group s consolidated revenues in 2009. Among these products is Lantus®, which, in 2009, became the Group s leading product with revenues of 3,080 million, representing 10.5% of the Group s consolidated revenues. Lantus® is a flagship product of the Diabetes division, one of the Group s recognized growth platforms. A reduction in sales or in the growth of sales of one or more of these flagship products (in particular sales of Lantus®) could affect the business, the results of operations and the financial condition of sanofi-aventis.

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. In some of these sectors the margins are lower than in the traditional pharmaceutical business. 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.

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

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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 Risks Relating to Our Business Counterfeit products could harm our business below)), corruption and fraud. Any difficulties in adapting to these markets 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. See Item 19. Exhibit 99.1 Report of the Chairman of the Board of Directors for 2009 for a further discussion of these issues. 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.

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.

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.

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

Democrats, who currently hold the majority in Congress and the presidency, have introduced a reform proposal designed to increase the government s role in determining the price, reimbursement and the coverage levels for healthcare-related expenses. This proposal includes notably provisions seeking to expand and increase rebates, to create an independent body to reduce expenditures, and to reinforce the authority of the government agency responsible for regulating and funding Medicaid and Medicare in particular to experiment with various payments schemes. Since this reform is currently under discussion, its scope and practical implications, in particular for the pharmaceutical industry, are uncertain. Nevertheless, its purpose, which is to reduce healthcare-related expenses and to prevent them from increasing, could result in a decrease in revenues and/or margins of sanofi-aventis, which could in turn affect its business, operating results, and financial condition (for further details concerning this reform project and a description of certain regulatory pricing systems that affect our Group see Item 4. Information on the Company B. Business Overview Markets Pricing & Reimbursement).

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A slowdown of global economic growth could have negative consequences for our business.[1]

Over the past several years, growth of the global pharmaceutical market has become increasingly tied to global economic growth. In this context, a substantial and lasting slowdown of the global economy or major national economies could negatively affect growth in the global pharmaceutical market and, as a result, adversely affect our business. This effect may be expected to be particularly strong in markets having significant co-pays or lacking a developed third-party payer system, as individual patients may delay or decrease out-of-pocket healthcare expenditures. Such a slowdown could also reduce the sources of funding for national social security systems, leading to heightened pressure on drug prices, increased substitution of generic drugs, and the exclusion of certain products from formularies.

Additionally, to the extent the slowing economic environment 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® and Aprovel® in the United States and several other countries, with Warner Chilcott for the osteoporosis treatment Actonel®, with Teva for Copaxone®, and with Merck & Co., Inc. for the distribution of vaccines in Europe. See Item 4. Information on the Company B. Business Overview ; our major alliances are detailed under Main pharmaceutical products . 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 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 its customers for the storage and distribution of many of our products, *e.g.*, cold storage for certain vaccines and insulin-based products. The complexity of these processes, as well as strict internal and government standards for the manufacture of our products, subject us to risks. The occurrence or suspected occurrence of out-of-specification production or storage can lead to lost inventories, and in some cases product recalls, with consequential reputational damage and the risk of product liability (See 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.

(1) Information in this section is complementary to Note B.8.8. to our consolidated financial statements included at Item 18 of this annual report, with regards 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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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® 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®. 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 the Group s 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 instances in the past where the use of biologically derived ingredients by sanofi-aventis 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 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.

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We are subject to the risk of non-payment by our customers.[(1)]

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 78% of our consolidated U.S. pharmaceutical sales were accounted for by just three wholesalers. In addition, the Group s three main customers represent 22% 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.18.1 to our consolidated financial statements included at Item 18 of this annual report).

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 from inflammable substances;
- storage tank leaks and ruptures; and
- discharges or releases of toxic or hazardous substances.

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

- the shutdown of affected facilities; and

the imposition of civil or criminal penalties.

The occurrence of any of these events may significantly reduce the productivity and profitability of a particular manufacturing facility and adversely affect our operating results.

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

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.

(1) Information in this section is complementary to Note B.8.8. to our consolidated financial statements included at Item 18 of this annual report, with regards 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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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[(1)]

Fluctuations in currency exchange rates could adversely affect our results of operations and financial condition.

Because we sell our products in numerous countries, our results of operations and financial condition could be adversely affected by fluctuations in currency exchange rates. We are particularly sensitive to movements in exchange rates between the euro and the U.S. dollar, the British pound, the Japanese yen, and to currencies in emerging countries. In 2009, approximately 32% of our net sales were realized in the United States. While we incur expenses in those currencies, the impact of currency exchange rates on these expenses does not fully offset the impact of currency exchange rates on our revenues. As a result, currency exchange rate movements can have a considerable impact on our earnings. When deemed appropriate and when technically feasible, we enter into transactions to hedge our exposure to foreign exchange risks. These efforts, when undertaken, may fail to offset the effect of adverse currency exchange rate fluctuations on our results of operations or financial condition. 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, 2009, the Group s net debt amounted to 4.1 billion. In addition to debt outstanding, the Group has contracted a number of credit lines and put into place commercial paper and medium term note programs with the aim of providing liquidity. See Item 11. Quantitative

and Qualitative Disclosures about Market Risk. In the event of a market-wide liquidity crisis, the Group might be faced with reduced access to

(1) Information in this section is complementary to Note B.8.8. to our consolidated financial statements included at Item 18 of this annual report, with regards 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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sources of financing, including under programs currently in place, or less favorable conditions. While liquidity conditions in the financial markets have improved somewhat in recent months, they could deteriorate once again, in which case our sources of financing could be substantially reduced, and we might find it difficult to refinance existing debt or to incur new debt on terms that we would consider to be commercially reasonable.

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.

As of December 31, 2009, Total and L Oréal, our two largest shareholders, held approximately 7.33% and 8.97% of our issued share capital, respectively, accounting for approximately 12.36% and approximately 15.32%, 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, Total and L Oréal 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 Total nor L Oréal 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 2009, our net sales amounted to 29,306 million. Based on 2009 sales, we are the fourth largest pharmaceutical group in the world and the second largest pharmaceutical group in Europe (source: IMS sales 2009). 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 pharmaceutical activity, which generated net sales of 25,823 million in 2009, we specialize in the following therapeutic areas:

Diabetes: our products include Lantus®, a long acting analog of human insulin which is the leading brand in the insulin market, Apidra®, a rapid-acting analog of human insulin and Amaryl®, an oral once-daily sulfonylurea;

Oncology: our leading products in the oncology market are Taxotere®, a taxane derivative representing a cornerstone therapy in several cancer types, and Eloxatine®, a platinum agent, which is a leading treatment of colorectal cancer;

Thrombosis and Cardiovascular: our thrombosis medicines include two leading drugs in their categories: Plavix®, an anti-platelet agent indicated for a number of atherothrombotic conditions, and Lovenox®, a low molecular weight heparin indicated for prophylaxis, and treatment of deep vein thrombosis and for unstable angina and myocardial infarction. Our cardiovascular medicines include Multaq®, a new anti-arrhythmic agent launched in the United States and a few other markets in 2009 and indicated for patients with atrial fibrillation, and two major hypertension treatments: Aprovel®/ CoAprovel® and Tritace®;

Other therapeutic areas are:

Central Nervous System (CNS): our major CNS medicines include Stilnox®/Ambien® CR, a sleep disorder prescription medication; Copaxone®, an immunomodulating agent indicated in multiple sclerosis; and Depakine®, a leading epilepsy treatment; and

Internal Medicine: in internal medicine, we are present in several fields. In respiratory/allergy, our products include Allegra®, a non-sedating prescription anti-histamine, and Nasacort®, a local corticosteroid indicated in allergic rhinitis. In urology, we are present with Xatral®, a leading treatment for benign prostatic hypertrophy. In osteoporosis, we are present with Actonel®.

The global portfolio of sanofi-aventis also comprises a wide range of other pharmaceutical 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 3,483 million in 2009, with leading vaccines in five areas:

Pediatric combination vaccines providing protection against diseases such as pertussis, diphtheria, tetanus, and *Haemophilus influenzae* type b infections. Our main products are Daptacel®, Tripedia®, Act-HIB®, Pentacel®, Pediacel® and Pentaxim®/Pentavac®. We are also a leading producer of injectable poliomyelitis (polio) vaccines, such as Ipol® and Imovax® Polio, as well as oral polio formulations, all of which contribute to polio eradication and disease control strategies in both developed and developing countries;

Influenza vaccines such as Fluzone® and Vaxigrip®, used for seasonal campaigns in both hemispheres, as well as Intanza®/IDflu® (the first intradermal influenza vaccine, approved in Europe in February 2009), and Fluzone® High Dose IM, approved in the U.S. in December 2009. Additionally, we manufactured and distributed: an A(H1N1) pandemic influenza vaccine in the United States; Panenza, another A(H1N1) pandemic influenza vaccine approved in several countries outside the United States, including in Europe; and pre-pandemic influenza vaccines (including H5N1 vaccines), as part of the global pandemic efforts in both our French and U.S. facilities;

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Adult and adolescent booster vaccines protecting against pertussis, tetanus, diphtheria and polio. Our main products include: Adacel® (the first trivalent booster against pertussis, tetanus and diphtheria for adolescents and adults, launched in the U.S. in 2005), Adacel Polio®, Decavac®, Repevax® and Revaxis®;

Meningitis vaccines, with Menactra®, a quadrivalent conjugate vaccine launched in the U.S. in 2005 and in Canada in 2006, Menomune®, a quadrivalent polysaccharide vaccine, and a bivalent meningococcal A and C vaccine; and

Travel and Endemic vaccines, which include a wide range of products against hepatitis A, typhoid, rabies, yellow fever, Japanese encephalitis, cholera, measles, mumps, rubella and anti-venoms. Key products include Imovax® Rabies, Verorab®, Typhim Vi®, Avaxim® and Vivaxim®.

In 2009, our vaccines activity was favorably influenced by the continued uptake of Pentacel® sales following its U.S. launch in 2008, and by the sales growth of Pentaxim® in the international(1) region. Sanofi Pasteur also strengthened its leadership position in both seasonal and pandemic influenza.

Our animal health activity is managed through Merial, formerly a joint venture in which we and Merck & Co., Inc. (Merck) each held 50%. On September 17, 2009 we acquired Merck s interest in Merial. 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 that would be equally owned by the new 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 (for more information see Item 8 B. Significant Changes Merial and Notes D.1 and D.8.1 to our consolidated financial statements included at Item 18 of this annual report). Merial is 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 2009 (which are not included in the Group s 2009 net sales) amounted to $2,554 million. The company s top-selling products include Frontline®, a topical anti-parasitic flea and tick brand for dogs and cats, Heartgard®, a parasiticide for control of heartworm in companion animals as well as Ivomec®, 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 that we use in France, except for Allegra® (sold in France as Telfast®), Tritace® (sold in France as Triatec®), and Amaryl® (sold in France as Amarel®) as well as Ambien® CR (an extended-release formulation of zolpidem tartrate, not sold in France) and Multaq® (not yet sold in France);

For our pharmaceutical activity, except where otherwise stated, all market share percentages and rankings are based on full-year 2009 sales figures from IMS Health MIDAS (retail and hospital);

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

We present our consolidated net sales for our leading products sold directly and through alliances. As regards the products sold through our alliance with 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.

(1) Worldwide excluding North America and Europe.

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We are present in approximately 110 countries on five continents with about 105,000 employees at year end 2009, not including an additional 5,600 employees of Merial. Our legacy companies, Sanofi-Synthélabo (formed by a merger between Sanofi and Synthélabo in 1999) 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, with 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.

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, sanofi-aventis acquired Merck s 50% interest in Merial and Merial is now a wholly-owned subsidiary of sanofi-aventis. 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 that would be equally owned by the new Merck and sanofi-aventis. Formation of the new animal health joint venture remains subject to approval by the relevant competition authorities and other closing conditions (for more information see Item 8 B. Significant Changes Merial and Notes 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.

On February 9, 2010 Sanofi-aventis successfully completed its tender offer for all outstanding shares of common stock of Chattem, Inc., (Chattem) 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.

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 [(1)], a portfolio of diabetes drugs including the biggest selling insulin in the world: Lantus®, a market-leading position in vaccines, 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.

(1) Worldwide excluding 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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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 as well as tougher regulatory hurdles. We have decided to respond to these major challenges by developing our platforms for growth.

Throughout 2009, we have been engaged in a wide-ranging transformation program 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 2010, 60% 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. The ongoing reorganization of our R&D is intended to help us become more flexible and innovative, with some of our existing resources being reallocated to external collaborations. In line with this policy, we have signed a number of alliance and licensing agreements with partners including Kyowa Hakko Kirin Co. Ltd (Kyowa Hakko Kirin), Exelixis, Inc. (Exelixis), Merrimack Pharmaceuticals, Inc. (Merrimack), Wellstat Therapeutics Corporation (Wellstat), Micromet, Inc. (Micromet), and Alopexx Pharmaceuticals LLC (Alopexx). These agreements are designed to give us access to new technologies, or to broaden or strengthen our existing fields of research. We have also signed additional agreements with Regeneron Pharmaceuticals, Inc. to broaden and extend our existing collaboration on the research, development and commercialization of fully human therapeutic monoclonal antibodies. In February 2010, 55% 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: for example Multaq®, which in 2009 was launched in the United States and approved in the European Union.

Adapting our structures to meet the challenges of the future

During 2009, we adapted our operating model, previously too focused on the most important prescription drugs in our traditionally important 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. 25% of our 2009 sales were in emerging markets. We strengthened our presence in vaccines and expanded our consumer health care operations, so as to address our customers needs more thoroughly and take better advantage of growth opportunities. We also realigned our industrial capacity to reflect our anticipation of changes in volumes and our analysis of the opportunities for growth. Streamlining our structures and our operating model have also enabled us to further improve our operating ratios. In 2009, the initial results of our cost control program fed into a one percentage point reduction in each of the ratios of our research and development expenses and our selling and general expenses to our net sales. Sanofi-aventis generated 480 million of savings in 2009 compared to 2008 cost structures.

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 2009, we conducted an active and targeted policy of acquisitions and R&D alliances. We successfully completed our offer for Zentiva N.V. (Zentiva), a branded generics group with products tailored to the Eastern and Central European markets, and we also acquired Laboratorios Kendrick (Kendrick), one of Mexico s leading generics manufacturers, and Medley, a leading generics company in Brazil. In R&D, we acquired two companies: BiPar Sciences, Inc. (BiPar), an American biopharmaceutical company developing novel tumor-selective approaches for the treatment of different types of cancers, and Fovea Pharmaceuticals SA (Fovea), a French biopharmaceutical R&D company specializing in ophthalmology. In consumer health care, we finalized the acquisition of Laboratoire Oenobiol (Oenobiol), one of France s leading players in health and beauty dietary supplements. At the end of the

year, we finalized an agreement to acquire Chattem, Inc. (Chattem), one of the leading manufacturers and distributors of branded consumer health products, toiletries and dietary supplements in the United States. In human vaccines, we took control of Shantha Biotechnics (Shantha), an Indian biotechnology company that develops, produces and markets vaccines to international

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standards. We also strengthened our animal health interests by acquiring the remaining 50% of Merial not previously held by us and subsequently exercised on March 8, 2010, our contractual right to combine the Intervet/Schering-Plough Animal Health business with Merial to form an animal health joint venture that would be equally owned by the new 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 (for more information see Item 8 B. Significant Changes Merial and Notes D.1 and D.8.1 to our consolidated financial statements included at Item 18 of this annual report).

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 therapeutic areas: diabetes, oncology, thrombosis & cardiovascular, central nervous system and internal medicine.

The sections that follow provide additional information on the indications and market position of these products in their principal markets. The Group s intellectual property relating to its pharmaceutical products is material to our operations and is 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, 2009. These products are major contributors to public health.

Therapeutic Area / Product Name	2009 Net Sales (million)	Drug Category / Main Areas of Use
Diabetes		
Lantus® (insulin glargine)	3,080	Long-acting analog of human insulin Type 1 and 2 diabetes mellitus
Apidra® (insulin glulisine)	137	Rapid-acting analog of human insulin Type 1 and 2 diabetes mellitus
Amaryl® (glimepiride)	416	Sulfonylurea Type 2 diabetes mellitus
Oncology		
Taxotere® (docetaxel)	2,177	Cytotoxic agent Breast cancer
		Non small cell lung cancer
		Prostate cancer
		Gastric cancer
		Head and Neck cancer
Eloxatine® (oxaliplatin)	957	Cytotoxic agent Colorectal cancer
Thrombosis & Cardiovascular		
Lovenox® (enoxaparin sodium)	3,043	Low molecular weight heparin Treatment and prevention of deep vein thrombosis
		Treatment of acute coronary syndromes
Plavix® (clopidogrel bisulfate)	2,623	Platelet adenosine disphosphate receptor antagonist Atherothrombosis
		Acute coronary syndrome with and without ST segment elevation
Aprovel® (irbesartan) / CoAprovel® (irbesartan & hydrochlorothiazide)	1,236	Angiotensin II receptor antagonist Hypertension
Tritace® (ramipril)	429	Angiotensin Converting Enzyme Inhibitor Hypertension
		Congestive heart failure
		Nephropathy
Multaq® (dronedarone)	25	Anti-arrhythmic drug Atrial Fibrillation
Others		
Central Nervous System		
Stilnox®/Ambien®/Myslee® (zolpidem tartrate)	873	Hypnotic Sleep disorders
of which Ambien® CR	506	

Copaxone® (glatiramer acetate)	467	Non-interferon immunomodulating agent Multiple sclerosis
Depakine® (sodium valproate)	329	Anti-epileptic Epilepsy
Internal Medicine		
Allegra® (fexofenadine hydrochloride)	731	Anti-histamine Allergic rhinitis Urticaria
Nasacort® (triamcinolone acetonide)	220	Local corticosteroid Allergic rhinitis
Xatral® (alfuzosin hydrochloride)	296	Uroselective alpha1-blocker Benign prostatic hypertrophy
Actonel® (risedronate sodium)	264	Biphosphonate Osteoporosis Paget s Disease

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Diabetes

The prevalence of diabetes is expected to increase significantly over the next 20 years, as a direct result of sedentary lifestyle, excessive weight and obesity, unhealthy diet and aging population. Our principal diabetes products are Lantus®, a long-acting analog of human insulin, Apidra®, a rapid-acting analog of human insulin and Amaryl®, a sulfonylurea.

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 24 million patient-years exposure since 2000. Over 70,000 patients throughout the world have been involved in Lantus® clinical trials.

Lantus® can be administered subcutaneously using syringes or specific pens including the Lantus® SoloSTAR® disposable pen and the new ClikSTAR® reusable pen:

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. In 2007, it was awarded a GOOD DESIGN Award by the Chicago Athenaeum Museum of Architecture and Design; and

ClikSTAR® is a new reusable insulin pen recently approved in the European Union and Canada and is available in Canada, Greece, the Netherlands and Switzerland. It is being reviewed by the U.S. Food and Drug Administration (FDA).

New meta-analyses and new studies have investigated the efficacy and safety of Lantus® in type 2 diabetes mellitus:

Versus detemir:

- A large (964 patients) head-to-head randomized controlled clinical trial has provided further evidence on the efficacy of once-daily, 24-hour basal insulin Lantus® compared to twice-daily insulin detemir. Lantus® and insulin detemir achieved similar, well tolerated glycemic control while a 76% higher dose was needed for insulin detemir.

Versus NPH (Neutral Protamine Hagedorn):

- A 5-year large randomized study comparing Lantus® with NPH confirmed findings from short-term studies of lower risk of hypoglycemia with Lantus® vs NPH (Rosenstock IDF 2009); and

- In October 2009, the FDA approved the inclusion in the Lantus® labeling of favorable results from this 5-year study comparing the effect of Lantus® with that of NPH insulin on the progression of retinopathy in patients with type 2 diabetes.

Versus Premixes:

- In 2008, the GINGER study demonstrated the superiority of a basal bolus regimen with Lantus® and Apidra® to a premixed insulin regimen in terms of blood glucose control in a population of advanced type 2 diabetes patients (A. Fritsche, Diabetes, Obesity and Metabolism, November, 2009).

In June 2009, four registry analyses discussing a potential link between the use of Lantus® and an increased risk of breast cancer were published in *Diabetologia* based on a retrospective follow-up of diabetic patients. Clinical studies have not indicated an association between insulin glargine and cancer, and no conclusion can be drawn from these analyses regarding a possible causal relationship between Lantus® use and the occurrence of malignancies, as their authors pointed out.

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Patient safety being the primary concern of sanofi-aventis, we convened a group of fourteen internationally-recognized experts in the fields of endocrinology, oncology and epidemiology to review the findings of the registry analyses. On July 15, 2009, they published a statement concluding that all four manuscripts had significant methodological limitations and shortcomings, and that they provided inconsistent and inconclusive results. This statement followed cautionary statements by the European Medicines Agency (EMA), the U.S. FDA as well as patient and scientific organizations such as the American Diabetes Association, the American Association of Clinical Endocrinologists, and the International Diabetes Federation warning against over-interpretation of and over reaction to these data.

On July 23, 2009, the EMA s Committee for Medicinal Products for Human Use (CHMP) re-confirmed its initial assessment of Lantus®, based on a review of existing evidence and of the recent publications of registry analyses in *Diabetologia,* and concluded that the available data does not provide a cause for concern and that changes to the prescribing advice were therefore not necessary. All four registry analyses were found to have methodological limitations and to provide inconsistent and inconclusive results regarding a potential link between Lantus® use and an increased risk of cancer.

In September 2009, 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 pre-clinical and clinical programs involving human insulin and insulin glargine and is designed to generate more information on whether there is any association between cancer and insulin use and to assess if there is any difference in risk between insulin glargine and other insulins. The plan is structured to yield short-term and longer-term results. Three epidemiological studies are planned (two retrospectives cohort studies and one case-control study). We expect to complete the two retrospectives cohort studies and analyze their results in time for scientific presentations at medical conferences in 2012. We aim to present the results of the case-control study in 2013. We are also conducting pre-clinical studies that for which we expect to have results in 2010 and in 2011.

The American Diabetes Association (ADA) and European Association for the Study of Diabetes (EASD) have maintained their 2008 treatment recommendations for type 2 diabetes. As a reminder, 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 number-one sold insulin in the world in both sales and units (source: IMS, 2009 sales) and is available in over 70 countries worldwide. The three leading countries for sales of Lantus® are 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 and in type 2 diabetes for supplementary glycemic control. Apidra® has a more rapid onset and shorter duration of action than fast-acting human insulin and can be associated with long-acting insulins such as Lantus® for supplementary glycemic control at mealtime.

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

Apidra® can be administered subcutaneously using syringes or specific pens including the Apidra® SoloSTAR® disposable pen and the new ClikSTAR® reusable pen:

Apidra® SoloSTAR® is a pre-filled disposable pen approved in 2009 by the U.S. FDA; and

ClikSTAR® is a new reusable insulin pen approved in the European Union and Canada and also available in Canada, Greece, the Netherlands and Switzerland. It is being reviewed by the U.S. FDA.

Apidra® 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® is now available in over 26 countries worldwide. The top three countries contributing to sales of Apidra® are the United States, Germany and Italy.

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Amaryl®/Amarel®/Solosa®

Amaryl® (glimepiride) is a latest-generation, orally administered once-daily sulfonylurea (a glucose-lowering agent) indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes. Amaryl® reduces the body s blood sugar level in two ways: by helping the body to produce more insulin both at mealtime and between meals and by decreasing insulin resistance. Amaryl® has a more rapid onset and longer duration of action than first-generation agents, allowing patients to achieve a very good level of control with a lower risk of hypoglycemia.

Amaryl® was the first oral diabetes drug in its class to receive approval for administration in one of three ways: either as a monotherapy or in combination with insulin or metformin.

The combination of metformin (which reduces hepatic glucose production and improves insulin resistance) with a sulfonylurea such as Amaryl® is the rational combination for counteracting the two defects seen in type 2 diabetes. It is one of the most prescribed combination of diabetes drugs worldwide. Amaryl M®, a fixed-dose combination of Amaryl® plus metformin in a single presentation was launched in 2007. The fixed dose treatment is more effective than either agent alone in patients with type 2 diabetes and has equal efficacy and better compliance than the free combination of glimepiride and metformin. In 2009, Amaryl M® was launched in Chile and in the United Arab Emirates.

Our leading market for Amaryl® is Japan, where it is the leading oral anti-diabetes product by volume (source: IMS 2009 sales). A number of generics have received marketing authorization and have been launched in Europe and the United States.

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

Lixisenatide (AVE0010 GLP-1: Glucagon-like peptide-1 agonist, type 2 diabetes mellitus; Phase III). In Phase IIb, once-a-day dosing with lixisenatide was shown to be effective in lowering blood sugar and decreasing body-weight with a good tolerability. The enrollment of the nine studies of the GetGoal Phase III program in adult patients with type 2 diabetes mellitus was completed at the end of 2009 (lixisenatide is licensed-in from Zealand Pharma A/S). A program evaluating the benefit of a combination of lixisenatide / Lantus® is currently in Phase I; and

PN2034 (novel oral insulin sensitizer, type 2 diabetes mellitus; Phase II). As an insulin sensitizer, PN2034 is expected to normalize and therefore enhance insulin action in the liver of diabetic patients. The initiation of a Phase IIb study in type 2 diabetes mellitus is projected for the third quarter of 2010. PN2034 is licensed-in from Wellstat.

Oncology

Sanofi-aventis is a leader in the oncology field, primarily in chemotherapy, with two major agents: Taxotere® and Eloxatine®.

Taxotere®

Taxotere® (docetaxel), a taxoid class derivative, inhibits cancer cell division by essentially freezing the cell s internal skeleton, which is comprised of microtubules. Microtubules assemble and disassemble during a cell cycle. Taxotere® promotes their assembly and blocks their disassembly, thereby preventing many cancer cells from dividing and resulting in death in some cancer cells.

Taxotere® 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® 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 for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck.

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In June 2009, the Committee for Medicinal Products for Human Use (CHMP) of the EMA issued a positive opinion on Roche s Avastin® (bevacizumab) in combination with Taxotere® as a first line treatment for women with metastatic breast cancer, based on the results of the AVADO study. This combination, which presents a better efficacy (significantly better Progression Free Survival PFS) than the Taxotere® monotherapy, allows a larger number of patients to be treated with Taxotere®. In the United States, a Taxotere® -bevacizumab combination is being reviewed by the FDA for an expected approval in the second quarter of 2010.

Based on the GEICAM 9805 trial results, which showed significant survival benefit in favor of the Taxotere®-based regimen compared to a fluorouracil-based regimen in 1,100 patients with node negative early stage breast cancer, sanofi-aventis filed a dossier with the EMA in November 2009 for a new indication of Taxotere® in association with doxorubicin and cyclophosphamide for the treatment of patients with node negative early stage breast cancer. In the United States, this Taxotere® regimen is already considered as a standard treatment in this indication.

For patients with androgen-independent (hormone-refractory) metastatic prostate cancer, Taxotere® remains the standard of care for a first-line treatment and new clinical studies on Taxotere® in combination with targeted therapies could lead to more frequent use of Taxotere®.

In November 2009, the European Commission approved a new single vial formulation of Taxotere® in Europe. This new formulation was also filed for approval in the United States in December 2008. A pediatric data dossier on Taxotere® was submitted for regulatory approval in the United States in November 2009, in response to the FDA s prior written request.

The top four countries contributing to sales of Taxotere® in 2009 are the United States, France, Germany and Japan.

Eloxatine®

Eloxatine® (oxaliplatin) is a platinum-based cytotoxic agent. Eloxatine® combined with infusional (given through 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.

In clinical studies of patients with stage III colon cancer who had their primary tumors surgically removed, Eloxatine® in the FOLFOX regimen has been shown to:

- Increase overall survival rates by 5.5% when the recommended dose of 12 cycles of therapy is completed; and
- Reduce the risk of colon cancer coming back.

For patients with stage IV colorectal cancer, the FOLFOX regimen is approved by the FDA for the treatment of advanced colorectal cancer (cancer of the colon and/or rectum). The FOLFOX regimen showed the following benefits in clinical trials of patients with advanced colorectal cancer:

Significantly prolonged survival;

Significantly shrank tumors; and

Significantly delayed cancer progression.

Following the end of the Eloxatine® 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 United States market, in August and September 2009, a number of oxaliplatin generics received final marketing authorization from the FDA and have since been launched.

Eloxatine® is in-licensed from Debiopharm and is marketed in more than 70 countries worldwide. The top countries contributing to the sales of Eloxatine® in 2009 were the United States, Canada, China and South Korea.

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The oncology pipeline includes a broad spectrum of novel agents with a variety of mechanisms of action for treating cancer and/or cancer side-effects, including cytotoxic agents, anti-mitotic agents, anti-angiogenic agents, anti-vascular agents, monoclonal anti-bodies, and supportive care therapies.

BSI-201 (PARP inhibitor, metastatic triple negative breast cancer (TNBC); Phase III). Developed by BiPar Sciences, Inc. (BiPar), a privately held U.S. biopharmaceutical company and a leader in the emerging field of DNA (deoxyribonucleic acid) repair that was acquired by sanofi-aventis in 2009, BSI-201 is a potential therapy designed to inhibit poly (ADP-ribose) polymerase (PARP1), an enzyme involved in DNA damage repair; BSI-201 is currently being evaluated for its potential to enhance the effect of chemotherapy induced DNA damage. It is the furthest advanced compound in clinical development in TNBC. A U.S. Phase III study to confirm Phase II data was initiated in July 2009 and is ongoing. In December 2009, the FDA granted Fast Track designation (accelerated review) for this indication. In parallel, BSI-201 is being developed in advanced non-small cell lung cancer and in ovarian cancer (Phase II);

Cabazitaxel (taxoid, prostate cancer; Phase III). Cabazitaxel is a new taxane derivative. A Phase III study in hormone resistant prostate cancer after failure of Taxotere® was successfully completed in 2009 and regulatory submissions are planned in the first half of 2010. The FDA has granted Fast Track Designation for this indication;

Alvocidib (cyclin-dependent kinase inhibitor, chronic lymphocytic leukaemia (CLL); Phase III). Alvocidib is being developed in collaboration with Ohio State University and the U.S. National Cancer Institute. A pivotal clinical Phase II/III program to support accelerated/conditional approval in refractory CLL patients is ongoing in Europe and the United States. Additional studies are expected to explore the potential benefit of alvocidib in other hematological malignancies;

Aflibercept (the VEGF Trap, anti-angiogenesis agent; solid tumors; Phase III). VEGF (Vascular Endothelial Growth Factor) Trap is being developed under an alliance with Regeneron Pharmaceuticals, Inc. Aflibercept is a novel anti-angiogenesis agent that acts as a decoy receptor or Trap for circulating VEGF. Three Phase III studies in combination with chemotherapy in patients with several solid tumors are ongoing in the following indications: in first-line advanced prostate cancer (with Taxotere® /prednisone: VENICE study) and in second-line non-small cell lung cancer (with Taxotere®: VITAL study), both of which are now fully enrolled; and in second-line metastatic colorectal cancer (with FOLFIRI; VELOUR study) where about 95% of the patients have been recruited. A fourth study, in first-line metastatic pancreas cancer with gemcitabine, was stopped 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;

AVE8062 (combretastatin derivative), new anti-vascular licensed from Ajinomoto, sarcoma, Phase III). Single agent and combination studies with cisplatin, docetaxel and oxaliplatin have been conducted with AVE8062 over recent years. A Phase III study in sarcoma in combination with cisplatin was initiated in 2008 and is currently ongoing;

In May 2009, two compounds were in-licensed from Exelixis: **XL147** (PI3K inhibitor) and **XL765** (PI3K/mTOR dual inhibitor). Multiple Phase I studies as single agent or in combination are ongoing with both compounds. Besides the license, under an exclusive discovery collaboration, sanofi-aventis and Exelixis will combine research efforts to establish several preclinical programs related to isoform-selective inhibitors of P13K (phosphoinositide-3 kinase).

An exclusive worldwide licence and collaboration agreement has been signed with the U.S. biotechnology company Merrimack relating to **MM-121**, currently in Phase I for solid malignancies.

A collaboration and worldwide license agreement was announced in October 2009 between Micromet and sanofi-aventis for the development of a BiTE® antibody, directed against an antigen present on the surface of tumor cells. BiTE® antibodies are novel therapeutic antibodies that activate T-cells so that they will identify and destroy tumor cells.

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Thrombosis and Cardiovascular

Thrombosis occurs when a thrombus, or blood clot, forms inside an artery or a vein. Left untreated, a thrombus can eventually grow large enough to block the blood vessel, preventing blood and oxygen from reaching the organ being supplied. Our principal products for the treatment and prevention of thrombosis are Lovenox®/Clexane® and Plavix®/ Iscover®.

Within the cardiovascular market, hypertension remains the most prevalent disease. Hypertension is defined as blood pressure above the normal level and is one of the main causes of severe heart, brain, blood vessel and eye complications. Our principal products for the treatment of cardiovascular diseases are Aprovel®/Avapro®/Karvea® and Tritace®/Triatec®/Delix®/Altace®.

The incidence of atrial fibrillation (AF) is growing worldwide in relation to aging populations. It is emerging as a public health concern and affects about 4.5 million people in Europe and 2.5 million people in the United States. AF leads to potential life-threatening complications, and increases the risk of stroke up to five-fold, worsens the prognosis of patients with cardiovascular risk factors, and doubles the risk of mortality and the risk of hospitalization with significant burden on patients, health care providers and payers. 70% of AF management costs are driven by hospital care and interventional procedures in the European Union. In July 2009, we launched Multaq® (dronedarone) in the United States. Multaq® is the first and only anti-arrhythmic drug to have shown a significant reduction in cardiovascular hospitalization or death in patients with AF/ Atrial flutter (AFL).

Lovenox®/Clexane®

Lovenox® (enoxaparin sodium) is the most widely studied and used low molecular weight heparin (LMWH) in the world. It has been used to treat an estimated 200 million patients in 100 countries since its launch and is approved for more clinical indications than any other LMWH. A comprehensive dossier of clinical studies has demonstrated the benefits and safety of Lovenox® in the prophylaxis and treatment of deep vein thrombosis and in treatment of acute coronary syndromes (ACS). It has become the product of reference in clinical trials for the development of new anti-coagulants in both venous and arterial indications.

In the field of venous thromboembolism (VTE) prevention, Lovenox® use continues to grow especially for prevention of VTE in hospitalized patients not undergoing surgery.

In 2009, two publications from the ENDORSE survey further highlighted the prevalence of patients at risk of VTE after undergoing surgery other than orthopedic surgery and the underuse of prophylaxis in those patients. It showed that the use of prophylaxis is even lower across different types of hospitalized patients not undergoing surgery and at risk of VTE, prompting the need to further improve the use of effective prophylaxis, as recommended by international guidelines.

After approval for the prevention of VTE in patients undergoing orthopedic surgery of the lower limbs such as total hip replacement, total knee replacement and hip fracture surgery in Japan (January 2008), Lovenox® was approved for VTE prevention in patients undergoing abdominal surgery in February 2009.

In the cardiovascular area, Lovenox® was approved in 2007 in the United States for the treatment of patients with ST-segment elevation myocardial infarction, and since then has been approved in more than 40 countries worldwide for this indication.

Lovenox® is the leader in anti-thrombotics in the United States, Germany, France, Italy, Spain, and the United Kingdom (source: IMS 2009 sales).

Plavix® / Iscover®

Plavix® (clopidogrel bisulfate), a platelet adenosine diphosphate (ADP) receptor antagonist with a rapid onset of action that selectively inhibits platelet aggregation induced by ADP, is indicated for long-term prevention of atherothrombotic events in patients with a history of recent myocardial infarction, recent ischemic stroke or established peripheral arterial disease. Plavix® is indicated for the secondary prevention of atherothrombosis regardless of the location of the arteries initially affected (heart, brain, lower limbs). This

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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 almost 62,000 patients altogether, Plavix® is now also indicated for the treatment of acute coronary syndrome (ACS) with and without ST segment elevation in combination with ASA. These indications are incorporated into the guidelines of the American Heart Association, the American College of Cardiology and the European Society of Cardiology.

In addition to the 75 mg tablet, a Plavix® 300 mg tablet was launched in 2008. This 300 mg tablet reinforces Plavix® early use by simplifying its approved loading dose administration in patients with ACS.

In December 2009, the CHMP adopted a positive opinion, recommending granting marketing authorization for DuoPlavin®, a new fixed combination of clopidogrel bisulfate and acetylsalicylic acid. The drug is indicated for prevention of atherothrombotic events in adult patients with acute coronary syndrome who are already taking both clopidogrel and ASA. The benefit of DuoPlavin® is its simplification of treatment. The combination was launched in Australia in December 2009.

The extensive clinical program for Plavix® including all completed, ongoing and planned studies, is among the largest of its kind as it has involved more than 130,000 patients overall. In addition, over 100 million patients worldwide are estimated to have been treated with Plavix® since its launch, providing significant evidence of real-life efficacy and safety experience with this product.

In 2009, ACTIVE-A study results (7,554 patients) demonstrated that, for patients with atrial fibrillation who were at increased risk of stroke and could not take an oral anti-coagulant medication, taking Plavix® (clopidogrel bisulfate) in addition to aspirin significantly reduced major vascular events over aspirin alone. The greatest benefit was seen in the reduction of stroke. Compared to aspirin alone, taking Plavix® in addition to aspirin significantly and as expected increased the rate of major bleeding. A dossier for a new indication was submitted to U.S. and E.U. authorities.

In addition, preliminary data of CURRENT-OASIS 7 trial (25,087 patients) that was designed to assess the efficacy and safety of an intensified clopidogrel regimen, have shown that the primary end-point (cardiovascular death, heart attack, or stroke at thirty days) for the entire study population did not reach statistical significance. For the population with percutaneous coronary interventions, however, the data have shown both a consistent reduction in major cardiovascular events and a significant increase in major bleeding.

The development of a pediatric indication for Plavix® is ongoing. The dose ranging Phase II study has helped determine the right dose to be studied in the Phase III study, study which is ongoing and the results of which are expected in 2010.

In addition to this clinical program, sanofi-aventis and Bristol-Myers Squibb (BMS), in close collaboration with the FDA, are conducting additional studies to further understand and characterize the variability of response with Plavix®. The objective of this program is to provide health care professionals with the best possible guidance on the use of Plavix®. Based on this program the label has been updated including new results on the pharmacological interaction with omeprazole. Sanofi-aventis and BMS continue to update the label especially with recent pharmacogenomics data and will make certain existing warnings more prominent.

Plavix® is marketed in over 115 countries. The marketing of Plavix® 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. In 2009, Plavix® obtained the highest level recommendation in the Japanese stroke and ACS guidelines.

Plavix® is the leading anti-platelet in the European and U.S. markets (source: IMS 2009 sales) even though European markets have been affected by launches of generic clopidogrel.

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

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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 various 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, in both Europe and the United States. 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).

Several clinical trials have been undertaken in recent years in an effort to demonstrate the effects of Aprovel® beyond blood pressure control including the ACTIVE-I study evaluating the effect of irbesartan in preventing cardiovascular events in patients with atrial fibrillation. The results were presented in September 2009 during the European Society of Cardiology congress. Although the study did not meet its principal goal, irbesartan demonstrated a reduction in hospitalization in heart failure. Irbesartan was also very well tolerated in these patients with atrial fibrillation.

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, where the product is licensed/sub-licensed to Shionogi Co. Ltd and Dainippon Sumitomo Pharma Co. Ltd, respectively, specific 50 mg and 100 mg dosages developed for the Japanese market were launched in June 2008.

Irbesartan generics in monotherapy are marketed in Spain and Portugal.

Alliance with BMS

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

There are three principal marketing arrangements that are used in the BMS alliance:

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

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

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

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

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

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

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

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

We use the co-marketing system in Brazil, Mexico, Argentina and Australia for Plavix® and Aprovel® and in Colombia only for Plavix®; and

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

In countries where the products are marketed by BMS on a co-marketing basis, or through alliances under the operational management of BMS, we often sell the active ingredients for the products to BMS or such entities.

The financial impact of our principal alliances on our financial condition or income is significant and is described under Item 5. Operating and Financial Review and Prospects Financial Presentation of Alliances , and see Item 3. Key Information D. Risk Factors 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.

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.

The Heart Outcomes Prevention Evaluation (HOPE) study showed it to be effective in reducing the incidence of stroke, heart attacks and cardiovascular-related death in high-risk patients. Tritace® is the only ACE inhibitor approved for the prevention of stroke, myocardial infarction and death in these patients and has the broadest spectrum of indications among ACE inhibitors for the treatment of cardiovascular diseases.

The most recent European Society of Hypertension / European Society of Cardiology guidelines on the management of hypertension highlighted the importance of taking into account global cardiovascular risk and the need to control hypertension. Based on the protective effect confirmed in the ON-TARGET study, the available combinations with diuretics (ramipril + hydrochlorothiazide) and calcium channel blockers (ramipril + felodipine) are listed as preferred combinations in the recent guidelines for physicians to help patients reach their blood pressure goals without worsening their metabolic profile.

Tritace® is available in tablets and capsules. It is marketed in over 70 countries including the United States where it is marketed by King Pharmaceuticals. The top two countries contributing to sales of Tritace® in 2009 are Italy and Canada. A number of generics have received marketing authorization and have been launched worldwide.

Multaq®

Multaq® (dronedarone) 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 or death in patients with Atrial Fibrillation (AF) / Atrial flutter (AFL). Multaq® has a convenient fixed dose regimen of twice daily 400 mg tablets to be taken with morning and evening meals. Treatment with Multaq® does not require a loading dose and can be initiated in an outpatient setting with minimal monitoring. The most common adverse reactions are diarrhea, nausea, vomiting, abdominal pain, asthenia (weakness) and cutaneous rash.

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Multaq® was approved in 2009 by the FDA, by Health Canada, by the Swiss Agency for Therapeutic Products (Swissmedic), by the European Commission, Mexico and Brazil.

In the United States, Multaq® 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.

In Canada, Multaq® is indicated for the treatment of patients with a history of or with current AF to reduce their risk of cardiovascular hospitalization due to this condition.

In Switzerland, Multaq® is indicated for the prevention of recurrence of AF/AFL or reduction of ventricular rate and to decrease the occurrence of cardiovascular hospitalizations in this patient population.

In Europe, Multaq® 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 use of Multaq® in unstable patients with New York Heart Association class III and class IV heart failure is contraindicated.

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

Multaq® has now been launched in the United States, Canada, Germany, Denmark and Switzerland. Launch is expected in 2010 in most other European countries and selected Asian and Latin American countries.

The main compounds currently in Phase II or III clinical development in the Thrombosis and Cardiovascular field are:

Semuloparin (indirect factor Xa/IIa inhibitor, prevention of VTE; Phase III) is an injectable ultra-low-molecular-weight heparin with a high ratio of anti-factor Xa activity to anti-factor IIa activity, as compared to current low-molecular-weight heparins. It is being developed primarily in the primary prevention of venous thromboembolic events in cancer patients undergoing chemotherapy and in patients undergoing abdominal surgery as well as in patients undergoing knee replacement surgery, hip replacement surgery or hip fracture surgery;

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 positive outcome from the SEPIA-ACS Phase II study is scheduled for initiation in 2010;

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; and

XRP0038 (NV1FGF, non-viral fibroblast growth factor 1, critical limb ischemia; Phase III). XRP0038 is an injectable non-viral DNA plasmid and gene therapy-based approach for the promotion of angiogenesis in patients with peripheral arterial disease that statistically significantly prolonged time to amputation as compared to placebo in a Phase IIb study in patients with critical limb ischemia. The enrollment and treatment of the Phase III program was completed in 2009, with a total of 526 patients enrolled. The study is now in the follow-up period. The primary objective is to demonstrate the safety and effectiveness of XRP0038 in the prevention of major amputations in critical limb ischemia patients. Phase III results are expected for late 2010. Submission to the FDA and the European Commission is planned for 2011.

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Central Nervous System

We have long-standing expertise in the Central Nervous System therapeutic area. Our principal products in this area are:

Stilnox®/Ambien®/Myslee®

Stilnox® (zolpidem tartrate) is the leading hypnotic worldwide (source: IMS 2009 sales) and is indicated in the short-term treatment of insomnia.

Stilnox® is available in 5 mg and 10 mg tablets. Stilnox® rapidly induces sleep that is qualitatively close to natural sleep and devoid of certain side effects that are characteristic of the benzodiazepine class as a whole. Its action lasts for a minimum of six hours, and it is generally well tolerated, allowing the patient to awaken with a reduced risk of impaired attention, decreased alertness or memory lapses throughout the day. The risk of dependence is minimal when Stilnox® is used at the recommended dosage and duration of use. Stilnox® is currently the only hypnotic demonstrated to be suitable for as needed use based on an extensive program of eight clinical trials, which together enrolled over 6,000 patients. This mode of administration avoids the systematic intake of a hypnotic by patients who suffer only occasionally from insomnia.

We have developed a controlled release formulation of zolpidem tartrate, sold in the United States under the brand name Ambien® CR in 6.25 mg and 12.5 mg tablets. Ambien® CR is marketed only in the United States.

Stilnox® is marketed in over 100 countries. It was launched in Japan under the brand name Myslee® in December 2000 and became the leading hypnotic on the market within three years of its launch (source: 2009 IMS sales). Myslee® has been co-promoted jointly with Astellas since 2006.

The top three markets contributing to sales of Stilnox® in 2009 (either immediate or controlled release formulations) are 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® have been available since 2007.

Copaxone®

Copaxone® (glatiramer acetate) is a non-interferon immunomodulating agent indicated for reducing the frequency of relapses in patients with relapsing-remitting multiple sclerosis. Copaxone® is available as a self-injectable pre-filled syringe storable at room temperature for up to one month. This formulation allows improved product delivery, increased patient comfort and convenient transportation and storage.

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

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

In addition, to minimize the patients discomfort experience with injection, Copaxone® is now available with a new, thinner needle. This new needle may help to ensure adherence by patients to their treatment.

Copaxone® is marketed through our alliance with Teva (see Alliance with Teva below).

Alliance with Teva

We in-license Copaxone® 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.

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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:

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; and

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® was sold and distributed by sanofi-aventis but marketed by Teva until March 31, 2008. On March 31, 2008, Teva assumed the Copaxone® business, including sales of the product, in the United States and Canada. As a result, sanofi-aventis no longer records product sales or shares certain marketing expenses with respect to the United States and Canada and, until March 31, 2010, will receive from Teva a royalty of 25% of sales in these markets.

Under the terms of our agreement, the Copaxone® business in countries other than the U.S. and Canada will be 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® business was transferred to Teva in Switzerland and Lichtenstein. See Item 3. Key Information D. Risk Factors 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.

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.

The top three markets for Depakine®, including both indications, are the United Kingdom, France and Italy.

The main compounds currently in Phase II or III clinical development in the Central Nervous System field are:

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, with results of the first pivotal study expected to be released in October 2010. In a Phase II adjunctive therapy study, teriflunomide, when added to background stable therapy with interferon (IFN-beta) showed acceptable tolerance and significant improvements of the disease (measured by magnetic resonance imaging -MRI);

Nerispirdine (K+ and Na+ Channel Blocker, symptomatic treatment for multiple sclerosis; Phase II). Randomization of patients into the Phase IIb study has been completed and the program for symptomatic treatment of all forms of multiple sclerosis is progressing according to plan with results expected in the second quarter of 2010;

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SSR411298 (FAAH inhibitor; Phase II). A dose finding study in Major Depressive Disorders in elderly patients is ongoing;

SAR164877 (anti-NGF (anti-Nerve growth factor) mAb, treatment of moderate to severe pain; Phase II). SAR164877, co-developed with Regeneron Pharmaceuticals, is a fully human anti-NGF monoclonal antibody. An extensive Phase II clinical development program in various types of moderate to severe pain is ongoing, with first results expected before mid-2010; and

A global licensing agreement was concluded with The Rockefeller University (New York, U.S.) concerning a novel monoclonal antibody, targeting certain specific forms of the Amyloid Beta parenchymal plaque for the treatment of Alzheimer s disease.

Internal Medicine

Our main products in the internal medicine therapeutic area are in the fields of respiratory/allergy, urology and osteoporosis.

Allegra®/Telfast®

Allegra® (fexofenadine hydrochloride) is a long-lasting (12- and 24-hour) non-sedating prescription anti-histamine for the treatment of seasonal allergic rhinitis (hay fever) and for the treatment of uncomplicated hives. It offers patients significant relief from allergy symptoms without causing drowsiness.

In January 2007, Allegra® Oral Suspension 30 mg/5 ml (6 mg/ml) was commercially launched in the United States for the treatment of hay fever symptoms in children aged 2-11 years and the treatment of the uncomplicated hives in children aged 6 months to 11 years. Allegra® Orally Disintegrating Tablets (ODT), 30 mg for treatment of these symptoms in children aged 6-11 years was launched in the United States in February 2008.

We also market Allegra-D® 12 Hour and Allegra-D® 24 Hour, anti-histamine/decongestant combination products with an extended-release decongestant for effective non-drowsy relief of seasonal allergy symptoms, including nasal congestion.

Pursuant to a settlement agreement, sanofi-aventis U.S. granted Barr Laboratories, Inc., now a subsidiary of Teva Pharmaceuticals U.S., a right to market and distribute a generic version of Allegra-D® 12 Hour, including a right to distribute an authorized generic version of Allegra® D-12 supplied by sanofi-aventis US. Barr is currently marketing and distributing an authorized generic version of Allegra® D-12 supplied by sanofi-aventis US under a Teva label. See Note D.22.b) to our consolidated financial statements included at Item 18 of this annual report.

Winthrop U.S., a division of sanofi-aventis U.S., also signed an agreement with Prasco Laboratories authorizing Prasco to provide sales support and distribution services to Winthrop U.S. for Winthrop U.S. s authorized generic of Allegra-D® 12 Hour under the Winthrop label. However, Allegra-D® 24 Hour, extended-release tablets have no generic competition.

On December 21, 2009, sanofi-aventis announced that it will seek to convert Allegra® (fexofenadine HCl) in the United States from a prescription medicine to an over-the-counter (OTC) product.

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

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 that was launched in 1996. 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. NAQ offers significant relief from nasal allergy symptoms to patients, with no scent, alcohol or taste.

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The top three countries contributing to Nasacort® AQ Spray sales in 2009 were the United States, France and Turkey. 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. See Note D.22.b) to our consolidated financial statements included at Item 18 of this annual report.

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. Since 2003, Xatral® has obtained authorizations of this extension of the indication in 56 countries worldwide including 16 European countries.

Xatral® OD (extended release formulation) is active from the first dose, provides a 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. The top three countries contributing to sales of Xatral® in 2009 are the United States, Italy and France. Generic alfuzosin became available in most European countries in 2009.

Actonel®/Optinate®/Acrel®

Actonel® (risedronate sodium) belongs to the bisphosphonate class that helps to 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 end point (hip, wrist, humerus, clavicle, leg and pelvis).

Actonel® is available in various dosage strengths and combination forms to better suit patients needs. According to 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 Alliance with Warner Chilcott below). In Japan, Actonel® is marketed by Eisai.

The top four countries contributing to Actonel® sales in 2009 are the United States, Canada, Spain and France.

Alliance with Warner Chilcott

We originally in-licensed Actonel® from Procter & Gamble (P&G) and entered into an alliance agreement with P&G in April 1997 for the co-development and marketing of Actonel®. The 1997 agreements were amended following the acquisition of Aventis by sanofi-aventis, and later with respect to the marketing rights for Actonel® in certain countries in Europe.

The alliance agreement includes the development and marketing arrangements for Actonel® worldwide (except Japan). The ongoing R&D costs for the product are shared equally between the parties, while the marketing arrangements vary depending on the country in which the product is marketed.

On October 30, 2009, P&G sold its pharmaceutical business to Warner Chilcott (WCRX), which became the successor in rights and interests to P&G for the Actonel® alliance.

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Under the alliance arrangements with WCRX, there are five principal territories with different marketing arrangements:

Co-promotion territory: the product is jointly marketed through the alliance arrangements under the brand name Actonel® with sales booked by WCRX. The co-promotion territory includes the United States, Canada and France. The Netherlands were also included until March 31, 2008;

Secondary co-promotion territory: the product is jointly marketed through the alliance arrangements under the brand name Actonel® with sales booked by sanofi-aventis. The secondary co-promotion territory includes Ireland, Sweden, Finland, Greece, Switzerland, Austria, Portugal and Australia. WCRX may also at a later date exercise an option to co-promote the product in Denmark, Norway, Mexico and/or Brazil;

Co-marketing territory: each company markets the products independently under its own brand name. This territory currently includes only Italy. In Italy, the product is sold under the brand name Actonel® by WCRX and under the brand name Optinate® by sanofi-aventis. Each company also markets the product independently under its own brand name in Spain, although Spain is not included in the co-marketing territory; the product is marketed in Spain under the brand name Acrel® by WCRX, and under the brand name Actonel® by sanofi-aventis;

WCRX only territory: the product was marketed by P&G independently under the brand name Actonel® in Germany, Belgium and Luxembourg from January 1, 2008, in the Netherlands from April 1, 2008 and in the United Kingdom from January 1, 2009, and is now marketed independently in these countries by WCRX; and

Sanofi-aventis only territory: the product is marketed by sanofi-aventis independently under the brand name Actonel® or another agreed trademark in all other territories.

The financial impact of our principal alliances on our financial condition or income is significant and is described under Item 5. Operating and Financial Review and Prospects Financial Presentation of Alliances . See Item 3.D. Risk factors 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.

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

Ferroquine (4-aminoquinoline, malaria; Phase IIb). Ferroquine is a new 4-aminoquinoline which is being developed for the treatment of acute uncomplicated *Plasmodium falciparum* malaria in combination with another anti-malarial (artesunate, an artemisinine derivative). A Phase IIb study (efficacy/safety) aimed at evaluating the optimal posology to be used in adults, adolescents and children (the most at risk population for the disease) began in 2009 in Africa;

SAR97276, the second anti-malarial in development, has an innovative mechanism of action. A Phase II study has started in Africa in adult patients with uncomplicated malaria as an initial step ahead of further assessment in younger subjects with severe *Plasmodium falciparum* malaria.

These projects are part of sanofi-aventis global commitment to fight neglected diseases which heavily impact populations of developing countries. In this context, sanofi-aventis and Medicines for Malaria Venture (MMV) have entered into an agreement to launch an extensive safety and efficacy study of an anti-malarial drug: ASAQ (fixed-dose combination of artesunate and amodiaquine).

A collaboration agreement and an option for a license have been signed with Alopexx for the development of a first-in-class human monoclonal antibody for the prevention and treatment of *S. aureus, S. epidermidis, E. coli, Y. pestis* (the bacterium that causes plague) and other serious infections; and

Kyowa Hakko Kirin and sanofi-aventis have signed a collaboration and licensing agreement for the development of an anti-LIGHT fully human monoclonal antibody which is expected to be the first-in-class in the treatment of Ulcerative Colitis and Crohn s disease.

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Ophthalmology

Sanofi-aventis acquired the French company Fovea in October 2009. Products in the pipeline include a Phase II eye-drop combination of prednisolone and cyclosporine for allergic conjunctivitis.

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.

Consumer Health Care (CHC)

Consumer Health Care is a core growth platform identified in sanofi-aventis broader strategy for achieving sustainable growth. In 2009, the Group recorded CHC sales of 1,430 million. We make nearly half of our CHC sales in emerging markets.

Organic growth was supported by the solid performance of our eight flagship brands (Doliprane®, Essentiale®, NoSpa®, Enterogermina®, Lactacyd®, Maalox®, Magne B6® and Dorflex®). Our 2009 portfolio focused on over-the-counter (OTC) brands that have a strong presence in gastro-intestinal, analgesics and respiratory areas.

Following the acquisition of Symbion in 2008, we conducted several additional acquisitions in 2009 that give the Group access to new market segments (such as beauty food supplements and a broad range of consumer health care products), to strengthen our presence in the U.S. consumer healthcare market, which we estimate to represent 25% of the current worldwide market, in terms of sales, and to enter the largest consumer healthcare segment in China (vitamins and mineral supplements):

In November 2009, we acquired Laboratoire Oenobiol (Oenobiol), one of France s leading players in nutritional, health and beauty supplements. Created in 1985, Oenobiol first became famous with the introduction in 1989 of Oenobiol Solaire®, a nutritional supplement that protects the skin and favors a better suntan by activating melanin synthesis. Following this successful launch, Oenobiol went on to develop a wide range of nutritional supplements for skin and hair care, as well as a range of slimming aids and products for menopause. In 2008, Oenobiol had sales of 57 million, 85% of which were generated in France;

Sanofi-aventis announced on February 9, 2010 that it had successfully completed its tender offer for all outstanding shares of common stock of Chattem, Inc. (Chattem). Sanofi-aventis held approximately 97% of Chattem s outstanding shares immediately following the tender offer and acquired the remaining shares through a « short form merger » on March 10, 2010. Chattem is a leading manufacturer and marketer of branded consumer healthcare products, toiletries and dietary supplements across niche market segments in the United States. Chattem s well known brands include Gold Bond®, Icy Hot®, ACT®, Cortizone-10®, Selsun Blue® and Unisom®. We will seek to convert Allegra® (fexofenadine HCl) in the United States from a prescription medicine to an OTC product to be commercialized through Chattem; and

On January 29, 2010, we signed an agreement with Minsheng Pharmaceutical Co., Ltd (Minsheng) to form a new consumer healthcare joint venture. Subject to certain conditions precedent and to regulatory approvals, sanofi-aventis will hold a majority equity stake in the future venture. The intended joint venture between sanofi-aventis and Minsheng will primarily focus on Vitamins and Mineral Supplements (VMS), the largest consumer healthcare segment in China, where Minsheng has established a strong presence with its flagship multivitamin brand of 21 Super-Vita®. The consumer healthcare market in China is driven by favorable market trends, such as increasing consumer affordability, governmental focus on health awareness and prevention driving an already well-established trend for self medication and proliferation of pharmacy chains and modern trade.

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Generics

Sanofi-aventis recorded 1,012 million of Generics sales in 2009 fueled by organic growth and acquisitions. See Item 5 Operating and Financial Review and Prospects Results of Operations Year Ended December 31, 2009 Compared with Year Ended December 31, 2008 Net Sales by Product Pharmaceuticals .

The following recent acquisitions have increased our portfolio of branded generics in emerging markets. In addition to their positions on new market segments, these acquisitions give sanofi-aventis access to new molecules in their respective countries:

- In March 2009 sanofi-aventis acquired Zentiva through a voluntary public offer. Zentiva has leading positions in the pharmaceutical markets in the Czech Republic, Slovakia, Romania, and Turkey, and is growing rapidly in Poland, Russia, Bulgaria, Hungary, Ukraine and the Baltic States;

- In March 2009, sanofi-aventis acquired Kendrick. Kendrick s portfolio incorporates active ingredients in the following therapeutic areas: analgesics, anti-histamines, anti-infectives, anti-rheumatics, cardiovascular and central nervous system drugs; and

- In April 2009, we acquired Medley in Brazil. Medley has a large generic portfolio.

We are already active in the generic drugs market through the Winthrop® brands, which combine the generic promotion of our own mature molecules with a broad-based portfolio of generic molecules originating from other laboratories.

Vaccines Products

Sanofi Pasteur is a fully integrated vaccines division offering the broadest range of vaccines in the industry (Source: based on internal estimates). In 2009, sanofi pasteur immunized over 500 million people against 20 serious diseases and generated net sales of 3,483 million. Sales were favorably impacted by the strong growth in markets outside of North America and Europe, the continued uptake of Pentacel® sales following its launch in the United States in 2008, the A(H1N1) pandemic influenza sales, the continued growth of Pentaxim® sales in the international region, and the successful seasonal influenza vaccine campaigns. See Item 5. Operating and Financial Review and Prospects Results of Operations Year Ended December 31, 2009 Compared with Year Ended December 31, 2008 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 (source: based on internal estimates).

In Europe, our vaccine products are marketed by Sanofi Pasteur MSD, a joint venture held equally by sanofi pasteur and Merck & Co., which serves 19 countries. Sanofi Pasteur MSD is the market leader in Europe overall and particularly in France. In 2009, Sanofi Pasteur MSD net sales, which are accounted for using the equity method, amounted to 1,132 million.

Sanofi Pasteur has established a leading position in the developing world (based on internal estimates). It has been expanding in Asia, particularly in China and India, in Latin America, particularly in Mexico and Brazil, in Africa, in the Middle-East and in Eastern Europe, and is very active in publicly-funded international markets such as UNICEF, the Global Alliance for Vaccines and Immunisation.

In August 2009, sanofi pasteur acquired a majority stake in Shantha, a vaccine company based in Hyderabad, India. Shantha develops, manufactures and markets several important vaccines such as SHAN5 or SHANVAC-B . It operates to international standards in a state-of-the-art facility. See Note D.1. to our consolidated financial statements included at Item 18 of this annual report.

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

(*million)*	2009 Net Sales
Influenza Vaccines *	1,062
Polio/Pertussis/Hib Vaccines	968
Meningitis/Pneumonia Vaccines	538
Adult Booster Vaccines	406
Travel and Other Endemic Vaccines	313
Other Vaccines	196
Total Human Vaccines	**3,483**

* Seasonal and pandemic influenza vaccines.

Pediatric Combination and Poliomyelitis (Polio) Vaccines

These vaccines vary in composition due to diverse immunization schedules throughout the world. This group of products which protect against up to five diseases in a single injection is anchored by acellular pertussis components.

Daptacel®, a trivalent vaccine against pertussis, diphtheria and tetanus, was launched in the United States in 2002 and has become a strong sales contributor due to its adaptation to immunization schedules. Daptacel® is now licensed in the United States for the entire immunization series to protect against diphtheria, tetanus, and pertussis, enabling health care professionals to administer the same brand of DTaP vaccines.

Act-HIB®, for the prevention of *Haemophilus influenzae* type b (Hib) infections, is also an important growth driver within the pediatric product line. In 2008, Act-HIB® became the first Hib vaccine to be approved in Japan. In the United States, sanofi pasteur successfully improved its market supply to respond to a competitor s supply shortage.

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

Pediacel®, another acellular pertussis-based pentavalent vaccine, was launched in the United Kingdom in 2004 and licensed in the Netherlands and Portugal in 2005.

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

In 2005, sanofi pasteur developed the first new polio vaccine in nearly 30 years for use in eradication, the Monovalent Oral Polio Vaccine-type 1. This product is still being used as part of the WHO strategy to end polio transmission in endemic countries. In 2007, Pentaxim®, an acelluar-based pentavalent vaccine containing eIPV, was launched in the international region including Mexico and Turkey. Mexico is the first Latin American country to integrate eIPV in its pediatric immunization schedule. We expect the use of eIPV to gradually increase given that the global eradication of polio is within reach, with only four countries in the world remaining polio-endemic. As a result, sanofi pasteur is expanding its production capacity to meet this growing demand. In 2008, an eIPV was launched in Russia following the decision by the Russian authorities to choose the inactivated polio vaccine from sanofi pasteur for the primary immunization of all infants. eIPV is regarded as the vaccine of choice for post-eradication polio immunization programs in the Russian Federation. Pentaxim® was launched in 2009 in South Africa.

SHAN5 , which is a combination vaccine protecting against five diseases (diphteria, pertussis, tetanus, *haemophilus influenzae* type b and hepatitis B), was developed by Shantha and is prequalified by the WHO for supplying to United Nations agencies globally.

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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 180 million doses in 2009 to better meet increasing demand. We expect the global demand for influenza vaccines to continue to grow within the next decade, due to an increased disease awareness as a result of the A(H1N1) influenza pandemic, and wider government immunization recommendations.

In recent years, influenza vaccine demand has experienced strong growth in many countries, particularly in China, South Korea, Brazil and Mexico. This trend is expected 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. In November 2007, sanofi pasteur signed an agreement with the Chinese authorities to build an influenza vaccine facility in Shenzhen (Guangdong Province) with the goal of producing influenza vaccines for the Chinese market by 2012. The cornerstone of this new facility was laid in October 2008. In November 2008, sanofi pasteur signed an agreement with Birmex and the Mexican Health Authorities for a project to build a new influenza vaccine facility in Ocoyoacac. Construction began in 2009.

On February 26, 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 its ease of administration, should help improve the coverage rate in Europe. This new vaccine for seasonal influenza will be marketed as Intanza® or IDflu®. Intanza®/IDflu® vaccine is now approved in the European Union for the prevention of seasonal influenza in both adult (ages 18 and over) and the elderly (ages 60 and over) populations.

In December 2009, the FDA approved sanofi pasteur s supplemental Biologics License Application (sBLA) for licensure of Fluzone® High-Dose (Influenza Virus Vaccine). This new vaccine, for adults 65 years of age and older, will be available to health-care providers for administration during the third quarter of 2010 in preparation for the 2010-2011 influenza season. 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 product.

In September 2009, the FDA approved the company s supplemental Biologics License Application for licensure of 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 six months of age 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 2009, sanofi pasteur received A(H1N1) orders from the U.S. Department of Health and Human Services (HHS), totaling 87 million doses. We began shipping the first doses of vaccine to the U.S. government (HHS) on September 29, 2009.

In November 2009, Panenza® (our non-adjuvanted vaccine) was registered by the *Agence Française de Sécurité Sanitaire des Produits de Santé*. 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. Sanofi Pasteur submitted the final registration file for our adjuvanted vaccine (Humenza) to the EMA in January 2010; following the positive opinion from the CHMP, we expect regulatory approval during the first half of 2010.

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, combined with an increased awareness of the dangers of vaccine-preventable diseases in general, has led to higher sales of this product group in recent years. Adacel®, the first trivalent adolescent and adult booster against diphtheria, tetanus and pertussis, was licensed and launched in the United States in 2005. Adacel® has since 2004, been the standard of care in Canada where most provinces provide routine adolescent immunization. This product plays an important role in efforts to better

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control pertussis, not only by preventing the disease in adolescents and adults but also by breaking the cycle of transmission among infants too young to be immunized or only partially vaccinated. Adacel® is now registered in more than 50 countries.

Meningitis and pneumonia vaccines

Sanofi Pasteur is at the forefront of the development of vaccines to prevent meningitis. Sanofi Pasteur introduced Menactra®, the first conjugate quadrivalent vaccine against meningococcal meningitis, arguably the deadliest form of meningitis in the world. In 2009, sales of Menactra® continued to grow in the United States following the 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 licensure to expand the indication of Menactra® to children two years through 10 years of age. Menactra® is now indicated for people ages 2-55 years in the United States and in Canada. Additional submission for infants aged 9-12 months is expected in the United States in 2010. Sanofi Pasteur has also begun launching Menactra® in other countries. Use of meningococcal meningitis vaccines is expected to grow significantly through anticipated future use in multiple segments of the population.

For over 30 years, sanofi pasteur has supplied vaccines against A and C meningococcal meningitis used to combat annual epidemics occurring in Sub-Saharan countries (African meningitis belt).

Travel and Endemic Vaccines

Sanofi Pasteur s Travel/Endemic vaccines provide the widest range of traveler vaccines in the industry, and include hepatitis A, typhoid, rabies, yellow fever, cholera, measles, mumps, rubella (MMR) and anti-venoms. These vaccines are used in the endemic 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 market leader in the majority of these vaccine markets (source: based on our own estimates), sanofi pasteur s Travel/Endemic activity has demonstrated stable growth.

In July 2009, sanofi pasteur submitted Imojev , a live attenuated vaccine that confers high level protection against Japanese encephalitis in just one dose, for regulatory approval in Thailand and Australia. Approval is targeted for 2010.

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

Other vaccines

ACAM2000 was licensed in August 2007 as a live, attenuated vaccine against smallpox that is manufactured using modern cell culture technologies. Its aim is to be used to guard against bioterrorism. In this regard, a warm-based manufacturing contract was entered into with the U.S. government in April 2008 in order to develop a vaccine stockpile.

In December 2008, sanofi pasteur received approval to market its smallpox VV Lister/CEP vaccine in the United Kingdom.

Animal Health: Merial

Merial is 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 2009). Its net sales for 2009 amounted to U.S.$2,554 million.

Merial was previously a joint-venture in which sanofi-aventis and Merck each held 50%. In September 2009, sanofi-aventis acquired from Merck its 50% stake in Merial and became the 100% owner of this business. On March 8, 2010, sanofi-aventis exercised its contractual right to combine the Intervet/Schering-

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Plough Animal Health business with Merial to form an animal health joint venture that would be equally owned by the new Merck and sanofi-aventis. In addition to the 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 (for more information see Item 8 B. Significant Changes Merial and Notes D.1 and D.8.1 to our consolidated financial statements included at Item 18 of this annual report).

The animal healthcare product range comprises four major segments: parasiticides, anti-infectious drugs, other pharmaceutical products (such as anti-inflammatory agents, anti-ulcerous agents, etc.) and vaccines. Merial s top-selling products include Frontline®, a topical anti-parasitic flea and tick brand for dogs and cats, as well as Ivomec®, a parasiticide for the control of internal and external parasites in livestock, Heartgard®, a parasiticide for control of heartworm in companion animals, and Eprinex®, a parasiticide for use in cattle.

In 2009, the compound patent protecting fipronil, the active ingredient of Frontline®, expired in Japan and in some European countries, including France, Germany, Italy, and the United Kingdom. However fipronil still enjoys compound patent protection in the United States until August 2010. In those markets where the fipronil compound patent has expired, Frontline® products are generally still protected through formulation patents (directed to combinations, methods of use and the like) which expire at the latest in 2017.

As for human pharmaceutical products, patent protection for animal pharmaceutical products extends for 20 years from the filing date of the priority application.

For regulatory exclusivity, in Europe, similar to human pharmaceutical products, there is an eight-year data exclusivity and a 10-year marketing exclusivity for veterinary medicinal products. In the United States, there is a 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 its 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.

In December 2009, Merial acquired selected assets in the Netherlands from Lelystad BV that will further strengthen its leadership in Foot & Mouth Disease (FMD) vaccines.

In 2009, Merial sales remained stable despite the general economic slowdown and the decreased concern about the Blue Tongue disease which had driven part of Merial s growth in the previous year. In this context, Merial enjoyed continued growth of its vaccines portfolio due to the success of its innovative avian and swine vaccines and to the continued expansion of its vaccines for pet franchise.

Pharmaceutical Research & Development (R&D)

Since the start of 2009, sanofi-aventis has been engaged in a wide-ranging transformation program designed to overcome the challenges facing the pharmaceutical industry. R&D is the first priority of this program. The 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 its innovative capacities, sanofi-aventis intends to set in place the most effective R&D organization in the pharmaceutical industry 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 (TSU) and Distinct Project Units (DPU) focused on patient needs and driving value in collaboration with the external academic and biotech communities. Two global divisions have been created Diabetes and Oncology to further strengthen the Group s position in these two areas. Five TSUs have been formed with a focus on major pathophysiologies, pressing public health needs (aging) or major geographic areas (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 sanofi-aventis 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 2009 with companies including Bipar, Merrimack, Wellstat and Exelixis. See Note D.1. to our consolidated financial statements included at Item 18 of this annual report.

Portfolio

During 2009, R&D undertook a rigorous and comprehensive portfolio review. The projects were assessed using six key criteria. These criteria 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;

- Execution: likelihood of development and manufacturing success;

- Market: existence of a market, positioning within this market and place of sanofi-aventis;

Reimbursement: likelihood of achieving the desired price and reimbursement based on Health Authorities positioning and sanofi-aventis competencies;

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

Financials: predicted return on investment for the project.

A Portfolio management group has been created in order to manage data and processes on a continuous basis. A complete R&D pipeline review will be conducted regularly.

At the end of 2009, the current clinical portfolio is the result of a number of decisions taken during these reviews plus compounds entering the portfolio from the discovery phase or from third parties through acquisition, collaboration or partnership.

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

	Phase I	Phase II	Phase III	Registration
Metabolic Disorders	SAR236553	PN2034	Lixisenatide	
	SAR161271			
	SAR153192		BSI-201	Cabazitaxel
	SAR3419		Aflibercept	
	MM-121		AVE8062	
Oncology				
	XL147		Alvocidib	
	XL765			
	SAR103168			
Cardiovascular		Celivarone	XRP0038	
			Otamixaban	
Thrombosis				
			Semuloparin	
Central	SSR125543	Nerispirdine	Teriflunomide	
Nervous	SAR110894	SAR164877		
System		SSR411298		
Internal	SAR153191	Ferroquine		
Medicine	SAR231893	SAR97276		
Ophthalmology	FOV2302	FOV1101		

Main changes in Diabetes/Other Metabolic Disorders portfolio

A promising candidate entered Phase I an anti-PCSK9 monoclonal antibody, SAR 236553 (from the Regeneron alliance) developed in the treatment of hypercholesterolemia and a combination of Lantus with AVE0010 was also evaluated in Phase I for type 2 diabetes.

One late Phase project was halted:

AVE5530 in hypercholesterolemia for insufficient benefit for the patient

The following approvals were obtained from the health authorities:

In Japan, Apidra® was approved for diabetes; Solostar® (disposable pen) was approved, for Apidra® in the United States and Japan. ClickStar® (new rechargeable pen) was approved in Europe and Canada for Lantus® and/or Apidra®.

Extension of indication in United States:inclusion in the Lantus® labeling of favorable results on the progression of retinopathy in patients with type 2 diabetes.

Main changes in Oncology portfolio

Two fast track designations from the FDA have been granted for compounds currently in Phase III development in oncology:

Cabazitaxel, developed for the treatment of prostate cancer (2nd line). Further to the positive results of TROPIC study (primary endpoint: overall survival) a rolling submission is already on going.

BSI-201 (PARP inhibitor), developed by BiPar Sciences, Inc. (BiPar) in the treatment of metastatic triple negative breast cancer (TNBC). BiPar, a privately held US biopharmaceutical company, leader in the emerging field of DNA repair, was acquired by sanofi-aventis in 2009. BSI-201 is a potential therapy designed to inhibit poly (ADP-ribose) polymerase (PARP1), an enzyme involved in DNA (deoxyribonucleic acid) damage repair; BSI-201 is currently being evaluated for its potential to enhance the effect of chemotherapy induced DNA damage. It is the furthest advanced compound that is in clinical development in TNBC. A US phase III study to confirm Phase II data has been initiated in July 09 and is on going. In December 2009, the FDA

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granted Fast Track designation (accelerated review) for this indication. In parallel, BSI-201 is developed in advanced squamous non-small cell lung cancer and in ovarian cancer (Phase II).

Late phase projects which were terminated:

Trovax®: the rights were returned to Oxford BioMedica after the results of a renal cancer study which did not reach statistical significance on the primary endpoint;

Phase III study evaluating xaliproden in the prevention of severe peripheral sensory neuropathy induced by oxaliplatin (metastatic colorectal cancer patients) did not attain its primary endpoint; consequently, its development was terminated;

Larotaxel, in pancreatic cancer Phase III was terminated due to lack of sufficient efficacy; and

AVE1642 was stopped due to lack of differentiation versus competitive environment

The following approvals were obtained from the health authorities:

In October 2009, the FDA approved Elitek® for the management of hyperuricemia in adults suffering from leukemia, lymphoma or solid malignancies who are receiving anti-cancer treatments that carry a risk of inducing tumor lysis syndrome and hence hyperuricemia. This product was approved in Japan under the name of Rasuritek® ; and

Taxotere®: a new formulation (one vial IV route 20-80mg) was approved in Europe . A dossier for the pediatric indication for Taxotere® was submitted for regulatory approval in the United States in November 2009; this dossier and designed to be responsive to the FDA s prior written request for pediatric data.

Main Change in Thrombosis and Cardiovascular portfolio

The approval of Multaq® in the United States as well as in Europe was a major achievement in 2009. (for more details see Main Pharmaceutical Products Thrombosis and Cardiovascular Multaq® above). Multaq® was launched in United States. in July and already in several countries in Europe.

After positive results in Phase II, otamixaban (injectable selective direct inhibitor of coagulation factor Xa) is now starting Phase III in moderate to high risk patients with UA/NSTEMI managed invasively.

Late phase projects which were terminated:

In the light of recent therapeutic advances in the field of thromboembolic events prevention in patients with atrial fibrillation, idrabiotaparinux did not appear able to bring significant improvement in the care of these patients and its development in this indication was discontinued.

SAR407899 (rho-kinase inhibitor, Phase II) in erectile dysfunction was stopped due to lack of efficacy.

Approvals from health authorities

Lovenox® was approved in Japan, for the prevention of venous thromboembolic events after abdominal surgery;

The CHMP recommended the marketing authorization for DuoPlavin®, a new fixed dose combination of clopidogrel hydrogen sulphate and acetylsalicylic acid. The drug is indicated for prevention of atherothrombotic events in adult patients with acute coronary syndrome who are already taking both clopidogrel and acetylsalicicylic acid.

Following the good results of the ACTIVE-A clinical trial evaluating Plavix® in addition to aspirin for patients with atrial fibrillation who were at increased risk for stroke and could not take an oral anticoagulant treatment, a dossier for labelling change was submitted to the U.S. and EU authorities.

Main Change in Central Nervous System portfolio

Teriflunomide (HMR 1726, orally active dihydroorotate dehydrogenase inhibitor, multiple sclerosis, Phase III). An extensive Phase III monotherapy development program in relapsing forms of multiple

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sclerosis is ongoing, with results of the first pivotal study expected to be released in October 2010. In a Phase II adjunctive therapy study, teriflunomide, when added to background stable therapy with interferon (IFN-beta) showed acceptable tolerance and significant improvements of the disease (measured by magnetic resonance imaging - MRI).

Late phase projects which were terminated:

Saredutant, Phase III trial did not give expected results in combination with escitalopram in depression;

Following the interim analysis of the Phase II CONNECT study, development of AVE1625 (CB1 antagonist) for schizophrenia was terminated;

Ataciguat, developed in neuropathic pain was stopped due to lack of efficacy;

Further to the complete response letter issued by the FDA in September 2009, and considering the need for significant further clinical development and market access constraints, the eplivanserin submission dossier in insomnia was withdrawn in the United States and in Europe; and

Two compounds in Phase II were also stopped: SSR180575 (diabetic neuropathy) for lack of efficacy and AVE0657 (sleep apnea) for insufficient benefit / risk ratio

Main changes in Internal Medecine portfolio

SAR164877 anti-NGF monoclonal antibody from Regeneron, evaluated in the treatment of pain is recruiting patients suffering from sciatica and osteoarthritis in a Phase II study; and

An anti-IL4 monoclonal antibody (Regeneron alliance) for the treatment of asthma and atopic dermatitis entered in Phase I.

Approvals from health authorities:

Scuptra® was approved by the FDA in July 2009 in a new indication: aesthetic dermatology; and

Actonel® (risedronate) was approved for pediatric indication (Osteogenesis Imperfecta) in the United States.

Ophthalmology portfolio

Several compounds designed for the treatment of eye disease were included in the portfolio through the acquisition of Fovea and collaboration agreement with Oxford BioMedica (see Main Pharmaceutical Products Internal Medicine Ophthalmology above)

Other discovery/ development partnerships

The first results of our transformation program are illustrated by the number of research and discovery collaborations/partnerships concluded during 2009.

In November 2009, the collaboration between sanofi-aventis and Regeneron to discover, develop and commercialize fully human therapeutic monoclonal antibodies, was expanded and extended. The aim is to advance an average of four to five antibodies into clinical development per year.

A strategic research alliance agreement with the California Institute of Technology (Caltech) was signed in December 2009. The goal of the research collaboration is to advance knowledge in the area of human health through basic and applied biology research and promote scientific exchange between Caltech and sanofi-aventis.

In February 2009, a partnership with the Salk Institute was set up. Designed as close research collaboration, the sanofi-aventis Regenerative Medicine Program at the Salk Institute, will support the institute s stem cell facility, for up to five years.

Vaccines Research and Development

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

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Portfolio

The sanofi pasteur R&D portfolio includes 18 vaccines currently in advanced development as shown in the table below. The portfolio is well balanced with 9 vaccines for novel targets and 9 vaccines which are enhancements of existing vaccine products.

Phase I	Phase IIa	Phase IIb	Phase III	Submitted
Streptococcus pneumonia*	**Flu [1] Cell Culture**	**DTP-HepB-Polio-Hib [2]**	**Hexaxim**	**Pediacel® EU**
Prevention of meningitis and pneumonia	New production method		DTP-HepB-Polio-Hib [2]	DTP-Polio-Hib [2]
		ACAM C. diff*		
	Rabies*	Prevention of C. difficile associated diarrhea	**ADACEL®**	**IMOJEV ***
Tuberculosis*	mAb post exposure		DTP[2] 4-6 years	Japanese encephalitis
Prevention of disease	prophylaxis			Single-dose vaccine
		Dengue*	**Menactra®**	
Rotavirus (Shantha)*		Mild-to-severe		
	Meninge A,C,Y,W conj.		Meningococcal disease	**Humenza ***
Prevention of disease		dengue fever vaccine		
	2nd generation		Infant/Toddler	A(H1N1) pandemic influenza vaccine, adjuvanted EU
	Meningitis in infants		9-12 months	
Pseudomonas aeruginosa*				
Anti-body fragment product				
	Rabies VRVg		**Fluzone® ID**	
	Purified vero rabies vaccine		Seasonal influenza, U.S. intradermal micro-injection	

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

Project highlights

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 alternate delivery systems. We remain actively engaged in pandemic preparedness activities, as evidenced by our response to the H1N1 pandemic in 2009.

Fluzone® High-Dose IM was licensed in the United States in December 2009. Fluzone® High-Dose vaccine was specifically designed to generate a more robust immune response in people 65 years of age and older. This age group which typically shows weaker immune response, has proven to respond better to the Fluzone® High- Dose product. Intanza®/IDflu®, the first influenza vaccine delivered by intradermal (ID) microinjection was granted market authorization by the European Commission in February 2009. A regulatory submission to the FDA for the licensure of Fluzone® ID in the United States is planned for 2010.

Pandemic preparedness activities in 2009 focused both on the H5N1 and H1N1 viral strains. The Emerflu® vaccine was licensed in Australia in March 2009 for the prevention of H5N1 influenza in Australia upon official declaration of a pandemic. Emerflu® is intended to be manufactured and distributed with the identified pandemic strain. The approval of the vaccine by the Australian Therapeutic Goods Administration (TGA) was based on clinical trials evaluating the safety and immunogenicity of an H5N1 alum-adjuvanted inactivated influenza vaccine candidate.

Sanofi Pasteur quickly responded to the public health efforts to prevent the circulation of the new influenza A(H1N1) virus that emerged during the spring of 2009. Within four months of receiving the new A(H1N1) seed virus, a non-adjuvanted vaccine was manufactured and tested in clinical trials involving 3,478 adults and 2,474 children. Safety was consistent with the traditional seasonal influenza vaccine and protective anti-body levels were observed across all age groups. Influenza A(H1N1) 2009 Monovalent Vaccine was licensed in the United States in September 2009. Panenza™ (15mcg dose, non-adjuvanted) was registered by the French regulatory agency on November 16 and has also been registered in Spain, Luxemburg, Germany, Brazil, Hong Kong, Slovakia, Thailand, Tunisia and Turkey. Humenza™ (3.8 mcg dose, adjuvanted H1N1 vaccine) was evaluated in clinical trials in Europe and shown to be safe and induce robust anti-body responses in adult and children. Humenza™ has been submitted to the European Commission for approval. Following the positive opinion from the CHMP, we expect regulatory approval during the first half of 2010.

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ACAM-FLU-A is a universal influenza vaccine approach based on the M2 antigen which is common to all influenza A viruses. The M2 sequence is highly conserved across human, porcine, and avian viruses. Potential opportunities for this vaccine include use as a pre-pandemic vaccine and as an adjunct to the seasonal vaccine to provide increased seasonal coverage in years where a strain mismatch occurs in the trivalent vaccine. Phase I clinical trials have been completed with ACAM-FLU-A in which the safety and immunogenicity of the vaccine candidate were evaluated. This project was moved back to the pre-clinical stage in 2009 in order to optimize the formulation by using proprietary sanofi pasteur adjuvants.

Pediatric Combination & Adolescent/Adult Booster Vaccines

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.

Pediacel® A regulatory submission was filed in December 2009 for licensing in the rest of Europe of this pentavalent pediatric vaccine that 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.

Hexaxim™ A hexavalent pediatric vaccine aimed specifically at the International Region is under development. The vaccine is currently in Phase III clinical trials which will continue throughout 2010.

Unifive (DTaP-hep B-Hib) Sanofi Pasteur has decided to focus on the development of its IPV-containing combination vaccines in light of the large demand increase in IPV vaccines and the Global Polio Eradication Initiative s plan to ensure IPV vaccination in the post-eradication era. As a result the Unifive project, a non-IPV containing pentavalent vaccine, has been discontinued.

Adacel® A trivalent vaccine to boost immunity in adolescents and adults against diphtheria, tetanus, and pertussis is currently marketed in Canada, Germany and the United States. In 2009, the Phase III clinical trial focused on extending the indication to include a booster for pre-school aged children (from four to six years old) was completed. A regulatory submission to the FDA for licensure in the United States is planned for 2010.

Meningitis Program

Neisseria meningitidis 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 one can first receive this vaccine.

Menactra® Infant/Toddler (9-12 months) This project is aimed at lowering the age of administration below twelve months of age. 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 2009, the FDA requested supplemental testing to be completed prior to regulatory filing. This testing is ongoing and a regulatory submission to the FDA for licensure in the United States is planned for the first half of 2010.

Meninge A, C, Y, W conj. Second Generation This project targets the infant primary/booster series schedule for introduction of a second generation meningococcal vaccine that uses an alternative conjugation technology. In 2009, an IND was submitted to the FDA in order to conduct the Phase II clinical trial in the United States. This trial started in December of 2009 and will continue throughout 2010.

Meninge B The MenB project is aimed at preventing severe disease in infants and young adults. This project is currently in the pre-clinical stage of development.

Pneumococcal Vaccine Program

Streptococcus pneumoniae 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 protein-based pneumococcal vaccine. This approach should result in a vaccine with superior serotype coverage as compared to current polysaccharide or conjugate based vaccines. In 2009, a regulatory submission was made to Swissmedic to conduct the first Phase I clinical trial in Switzerland. This clinical trial, which evaluates a new multi-protein formulation, started in January 2010 and will continue throughout 2010.

Rabies Vaccine

VRVg The Vero serum-free improvement of our current Verorab® rabies vaccine would provide a worldwide, single rabies vaccine as a follow-up to our current rabies vaccine offerings. In 2009, VRVg entered Phase II clinical trials.

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. The Phase II study in adolescents and children in the Philippines showed that the antibody combination was safe and well tolerated. Additional clinical trials are planned for 2010.

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 dengue s four viral serotypes 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 that is based on the ChimeriVax technology. Sanofi Pasteur has maintained its relationship with the WHO and the Pediatric Dengue Vaccine Initiative, a program of the International Vaccine Institute funded by the Gates Foundation to make dengue a vaccine preventable disease and to accelerate vaccine introduction in pediatric populations where the disease is endemic through disease burden evaluation, vaccine advocacy and vaccine access. Sanofi Pasteur s dengue vaccine research program includes ongoing clinical studies (adults and children) in several countries in endemic regions: Mexico, Colombia, Honduras, Puerto Rico, Peru, the Philippines, Vietnam, Singapore, and Thailand.

IMOJEV The ChimeriVax technology was further leveraged to develop a vaccine for protection against infection by the Japanese Encephalitis Virus (JEV). Japanese encephalitis is endemic in Southeast Asia. Replacement of the currently available vaccines with the single dose product is anticipated to provide a strong competitive advantage and facilitate expansion of vaccination programs. In July 2009, marketing authorization applications were filed in Thailand and Australia. Regulatory approval is expected in 2010.

West Nile virus Although the West Nile virus vaccine was safe and immunogenic in Phase II studies, the decision was made in 2009 to place this project on hold due to the current low incidence of the disease.

Tuberculosis Statens Serum Institute of Denmark (SSI) granted sanofi pasteur a license to its technology with regard to the use of certain fusion proteins in the development of a tuberculosis vaccine. The license from SSI includes access to the Intercell IC31® adjuvant. The candidate vaccine is made up of recombinant protein units. Enrollment in the Phase I clinical trial was completed in 2008 and analysis of the clinical samples is ongoing. Additional clinical trials are planned for 2010.

Melanoma The Phase II clinical study was terminated due to low enrollment and the project was cancelled.

HIV The Phase III clinical trial in Thailand involving more than 16,000 adult volunteers was completed in 2009. The trial was a collaboration between 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, sanofi pasteur and VaxGen. The prime-boost combination of ALVAC® HIV (from sanofi pasteur) and AIDSVAX® B/E (from VaxGen) vaccines lowered the rate of HIV infection by 31.2% compared with placebo. This is 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 licensure and worldwide use. Future research will be conducted through public-private partnerships.

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ACAM-Cdiff *Clostridium difficile* is a major public health concern in North America and Europe. It is the leading cause in hospitals of infectious diarrhea in adults, particularly the elderly. The epidemiology of *C. 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, based on a formalin-inactivated toxin principle similar to the tetanus and diphtheria toxoids used in licensed vaccines. This vaccine candidate has successfully completed Phase I clinical trials with more than 200 participants in which safety and immunogenicity were evaluated. In February 2009, a Phase II clinical trial in patients recently infected with *C. difficile* started in the United Kingdom. This trial was expanded to the United States in December 2009. While the target indication for the vaccine is prevention, this trial with recently infected patients aims to provide early proof-of-concept of a vaccine approach for the prevention of recurring infection.

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 2009, an EPO patent application may cover the 36 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 EP Convention accession of some current EP Convention member states, resulting in different treatment in those countries. See Note D.22.b) to the consolidated financial statements included in Item 18 of this annual report.

We monitor our competitors and vigorously seek to challenge patent infringement when such challenges would further negatively impact our business objectives.

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.D. Risk

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Factors 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 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.

One of the main limitations on our operations in some countries outside the United States and Europe is the lack of effective intellectual property protection or enforcement for our products. The World Trade Organization s (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. 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 (see Item 3.D. Risk Factors The globalization of the Group s business exposes us to increased risks.). 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.

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. 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.

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

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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).

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 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®, Lantus®, Amaryl®, Allegra®, Eloxatine®, and Ambien®/Ambien® CR. Written requests have also been issued to us with respect to Plavix®, Taxotere® and Lovenox®.

In Europe, a regulation on pediatric medicines entered into force on January 26, 2007. This regulation provides for the progressive implementation in 2009 of pediatric research obligations with associated possible rewards including an 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

We summarize below the intellectual property coverage in our major markets of the marketed products described above at Pharmaceutical Products Main Pharmaceutical Products . Concerning animal health products, Merial s intellectual property coverage is described above (see Animal Health: Merial). In the discussion of patents below, we focus on active ingredient patents (compound patents) and any later filed improvement patents listed 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 products concerned (Aprovel®, Lantus®, Amaryl®, Eloxatine®, Stilnox®/Ambien® CR and Allegra®). 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.

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

Lantus® (insulin glargine)

U.S.	**E.U.**	**Japan**
Compound: August 2014	Compound: November 2014 in most of EU; no compound patent in force in much of Eastern Europe	Compound: November 2014
		Regulatory exclusivity: October 2011
	Regulatory exclusivity until June 2010	

Apidra® (insulin glulisine)

U.S.	**E.U.**	**Japan**
Compound: June 2018	Compound: September 2019 in most of EU	Compound: June 2018
Later filed improvement patents: formulation March 2022 and January 2023		Later filed improvement patent: formulation March 2022
	Regulatory exclusivity: September 2014	
Regulatory exclusivity:		Regulatory exclusivity: April 2017
expired April 2009		

Amaryl® (glimepiride)

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

Taxotere® (docetaxel)

U.S.	**E.U.**	**Japan**
Compound: May 2010	Compound: November 2010 in most of EU; no compound patent in force in Spain, Portugal, Finland, Norway and much of Eastern Europe	Compound: June 2012
Later filed improvement patents: formulation (2012 to 2013)	Later filed improvement patents: additional patent coverage (2012 to 2013)	Later filed improvement patents: formulation (2012 to 2013)

Eloxatine® (oxaliplatin)[1]

U.S.	**E.U.**	**Japan**
Compound: expired	Compound: expired	N/A
Later filed improvement patents: coverage ranging through 2016	Genericized	
Genericized		

[1] We do not own most Eloxatine® patents but license them from Debiopharm for marketing.

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Lovenox® (enoxaparin sodium)

U.S.	**E.U.**	**Japan**
Compound: no compound patent coverage	Compound: June 2011 in most of EU; exceptions: June 2010 in France, no compound patent in force in Germany, Spain, Portugal, Finland, Norway, Greece and much of Eastern Europe	Compound: expired Regulatory exclusivity: 2016

Plavix® (clopidogrel bisulfate)

U.S.	**E.U.**	**Japan**
Compound: November 2011	Compound: 2013 in most of EU; no compound patent in force in Spain, Portugal, Finland, Norway and much of Eastern Europe. Genericized	Compound: 2013 Regulatory exclusivity: 2014

Aprovel® (irbesartan)

U.S.	**E.U.**	**Japan**
Compound: September 2011	Compound: August 2012 in most of 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	Compound: 2016
Later filed improvement patent: formulation (2015)	Later filed improvement patents: formulation coverage ranging through 2016	Later filed improvement patent: formulation (2021) Regulatory exclusivity: 2016

Tritace® (ramipril)

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

Multaq® (dronedarone hydrochloride)

U.S.	**E.U.**	**Japan**
Compound: July 2011 (2016 if PTE petition is granted)	Compound: August 2011 (2016 if SPC is granted)	Compound: August 2011
Later filed improvement patent: formulation (2018)	Later filed improvement patent: formulation (2018)	
Regulatory exclusivity: July 2014	Regulatory exclusivity: 2019	

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Stilnox® (zolpidem tartrate)

U.S.	E.U.	Japan
Compound patent: expired	Compound patent: expired	Compound patent: expired
Later filed improvement patent: Ambien® CR formulation (2019)	Genericized	Later filed improvement patent: Ambien® CR formulation (2019)
		Regulatory exclusivity: September 2010 on all formulations

Copaxone® (glatiramer acetate)[1]

U.S.	E.U.	Japan
Compound: 2014	Compound: 2015	N/A

Depakine® (sodium valproate)

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

Allegra® (fexofenadine hydrochloride)

U.S.	E.U.	Japan
Compound: expired	Compound: expired	Compound: expired
Later filed improvement patents: coverage ranging through 2017	Genericized	Later filed improvement patents: coverage ranging through 2016
Single entity form genericized, licensed generic D® -12 Hour form since November 2009[2]		

Nasacort® (triamcinolone acetonide)

U.S.	E.U.	Japan
Compound: expired	Compound: expired	Compound: expired
Later filed improvement patents: formulation and method of use 2016	Later filed improvement patent: formulation 2017	

Generic licensed as early as 2011[2]

Xatral® (alfuzosin hydrochloride)

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

1. Sanofi-aventis has licenced Copaxone® from Teva, with which we co-promote the product.
2. A license was granted to Barr Laboratories, Inc. in settlement of patent litigation. For more information, see Note D.22.b) to the consolidated financial statements included at Item 18 of this annual report.

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	Actonel® (risedronate sodium)[1]	
U.S.	**E.U.**	**Japan**
Compound: December 2013	Compound: December 2010 in Austria, Belgium, France, Germany, the Netherlands, the United Kingdom, Sweden, Switzerland and Italy; 2013 in Spain; expired elsewhere	N/A
Later filed improvement patents: coverage ranging through 2018	Later filed improvement patents: coverage ranging through 2018	

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 and Plavix® in Europe.

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 litigations concerning the patent protection of a number of products.

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

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 is reduced to four years if the ANDA includes a challenge to a patent listed in the FDA s Orange Book, and owned by or licensed to the manufacturer of the original version. However, in such a case if the patent holder or licensee brings suit in response to the patent challenge within the statutory window, then the FDA is barred from granting final approval to an ANDA during the 30 months following the patent challenge (this bar 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. 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.

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

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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.D. Risk Factors 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.

The degree of trademark protection varies country by country, as each state implements 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. 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 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. As a result, we outsource a portion of the production of the active ingredients used in Stilnox® and Xatral®, a part of the chemical activity linked with Lovenox® and certain formulations of various pharmaceutical products. Our main subcontractors are Patheon, Famar, Catalent, GSK-NDB, Haupt and Sofarimex. These subcontractors are required to follow our guidelines in terms of quality, logistics and other criteria. See Item 3.D. Risk Factors 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®. 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® 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® / clopidogrel bisulfate and Aprovel® / irbesartan.

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

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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) 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.

All of our 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 and our vaccines facilities of Marcy l Etoile and the Val de Reuil 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® for example.

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 130 million in 2009.

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 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, 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 subsoil 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 has been completed or is in progress in Rochester, Cincinnati, Mount-Pleasant, East Palo Alto, Ambler and Portland in the United States; Frankfurt in Germany; Beaucaire, Valernes, Limay, Rousset and Vitry in France; Dagenham in the United Kingdom; Brindisi and Garessio in Italy; 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 2009, sanofi-aventis spent 38 million on rehabilitating sites previously contaminated by ground

pollution. During the year ended December 31, 2009, 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 695 million as at December 31, 2009.

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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 Activity .

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 (38 in 2009) are carried out by the Group in order to detect possible instances of non-compliance with regulations and to initiate corrective measures. Moreover, 89 loss prevention technical visits were carried out in 2009.

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.

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.D. Risk Factors 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 of 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.

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. 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.

The French chemical manufacturing sites in Aramon, Neuville-sur-Saône, Saint-Aubin-lès-Elbeuf, Sisteron, Vertolaye and Vitry, as well as the plants located in the Hoechst Industry Park in Frankfurt, Germany, and the chemical production site in Budapest, Hungary, are listed Seveso II (from the name of the European directive that deals with potentially dangerous sites through a list of activities and substances associated with classification

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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.

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 material damages, are consistent with legal requirements and the best practices in the industry.

Environment

The main objectives of the environmental policy of sanofi-aventis are to implement clean manufacturing techniques, minimize the use of natural resources and reduce the environmental impact of its activities. In order to optimize and improve our environmental performance, sanofi-aventis is committed to progressively obtaining ISO 14001 certification. 39 manufacturing sites and three Research & Development sites are currently certified. This commitment is part of a strategy of continuous improvement practiced at all Group sites through the annual implementation of HSE progress plans. We believe that this strategy clearly expresses the commitment of both management and individuals to health, safety and the environment. In 2008 and 2009, six of the Group s European sites are included in the scope of the European CO_2 Emissions Credit Trading Scheme aimed at helping to reach the targets set by the Kyoto protocol.

The recent efforts of the Group 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. Since 2005 we have reduced carbon dioxide emissions caused by our sales representation car fleet by 14%, our direct carbon dioxide emissions by 11 % and our indirect emissions by 16% in terms of our activity level per unit produced.[(1)]

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 activity and by geographic market for 2007, 2008 and 2009 can be found at Note D.35. to our consolidated financial statements included at Item 18 of this annual report.

(1) The CO2 emissions variations per produced unit are calculated for each business and added proportionally to their contribution to the total. Each business defines a specific indicator of its activity (e.g., hours worked for vaccines, number of boxes produced for pharmacy). An important evolution in chemistry occurred this year regarding the production mix between chemical synthesis, fermentation and biotechnology. It was decided that from 2008, the added value would be considered as the new activity indicator instead of the quantity of API and isolated intermediates produced, which was previously used from 2005 to 2008.

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The following market shares and ranking information is based on sales data from IMS Health MIDAS, retail and hospital, for 2009, 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 110 countries, and our products are available in more than 170. Our main markets in terms of net sales are, respectively:

The United States, also the world s largest pharmaceutical market, where we rank 1st 2, and where our market share is 3.4% in 2009 (3.4% in 2008). The United States represents 32% of the Group s net sales. Key events in 2009 affecting American market share include:

- Strong performance by Lantus® driven by SoloSTAR®, and by Taxotere® and Lovenox®;
- Launch of Multaq® in July 2009, the first anti-arrhythmic to be approved with a clinical benefit in reducing cardiovascular hospitalization in patients with atrial fibrillation or atrial flutter; and
- Market entry of generics of Eloxatin® in August and of Allegra® D-12 Hour in November 2009.

Europe: represents 41% of the Group s net sales; we are the leading pharmaceutical company in France where our market share is 11.5% in 2009 (13.1% in 2008), and we rank second in Germany with a 5.6% (5.7% in 2008) market share. Key events in 2009 affecting European market share include:

- Eastern Europe, which since the beginning of April 2009 has included Zentiva was the main growth driver;
- Good performance by Lantus®, Lovenox® and Copaxone®;
- Ongoing competition from generics of Eloxatine® and from clopidogrel generics;
- Multaq® approval by European Commission; Multaq® was launched in Germany in January 2010; and
- The new generics platform combining the operations of Zentiva and sanofi-aventis is now fully operational.

Japan represents 6% of the Group s net sales; our market share is 3.0% (2.8% in 2008). Our main products are Allegra®, Plavix®, Myslee®, Amaryl® and Taxotere®. Key events affecting Japanese market share include:

- Good performance by Plavix®, Myslee® and Allegra®;

- Approval of Lovenox® for the prevention of venous thromboembolic events after abdominal surgery; and

- Launch of Apidra® in June 2009.

Emerging markets (see definition in B. Business Overview Strategy , above) represent 25% of the Group s net sales; we are the leading healthcare company in emerging markets with a 5.7% market share.

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, 2009 Compared with Year Ended December 31, 2008.

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 CHC products, these drugs are ordinarily dispensed to patients by pharmacies upon presentation of a doctor s prescription.

We use a selection of channels to disseminate information about and promote our products among healthcare professionals and patients, ensuring that the channels not only cover our latest therapeutic advances but also our mature products, as they provide the foundation for satisfying major therapeutic needs.

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Our medical sales 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, 2009, we have a global sales force of some 34,300 representatives, including approximately 11,100 in Europe, 7,100 in the United States, 3,200 in Japan and 3,600 in China.

As is common in the pharmaceutical industry, we market and promote our products through a variety of advertising, public relations and promotional tools. 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 specific media channels to market our products. National education and prevention campaigns can be used to improve patients knowledge of conditions such as deep vein thrombosis, osteoporosis, uncontrolled diabetes, influenza and arterial diseases in markets such as Germany, France and the United States.

Although we market most of our products with 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 Main pharmaceutical products above.

Our vaccines are sold and distributed through multiple channels, including physicians, pharmacies 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 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.

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 in thrombosis; 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, Roche in oncology and osteoporosis, and Bayer in thrombosis.

In our Vaccines business, we compete primarily with Merck outside of Europe, GlaxoSmithKline, Wyeth (recently acquired by Pfizer) 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 local manufacturers, which are 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.

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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 issue is of particular relevance to the European Union, where these practices have been encouraged by the current regulatory framework. Parallel traders take advantage of the price differentials between markets arising from factors including sales costs, market conditions (such as intermediate trading stages), tax rates, or national regulation of prices.

Finally, pharmaceutical companies face illegal competition from counterfeit drugs. The WHO estimates that counterfeit products account for 10% of the market worldwide, rising to 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 2009.

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 sector is highly regulated. National and supranational regulatory authorities administer a vast array of legislative and regulatory requirements that dictate pre-approval testing, and quality standards ensure the safety and efficacy of a new product. These authorities also regulate product labeling, manufacturing, importation/exportation and marketing as well as post-approval commitments which the product manufacturer is required to honor.

The submission of an application to a regulatory authority does not guarantee that a license to market the product will be granted. Furthermore, each regulatory authority may impose its own requirements during the course of the development or during product review. It may refuse to grant approval, or may require additional

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data before and also after granting an approval, even though the relevant product has already been approved in other countries. Regulatory authorities also have the authority to request product recalls, product withdrawals and other penalties for violations of regulations based on data that are made available to them.

The International Conference on Harmonization (ICH) regulatory agencies (the three founder members being the European Union, Japan and the United States), plus Health Canada and Swissmedic as observers, all have high standards for pharmaceutical technical appraisal. Product approval usually takes one to two years, but depending on the country it can vary from six months to, in some cases, several years from the date of application. 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, intensive efforts have been made by the ICH area regulatory agencies to harmonize product development and regulatory submission requirements. An example of this is that many pharmaceutical companies are now able to prepare and submit a Common Technical Document (CTD) that can be used in different regions for a particular product with only local or regional adaptation. Electronic CTD is becoming the standard for submission.

Pharmaceutical manufacturers have committed to publishing protocols and results of clinical studies performed with their compounds in publicly accessible registries (Clinical Trials Registry and Clinical Trial Results Registry). In addition, regulatory frameworks in the various ICH countries and non-ICH countries tend to impose mandatory disclosure of clinical trials information (protocol-related information as well as results-related information).

However, 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 to long after initial marketing approval is granted. 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. See Pricing & Reimbursement below.

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 and optional for others. An application is typically submitted to the EMA. The scientific evaluation of the application is carried out by the Committee for Medicinal Products for Human Use (CHMP) of the EMA, and a scientific opinion is prepared. The 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.

If a company is seeking a national marketing authorization in more than one Member State, the mutual recognition or decentralised procedure is available to facilitate the granting of harmonized national authorizations across Member States. Both the decentralised 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.

The co-called « sunset clause » is a provision leading to the cessation of the validity of any marketing authorization which is not followed by the actual placing on the market within 3 years or which does not remain present on the market for a consecutive period of 3 years.

Generic products are subject to a harmonized procedure in all countries of the European Union. A generic product contains 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.* that it works in essentially the same way in the patient s body, but there is no need to submit safety or efficacy data as regulatory authorities refer to the originator product s dossier. Generic

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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 openness and the transparency of its activities, such as the publication of the European Public Assessment Report (for approved, withdrawn or rejected products), which will now be more structured and oriented to comparative effectiveness. New initiatives have been proposed with regard to the disclosure of a minimum amount of information on applications that have been submitted for marketing authorization. Also the EMA has become more proactive on the disclosure of documents/information throughout the product lifecycle, more specifically in the safety area. In addition patients and consumers are increasingly involved in the work EMA s scientific committees of the Agency.

A new 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 specifically 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 plays a central role in the scientific assessment of ATMPs.

A new regulatory framework on variations to marketing authorizations is being implemented 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 is developing with the implementation of the confidentiality arrangements between ICH regulatory authorities, and also with other non-ICH regulatory authorities. Several examples have begun such as work-sharing on Good Clinical Practices (GCP) inspections between the United States and the European Union and permanent representatives of the U.S. Food and Drug Administration (FDA) and Japanese Pharmaceutical and Medical Devices Agency (PMDA) now based in London, as well as a permanent representative of EMA at the FDA.

In the United States, applications for drug approval are submitted for review by the U.S. FDA. The FDA has broad regulatory powers over all pharmaceutical products that are intended for sale and marketing in the United States. To commercialize a product in the United States, a New Drug Application (NDA) or Biological License Application (BLA) is filed with the FDA with data that sufficiently demonstrate the drug s quality, safety and efficacy. Specifically, the FDA must decide whether the drug 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 registered drug requires the submission of a supplemental NDA (sNDA).

In the United States, generic drug manufacturers may file an Abbreviated NDA (ANDA). These applications are abbreviated because they are generally not required to include preclinical data, such as animal studies and human clinical data to establish safety and effectiveness. Instead, generic manufacturers need only demonstrate that their product is bioequivalent, *i.e.*, that it performs in humans in the same manner as the originator s product. Consequently, the length of time and cost required for development of such product can be considerably less than for the originator s drug. See Patents, Intellectual Property and Other Rights above for additional information. The ANDA procedures in the United States can be only used for pharmaceutical products approved under an NDA. See Focus on Biologics below.

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 delay in the registration of some innovative products in Japan compared to the European Union and United States.

For animal health products, see Animal Health: Merial above.

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Focus on Biologics

Products are usually referred to as biologics when they are derived from plant or animal tissues (e.g., blood products) or manufactured within living cells (e.g., anti-bodies, insulins, vaccines). Most biologics are complex molecules or mixtures of molecules which are difficult to completely characterize. To characterize and determine the quality, these products 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 complexity. It is the concept of biosimilar products that applies. A full comparison of the quality, safety and efficacy of the biosimilar product against the reference biological product should be undertaken and must include 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 pre-clinical and clinical development of biosimilars of low molecular weight heparins. This means that 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.

In the United States, the regulations do not currently establish procedures for biosimilar versions of a reference drug registered as a biological under the Public Health Service Act, but accelerated generic approval procedures for large-molecule biologicals have been proposed that would require the law to be revised.

However, in the United States for historical reasons a few biologicals have been registered under the Food, Drug & Cosmetic Act (FDCA) following the NDA scheme used for traditional well characterized small molecules. It is currently still technically possible to file an ANDA with respect to those particular products (among the Group s products Lovenox® is one example). Because an ANDA provides for no clinical trials other than bioequivalence studies, the appropriateness of an ANDA with respect to these NDA-registered biologicals raises significant policy issues for the FDA.

The FDCA provides for another abbreviated registration pathway for some biosimilar products; the so-called 505(b)(2) route. This pathway may in particular be used for recombinant proteins. The registration file may partially refer to the existing data for the reference product but must be completed with data specific to the biosimilar version, in particular with preclinical and clinical data. However the FDA indicated that this pathway should remain limited to relatively simple cases and that taking into consideration the current state of scientific knowledge, it is unlikely that it could be applied to more complex products either from a structural or pharmacological point of view.

Pricing & Reimbursement

Rising overall health care 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 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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In the United States, the U.S. government does not currently control pharmaceutical costs directly except in the case of prescriptions purchased or reimbursed by government entities such as Medicaid, Veterans Affairs, and the Department of Defense. These entities provide health insurance coverage to less than 20% of the U.S. population. The U.S. government also authorizes some qualifying private market entities to purchase pharmaceuticals at government controlled prices through the 340B Drug Pricing Program. Third-party payers administer private plans that cover part of the U.S. population, as well as the Medicare prescription benefit for the elderly, which the federal government funds and regulates. While the U.S. government does not directly control prices in the private and Medicare prescription drug markets, third-party payers seek to decrease drug costs through reimbursement restrictions such as patient co-pays, step therapy protocols (protocols under which a brand product may be prescribed and reimbursed only if therapy has already failed using at least one low-cost generic drug, also known as fail first), and prior authorization (requirements that a prescriber obtain third-party payer authorization prior to prescribing certain medications), in addition to rebate contracting with manufacturers. For pharmaceuticals and biologics administered to Medicare and patients in a medical setting, the U.S. government does not directly control prices, but does have the authority to make coverage determinations and has initiated various reimbursement policies, both of which than can reduce access. The Democratic leadership in both the presidency and Congress has put forward proposals to increase the scope of direct government involvement in drug pricing and reimbursement with an aim to reign in future healthcare expenditures which are otherwise expected to increase significantly. For example, the current federal legislative activity on health care reform contains provisions to: extend and increase Medicaid rebates; apply Medicaid rebates to Medicare Part D dual-eligibles; repeal the existing non-interference provision in Part D; create an independent body whose purpose is reduce expenditures; and grant more authority to the current agency responsible for regulating and funding Medicare and Medicaid to experiment with various payment schemes, among other things.

Outside the United States, governments frequently directly control pricing of drugs. The level of evidence requested to access the market, after regulatory approval is constantly rising. In addition to traditional clinical efficacy and safety criteria, more and more health authorities are asking for relative effectiveness data, and in some cases cost-effectiveness evidence. Cost-containment measures are often used to limit the financial impact of pharmaceuticals on payers who in many emerging markets may be the patients themselves. Across Europe, healthcare systems are continuously under scrutiny in order to strike a balance between funding, organization and the needs of the population. In 2009, measures taken in France included the decentralization of the healthcare system via the creation of regional health agencies (*Agences Régionales de Santé*, ARS) similar to those existing in other EU countries (*e.g.*, Italy, Spain, UK). In Germany, allocation of contributions to the healthcare funds dramatically changed from 2008 to 2009 with the introduction of a common financial collection mechanism within the GKV based on a health fund (*Gesundheitsfonds*) from January 1, 2009. The new scheme provides for unitary health insurance at a contribution rate set by law. Health funds are responsible for their budget and the needs of their population. Although the scheme is regulated at the federal level, the provision and financing of care is determined at regional level, with the regional associations of each type of health insurance fund and the regional physicians associations playing key roles. In Eastern Europe, Poland, the Czech Republic, and Hungary are examples of countries which are moving towards more stringent measures to control pricing and reimbursement of drugs, with certain countries calling for exceptional measures in face of the economic crisis (e.g., Greece, Romania).

In addition the European Commission s Directorate General for Competition published its final report on July 8, 2009 in connection with the investigation of the pharmaceutical industry initiated in January 2008. This report contains a number of conclusions and arguments in favor of modifying the regulatory environment, notably in order to improve price negotiation and drug reimbursement levels.

Several countries have announced stronger pricing controls, among them, China, India and Russia. In China, however, this is part of a broader plan to structure its healthcare system: a basic health insurance is to reach 90% of the population by the end of this year and hospitals are to be built to cover rural and remote areas. Centralised purchasing has been on the agenda in China, India and Brazil, while tendering for generics, flourishing in Germany, is now being looked at in several countries, including Italy.

All of these factors, which are specific to each country, represent additional financial and logistical challenges to pharmaceutical companies.

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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, sanofi-aventis is taking the necessary steps to defend the accessibility and price of our products which reflects the value of our innovative product offerings:

We actively engage with our key stakeholders on the value of our products as it specifically pertains to their needs. These stakeholders including physicians, patient groups, pharmacists, government authorities and third-party payers can have significant impact on the market accessibility of our products;

We continue to add flexibility and adaptability to our operations to better prepare, diagnose, and address issues in individual markets. For instance, in several countries, account management and sales functions have been reorganized and empowered to make decisions based on regional 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 reward 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.

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 Group entities, enabling us to set deductibles 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. Over the last three years, we have been working with our insurers to develop a prevention program, 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

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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.

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

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

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

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

C. Organizational Structure

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, 2009. For a complete list of our main consolidated subsidiaries, see Note F. to our consolidated financial statements, included in this annual report at Item 18.

Significant Subsidiary or Affiliate	Country	Ownership Interest
Aventis Inc.	United States	100%
Aventis Pharma S.A.	France	100%
Hoechst GmbH	Germany	100%
Merial Ltd	United Kingdom	100%

Sanofi-aventis Amerique du Nord S.N.C.	France	100%
Sanofi-aventis Deutschland GmbH	Germany	100%
Sanofi-aventis Europe S.A.S.	France	100%
Sanofi-aventis France S.A.	France	100%
Sanofi-aventis Participation S.A.S.	France	100%
Sanofi-aventis U.S. LLC	U.S.	100%
Sanofi-aventis U.S. Inc.	U.S.	100%
Sanofi Pasteur Inc.	U.S.	100%
Sanofi Pasteur S.A.	France	100%
Sanofi Winthrop Industrie S.A.	France	100%

Sanofi-aventis and its subsidiaries form a group, organized around two activities: pharmaceutical products and human vaccines. The Group is also present in animal health through Merial.

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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 the 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® and Aprovel®) 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.

We operate our business through offices and research, production and logistics facilities in approximately 110 countries. All our support functions operate out of our office premises.

A breakdown of these sites by nature and ownership/leasehold status is provided below. Breakdowns are based on surface area. All surface area figures are unaudited.

Breakdown of sites by nature

Industrial	44%
Research	15%
Offices	21%
Logistics	6%
Vaccines	11%
Others	3%

Breakdown of the Group s sites between owned and leased

Leased	68%
Owned	32%

We believe that our production plants and research facilities are in full compliance with regulatory requirements, well maintained, and generally adequate to meet our needs for the foreseeable future. However, we review our production facilities on a regular basis with regard to environmental, health, safety and security issues, quality compliance, and capacity utilization. Because our production lines are specific to a given product, and in many cases cannot be easily switched to another product, while our capacity utilization is considered appropriate as a whole, we are constantly adding capacity for products with increasing volumes while decreasing that of other lines facing reduced demand. See Capital Expenditures and Divestitures, below. For more information about our property, plant and equipment, see Note D.3. to our consolidated financial statements included at Item 18 of this annual report.

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Research and Development Sites for the Pharmaceutical Activity

Research and Development activities are housed at 25 sites:

- 11 sites in France , the largest in terms of surface area being in Vitry/Alfortville (approximately 110,000 sq.m), Montpellier (98,000 m^2), Chilly/Longjumeau (77,000 m^2) and Toulouse (38,000 m^2);
- 5 sites in other European countries (Germany, United Kingdom, Hungary, Spain and Italy), the largest being in Frankfurt, Germany (84,000 m^2);
- 6 sites in the United States, the largest being in Bridgewater, New Jersey, United States (111,000 m^2);
- In Japan, Research & Development is represented in Tokyo;
- In China, the main Research and Development operations are located in Shanghai, with a Clinical Research Unit in Beijing.

Industrial sites for the Pharmaceutical Activity

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

We have 72 industrial sites worldwide. The sites where the major sanofi-aventis drugs, active ingredients and medical devices are manufactured are:

- France: Ambarès (Aprovel®, Depakine®, Multaq®), Le Trait (Lovenox®), Maisons Alfort (Lovenox®), Neuville (dronedarone), Quetigny (Stilnox®, Plavix®), Sisteron (clopidogrel bisulfate, dronedarone, zolpidem tartrate), Tours (Stilnox®, Aprovel®, Xatral®), Vitry/Alfortville (docetaxel) ;
- Germany: Frankfurt (insulins, ramipril, Lantus®, Tritace®, pens, Apidra®);
- Italy: Scoppito (Tritace®, Amaryl®);
- United Kingdom: Dagenham (Taxotere®), Fawdon (Plavix®, Aprovel®); Holmes Chapel (Nasacort®)
- Hungary: Ujpest (irbesartan), Csanyikvölgy (Lovenox®);

Japan: Kawagoe (Plavix®);

United States: Kansas City (Allegra®).

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* and Canton* (United States), Toronto (Canada), Marcy l Etoile and Val de Reuil (France), Shenzhen (China), Pilar (Argentina), Chachoengsao (Thailand), and Hyderabad (India).

In 2009, sanofi pasteur continued with its policy of reinforcing its presence in emerging markets by acquiring the vaccines activity of Shantha in India.

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.

Acquisitions, Capital Expenditures and Divestitures

The Real Estate Department was largely involved in the Zentiva combination project. 14 countries were impacted by the project : Bulgaria, the Czech Republic, Estonia, Hungary, Kazakhstan, Latvia, Lithuania, Poland, Romania, Russia, Slovakia, Turkey, Ukraine, and Uzbekistan. The objective of the combination process was to ensure that both Zentiva and sanofi-aventis staff were housed in the same office premises as soon as possible after the acquisition.

Because we intend to contribute Merial to a joint venture 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

* Sites acquired in 2008 with Acambis.

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included Merial sites in the discussion above notwithstanding the fact that on December 31, 2009, Merial was a wholly owned subsidiary of sanofi-aventis. Merial has approximately 15 industrial sites, 9 research and development sites and numerous administrative offices with its principal headquarters located at Lyon (France) and Duluth (Georgia).

The net book value of our property, plant and equipment at December 31, 2009 was 7,830 million. During 2009, we invested 1,353 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 the years 2007, 2008 and 2009 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. and Note D.4. to our consolidated financial statements included at Item 18 of this annual report).

Our principal investments in progress are described below:

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. The construction of syringe filling and packaging lines at Le Trait (France) increased our production capacity in Lovenox® and vaccines.

We also started the conversion of our chemical sites to biotechnologies with a project to create a monoclonal antibody production facility at the Vitry-sur-Seine site in France from 2012.

In emerging markets, we currently rely on industrial sites dedicated to serving regional markets, a situation reinforced by our 2009 acquisitions (Zentiva in Eastern Europe and Medley in Brazil). In China, the project to extend our current manufacturing facility located at the Beijing Economic and Technological Development Area will enable us to install production lines for SoloSTAR®, the pre-filled injection pen used to administer Lantus® (insulin glargine).

The Vaccines activity invested in 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 formulation and filling facilities in Val de Reuil (France), of a bacteriological bulk facility in Marcy l Étoile (France), and of bulk flu 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.

We believe that our existing cash resources and unused credit facilities will be sufficient to finance these investments. No individual capital expenditure or divestiture project is considered to be material to the Group as a whole.

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, 2009.

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.

2009 Overview

Since the start of 2009, we have been engaged in a wide-ranging transformation program designed to meet the challenges facing the pharmaceutical industry to make ourselves a global, diversified healthcare leader, and deliver sustainable growth to our business.

In 2009, we once again delivered solid performances in a world market experiencing profound change. Our net sales for the year were 29,306 million, up 5.3% at constant exchange rates[1] relative to 2008 and up 6.3% on a reported basis, with strong performances from our Emerging Markets, Diabetes, Human Vaccines and Consumer Health Care growth platforms more than offsetting the impact of genericization of Eloxatine® in the United States and Plavix® in Europe. Other highlights of 2009 included the launch of Multaq® in the United States, and its approval in the European Union.

The ongoing adaptation of our structures and resources was reflected in a further improvement in our operating ratios. The ratio of research and development expenses to net sales improved from 16.6% in 2008 to 15.6% in 2009, while the ratio of selling and general expenses to sales fell from 26.0% to 25.0% over the same period. In 2009, the initial benefits of our cost management program were reflected in 480 million of cost savings compared to 2008. Our transformation program is intended to improve the efficiency of our operations, with a target of 2 billion of recurring pre-tax and pre-inflation cost savings in 2013 relative to 2008.

Business net income totaled 8,629 million in 2009 (18.0% higher than in 2008) due to growth in our sales and control over operating costs, plus favorable trends in the U.S. dollar exchange rate over the period. Business earnings per share were 6.61, 18.2% up on the 2008 figure. 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 the Company for 2009 was 5,265 million, up 36.7% from the 2008 figure.

During 2009, we deployed our strategy of focusing on reorganizing our research efforts and redefining our R&D programs; building on the positions we have acquired in emerging markets; and reinforcing our operations in Vaccines, Consumer Health Care, Generics and Animal Health.

We pursued an active policy of targeted acquisitions and research and development (R&D) alliances during 2009.

In Pharmaceuticals, we successfully completed our offer for Zentiva N.V., a branded generics group with products tailored to the Eastern and Central European markets. A number of other companies were acquired, including Laboratorios Kendrick, one of the leading manufacturers of generics in Mexico; Medley, the leading generics company in Brazil; BiPar Sciences, Inc., a U.S. biopharmaceutical company developing novel tumorselective approaches for the treatment of different types of cancers; Fovea Pharmaceuticals SA, a French biopharmaceutical R&D company specializing in ophthalmology; and Laboratoire Oenobiol, one of France s leading players in health and beauty dietary supplements. At the end of the year, we finalized an agreement to acquire Chattem, Inc. (Chattem), one of the leading manufacturers and distributors of branded consumer health care products, toiletries and dietary supplements in the United States.

(1) See definition below under Presentation of net sales

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In Human Vaccines, we took control of Shantha Biotechnics, an Indian biotechnology company that develops, produces and markets vaccines in accordance with international standards.

We have significantly reinforced our presence in Animal Health by acquiring the remaining 50% of Merial Limited not already held by us. 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 that would be equally owned by the new 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 (for more information see Item 8 B. Significant Changes Merial and Notes D.1 and D.8.1 to our consolidated financial statements included at Item 18 of this annual report).

We have also signed a number of alliance and in-licensing agreements, with partners such as Kyowa Hakko Kirin Co. Ltd; Exelixis, Inc.; Merrimack Pharmaceuticals, Inc.; Wellstat Therapeutics Corporation; Micromet, Inc.; and Alopexx Pharmaceuticals LLC. These agreements enable us to gain access to new technologies or to strengthen our existing research fields. We also signed agreements with Regeneron Pharmaceuticals, Inc. to broaden and extend the duration of our existing collaboration, focused on the research, development and commercialization of fully human therapeutic monoclonal antibodies.

Our operations generate significant cash flow. We recorded 8,515 million of net cash provided by operating activities in 2009 compared to 8,523 million in 2008. During the course of 2009, we paid out 2.9 billion in dividends and funded part of the cost of our acquisitions by contracting new debt. In terms of financial position, we ended 2009 with our debt, net of cash and cash equivalents (meaning the sum of short-term debt and long-term debt less cash and cash equivalents) at 4.1 billion (2008: 1.8 billion). Debt, net of cash and cash equivalents, is a financial indicator 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). The gearing ratio stood at 8.5% at the end of 2009 versus 3.9% at the end of 2008. 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, 2009, December 31, 2008 and December 31, 2007 have been significantly affected by our August 2004 acquisition of Aventis and certain subsequent transactions.

The Aventis acquisition gave rise to significant amortization (3,175 million in 2009, 3,298 million in 2008 and 3,511 million in 2007) and impairments of intangible assets (344 million in 2009, 1,486 million in 2008 and 58 million in 2007).

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, 2009, 2008 and 2007 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

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and on the arrangements governing those alliances. For more information about our alliances, see Financial Presentation of Alliances below. When we sell products through licensees, we receive royalty income that we record in Other revenues. See Note C. to the consolidated financial statements included at Item 18 of this annual report.

Cost of Sales. Our cost of sales consists primarily of the cost of purchasing active ingredients and raw materials, labor and other costs relating to our manufacturing activities, packaging materials, payments made under licensing agreements and distribution costs. We have license agreements under which we distribute products that are patented by other companies and license agreements under which other companies distribute products that we have patented. When we pay royalties, we record them in cost of sales, and when we receive royalties, we record them in Other revenues as discussed above.

Operating Income. Our operating income reflects our revenues, our cost of sales and the remainder of our operating expenses, the most significant of which are research and development expenses and selling and general expenses. We also present our operating income before restructuring, impairment of property, plant and equipment and intangibles, gains and losses on disposals and litigation, which appears on the face of our financial statements in accordance with IFRS, and which reflects our operating income before the impact of a number of items that do not reflect the results of our current business activities. 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

Business Segments

In accordance with IFRS 8, Business 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.

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.

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

Inter-segment transactions are not significant.

Business Operating Income of Segments

We measure the results of operations of our business 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.

Business Operating Income is equal to Operating income before restructuring, impairment of property, plant and equipment and intangibles, gains and losses on disposals, and litigation, modified as follows:

- amortization of intangible assets is eliminated;
- the share of profits and losses of associates is added and net income attributable to minority interests is deducted; and
- other impacts associated with acquisitions (primarily, the workdown of acquired inventories remeasured at fair value at the acquisition date, and the impact of purchase accounting on associates) are eliminated.

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The following tables present our business operating income for the years ended December 31, 2009 and 2008.

(*million*)	2009 Pharmaceuticals	Vaccines	Other	Total
Net sales	**25,823**	**3,483**		**29,306**
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 excluding Merial [(1)]	792	41	8	841
Share of profit/loss of Merial [(1)]			241	241
Net income attributable to minority interests	(426)	(1)		(427)
Business operating income	**10,608**	**1,173**	**247**	**12,028**

(1) Net of tax

(*million*)	2008 Pharmaceuticals	Vaccines	Others	Total
Net sales	**24,707**	**2,861**		**27,568**
Other revenues	1,208	41		1,249
Cost of sales	(6,231)	(1,104)		(7,335)
Research and development expenses	(4,150)	(425)		(4,575)
Selling and general expenses	(6,662)	(520)	14	(7,168)
Other operating income and expenses	297	1	(95)	203
Share of profit/loss of associates excluding Merial [(1)]	671	28	21	720
Share of profit/loss of Merial [(1)]			170	170
Net income attributable to minority interests	(441)			(441)
Business operating income	**9,399**	**882**	**110**	**10,391**

(1) 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 business segments, less net financial expenses and the relevant income tax charges. We believe that this non-GAAP financial measure allows investors to understand the performance of our Group because it segregates the results of operations of our current business activities, as opposed to reflecting the impact of past transactions such as acquisitions.

Our management uses business net income to manage and to evaluate our performance, and we believe it is appropriate to disclose this non-GAAP financial measure, as a supplement to our IFRS reporting, in order to assist investors in analyzing the factors and trends affecting our

business performance. Our management also intends to use business net income as the basis for proposing the dividend policy for the Group. Accordingly, management believes that an investor s understanding of trends in our dividend policy is enhanced by disclosing business net income.

We have also decided to report Business Earnings per Share . Business earnings per share is a specific non-GAAP financial measure, which we define as business net income divided by the weighted average number of shares outstanding. Our management intends to give earnings guidance based on business earnings per share. We also present business earnings per share on a diluted basis.

Business net income is defined as Net income attributable to equity holders of the Company , 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); (iv) restructuring costs;

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gains and losses on disposals of non-current assets; 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 minority interests on (i) through (vi). Items listed in (iv) correspond to those reported in the line items Restructuring costs and Gains and losses on disposals, and litigation , which are defined in Note B.20. to our consolidated financial statements.

The following table reconciles our business net income to our Net income attributable to equity holders of the Company for the years ended December 31, 2009, 2008 and 2007:

(million)		**2009**	**2008**	**2007**
Business net income		**8,629**	**7,314**	**7,060**
(i)	amortization of intangible assets	(3,528)	(3,483)	(3,654)
(ii)	impairment of intangible assets	(372)	(1,554)	(58)
(iii)	expenses arising on the workdown of acquired inventories [1]	(27)	(2)	
(iv)	restructuring costs	(1,080)	(585)	(137)
(iii)/(iv)	other items [2]		114	(61)
(v)	tax effect on the items listed above	1,629	1,904	1,939
(iii)/(vi)	other tax items [3]	106	221	337
(vii)	share of minority interests on the items listed above	1		
(iii)	expenses arising from the impact of the Merial acquisition [4]	(66)	(50)	(30)
(iii)	expenses arising from the impact of acquisitions on associates [5]	(27)	(28)	(133)
Net income attributable to equity holders of the Company		**5,265**	**3,851**	**5,263**

(1) Expenses arising from the impacts of acquisitions on inventories: workdown of inventories remeasured at fair value at the acquisition date.

(2) Other items comprise:

- harmonization of welfare and healthcare plans for retirees		(61)
- gain on sale of investment in Millennium	38	
- reversal of provisions for major litigation	76	

(3) Other tax items comprise:

- net charge to/(reversal of) provisions for tax exposures	221	337
- reversal of deferred taxes following ratification of the Franco-American Treaty (see Note D.30. to our consolidated financial statements)	106	

(4) 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 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.

(5) Expenses arising from the impacts of acquisitions on associates: workdown of acquired inventories, amortization and impairment of intangible assets, and impairment of goodwill.

The most significant reconciliation items in the table above relate to the purchase accounting effect of our acquisitions, particularly the amortization and impairment of intangible assets such as acquired research and development. 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 the goodwill; and
- charges related to the amortization and impairment of intangible assets, net of tax and minority interests.

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

- the elimination of charges related to the purchase accounting effect of our acquisitions (particularly amortization and impairment of definite-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 integration and restructuring costs relating to our acquisitions and to the implementation of our transformation strategy enhances comparability because these costs are directly, and only, incurred in connection with the relevant acquisitions or 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 the Company 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 the Company 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, will be amortized over their useful lives, which represents 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.

Integration and restructuring costs. Business net income does not reflect integration and restructuring costs even though it does reflect any synergies that arise from the acquired assets, as well as the benefits of the optimization of our research and development activities, much of which we could not achieve in the absence of restructuring costs.

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

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

In determining the level of future dividend payments, and in analyzing dividend policy on the basis of business net income, our management intends to take into account the fact that many of the adjustments reflected in business net income have no effect on the underlying amount of cash available to pay dividends. However,

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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 integration and restructuring costs represent significant cash charges in the periods immediately 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 2009, 2008 and 2007. We break down our net sales among various categories, such as 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. In 2009, we changed our method of isolating these factors, so that the measures we use for purposes of comparing our net sales in 2009 and 2008 are not the same as the measures we use for purposes of comparing our net sales in 2008 and 2007. For the years ended December 31, 2009 and December 31, 2008, we adjust net sales for changes in exchange rates by applying the exchange rates used for the year ended December 31, 2008 to net sales for the year ended December 31, 2009. As more fully explained below, in our comparison of the years ended December 31, 2008 and December 31, 2007, we adjust net sales by applying exchange rates used for the year ended December 31, 2008 to the net sales for the year ended December 31, 2007. As a result, we use 2008 exchange rates for 2009 and for 2007. Using prior period exchange rates rather than current period exchange rates could modify the result of the calculations of our net sales at constant exchange rates, impacting the sales growth information presented below. This impact could be either positive or negative depending on the currency mix of our net sales for each year.

Years ended December 31, 2009 and 2008

For the years ended December 31, 2009 and December 31, 2008, 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 year ended December 31, 2009 using the exchange rates that were used for the year ended December 31, 2008. 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 (i.e., in this case 2008) 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 (i.e., 2008) 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;

similarly, by excluding sales for a portion of the previous period (i.e., 2008) 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 (i.e., 2008) 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, 2009 Compared with Year Ended December 31, 2008 Net Sales below.

Years ended December 31, 2008 and 2007

For the years ended December 31, 2008 and December 31, 2007, we present and discuss net sales on a comparable basis, a non-GAAP financial measure. When we refer to the change in our net sales on a comparable basis, we mean that we exclude the impact of exchange rate fluctuations and changes in our Group structure (due to acquisitions and divestitures of entities and rights to products, and changes in the consolidation

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percentage or method for consolidated entities). In contrast to our comparison of 2009 and 2008, where we isolate the impact of changes in exchange rates and changes in structure separately, we generally isolate the two impacts jointly in our discussion of comparable sales in 2008 and 2007.

With respect to the discussion of net sales for the year ended December 31, 2008 and December 31, 2007, we exclude the impact of exchange rates by recalculating net sales for the year ended December 31, 2007 on the basis of exchange rates used for the year ended December 31, 2008.

We exclude the impact of acquisitions, consolidations, divestitures and changes in consolidation method in the same manner as described above for 2009 and 2008.

A reconciliation of our reported net sales to our comparable net sales is provided at Results of Operations Year Ended December 31, 2008 Compared with Year Ended December 31, 2007 Net Sales below.

Financial Presentation of Alliances

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

The financial impact of the alliances on the Company s income statement is described in Results of Operations , in particular in Net sales , Other Revenues , Share of Profit/Loss of Associates and Net Income Attributable to Minority Interests .

Alliance Arrangements with Bristol-Myers Squibb (BMS)

Our revenues, expenses and operating income are affected significantly by the presentation of our alliance with BMS in our consolidated financial statements.

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 arrangement 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® and Plavix® sold in alliance countries regardless of the marketing system. The discovery royalty 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® and Plavix®.

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.

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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® has been marketed jointly by Shionogi Pharmaceuticals and Dainippon Sumitomo Pharma Co. Ltd since June 2008. Our alliance with BMS does not cover distribution rights to Plavix® in Japan, which is marketed by sanofi-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® and Plavix® and for certain Asian countries for Plavix®. 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 minority interests ;

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

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

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 and Canada, 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 . 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® and Aprovel® and in Colombia for Plavix®;

- 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 the United States, Canada and France. This co-promotion scheme also included the Netherlands until March 31, 2008. 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 . 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 ;

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

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

sanofi-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 .

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 British pound, 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 2009, we earned 32.2% 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 exchange rate risks as well as our hedging policy, see Item 11. Quantitative and Qualitative Disclosures about Market Risk , and Item 3.D. Risk factors Fluctuations in currency exchange rates could adversely affect our results of operations and financial conditions .

Divestments

There were no material divestments during 2009, 2008 or 2007.

Acquisitions

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 sales of $2.6 billion in 2009. 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 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. On completion of the valuation of Intervet/Schering-Plough and after taking account of certain adjustments customary in this type of transaction, a balancing payment would be made to establish 50/50 parity between Merck and sanofi-aventis in the combined entity.

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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 approval by the relevant competition authorities and other closing conditions (for more information see Item 8 B. Significant Changes Merial). Detailed information about the impact of Merial on the consolidated financial statements of sanofi-aventis is provided in Note D.8. Assets held for sale or exchange to our consolidated financial statements included at Item 18 of this annual report.

On March 11, 2009, sanofi-aventis successfully concluded its offer for Zentiva N.V. (Zentiva). As of December 31, 2009, sanofi-aventis held approximately 99.1% of Zentiva s share capital. The purchase price was 1,200 million, including acquisition costs. The Zentiva Group reported net sales of 735 million in 2008 and has generated net sales of 457 million since the acquisition date. See Note D.1. to our consolidated financial statements included at Item 18 of this annual report.

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 100% of the shares of Medley, Brazil s third largest pharmaceutical company and a leading generics company, with net sales of approximately 160 million in 2008 (more than two thirds of which were in generics) and 163 million in 2009 since the acquisition date. The purchase price, based on a 500 million enterprise value, was 348 million inclusive of acquisition-related costs.

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 pivotal Phase III trial for BSI-201, BiPar s lead product candidate in metastatic triple negative breast cancer, started in July 2009. The purchase price is contingent on the achievement (regarded as probable) of milestones related to the development of BSI-201, and could reach $500 million. See Notes D.1. and D.21. to our consolidated financial statements included at Item 18 of this annual report.

On August 31, 2009, sanofi-aventis took control of Shantha Biotechnics (Shantha), a biotechnology company based in Hyderabad (India), which develops, manufactures and markets several important vaccines to international standards. Shantha generated net sales of approximately 50 million in 2009. The purchase price amounted to 571 million. As of December 31, 2009, sanofi-aventis held approximately 95% of Shantha. See Note D.1. to our consolidated financial statements included at Item 18 of this annual report.

On October 30, 2009, sanofi-aventis took 100% control of Fovea Pharmaceuticals SA. (Fovea), a privately-owned French biopharmaceutical company specializing in ophthalmology. Created in 2005 in Paris, Fovea has a portfolio of three clinical compounds, a unique technology platform and several discovery programs dedicated to back of the eye diseases. Under the terms of the agreement, sanofi-aventis has agreed to purchase Fovea for a total enterprise value of up to 370 million, including an immediate upfront payment of 90 million and subsequent milestone payments related to the three clinical compounds.

On November 30, 2009, sanofi-aventis completed the acquisition 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 25, 2008, sanofi-aventis completed the acquisition of Acambis plc for £285 million. Acambis plc 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 plc were already developing vaccines in a successful partnership of more than a decade: Acambis plc was conducting three of its major projects under exclusive collaboration agreements with sanofi pasteur, for vaccines against dengue, Japanese Encephalitis and West Nile virus. See Note D.1. to our consolidated financial statements included at Item 18 of this annual report.

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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. In 2007, Symbion Consumer sales amounted to approximately AUD190 million. See Note D.1. to our consolidated financial statements included at Item 18 of this annual report.

The principal acquisitions during 2007 are described below:

In June 2007, sanofi-aventis bought preferred shares representing a financial interest of 36.7% in Carderm Capital LP for $250 million.

In November 2007, sanofi-aventis acquired 12 million newly-issued shares in the biopharmaceutical company Regeneron Pharmaceuticals for $312 million, raising its interest in Regeneron from approximately 4% to approximately 19%. These shares are classified as an available-for-sale financial asset, and are included in Financial assets non-current (see Note D.7. to our consolidated financial statements included at Item 18).

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Results of Operations

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)	2009		2008	
(million)		as % of net sales		as % of net sales
Net sales	**29,306**	**100.0%**	**27,568**	**100.0%**
Other revenues	1,443	4.9%	1,249	4.5%
Cost of sales	(7,880)	(26.9%)	(7,337)	(26.6%)
Gross profit	**22,869**	**78.0%**	**21,480**	**77.9%**
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 intangibles	(3,528)		(3,483)	
Operating income before restructuring, impairment of property, plant & equipment and intangibles, gains & losses on disposals, and litigation	**7,818**	**26.7%**	**6,457**	**23.4%**
Restructuring costs	(1,080)		(585)	
Impairment of property, plant & equipment and intangibles	(372)		(1,554)	
Gains and losses on disposals, and litigation			76	
Operating income	**6,366**	**21.7%**	**4,394**	**15.9%**
Financial expenses	(324)		(335)	
Financial income	24		103	
Income before tax and associates	**6,066**	**20.7%**	**4,162**	**15.1%**
Income tax expense	(1,364)		(682)	
Share of profit/loss of associates	814		692	
Net income excluding the held-for-exchange Merial business [(1)]	**5,516**	**18.8%**	**4,172**	**15.1%**
Net income from the held-for-exchange Merial business [(1)]	175		120	
Net income	**5,691**	**19.4%**	**4,292**	**15.6%**
- attributable to minority interests	426		441	
- attributable to equity holders of the Company	**5,265**	**18.0%**	**3,851**	**14.0%**
Average number of shares outstanding (million)	1,305.9		1,309.3	
Basic earnings per share (in euros)	4.03		2.94	

(1) 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.

(million)	2009	2008	Growth (%)
Net Sales	**29,306**	**27,568**	**+6.3%**
Impact of exchange rates	(274)		
Net Sales at constant exchange rates	**29,032**	**27,568**	**+5.3%**
Impact of changes in structure		339	
Net Sales on a constant structure basis and at constant exchange rates	**29,032**	**27,907**	**+4.0%**

Our net sales are generated by our two business segments: Pharmaceuticals and Human Vaccines (Vaccines). The following table breaks down our 2009 and 2008 net sales by business segment:

(million)	2009 Reported	2008 Reported	Change on a reported basis (%)	Change at constant exchange rates (%)	Change on a constant structure basis and at constant exchange rates (%)
Pharmaceuticals	25,823	24,707	+4.5%	+3.7%	+2.3%
Vaccines	3,483	2,861	+21.7%	+19.2%	+18.9%
Total	**29,306**	**27,568**	**+6.3%**	**+5.3%**	**+4.0%**

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) advanced by 4.6% at constant exchange rates to 13,278 million, representing 51.4% of Pharmaceuticals net sales, versus 50.5% in 2008. This growth rate was 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.

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 net sales for the Pharmaceuticals business by product:

(million)

Product	Indication	2009 Reported	2008 Reported	Change on a reported basis (%)	Change at constant exchange rates (%)	Change on a constant structure basis and at constant exchange rates (%)
Lantus®	Diabetes	3,080	2,450	+25.7%	+22.5%	+22.5%
Lovenox®	Thrombosis	3,043	2,738	+11.1%	+8.8%	+8.8%
Plavix®	Atherothrombosis	2,623	2,609*	+0.5%	+0.2%	+0.2%
Taxotere®	Breast, Non small cell lung, Prostate, Gastric, Head and neck cancers	2,177	2,033	+7.1%	+6.1%	+6.1%
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%
Apidra®	Diabetes	137	98	+39.8%	+38.8%	+38.8%
Multaq®	Atrial fibrillation	25				
Sub-total flagship products		**13,278**	**12,475**	**+6.4%**	**+4.6%**	**+4.6%**
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, Congestive heart failure, Nephropathy	429	491*	-12.6%	-9.2%	-9.2%
Amaryl®	Diabetes	416	379*	+9.8%	+4.2%	+4.2%
Depakine®	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%
Other products		6,078	6,484	-6.3%	-6.0%	-2.5%
Consumer Health Care		1,430	1,203	+18.9%	+26.8%	+8.1%
Generics		1,012	354	+185.9%	+198.0%	+8.7%
Total Pharmaceuticals		**25,823**	**24,707**	**+4.5%**	**+3.7%**	**+2.3%**

* Part of the 2008 net sales for these products has been reclassified to the lines Consumer Health Care and Generics . For net sales before reclassifications, see Year Ended December 31, 2008 Compared with Year Ended December 31, 2007 Net sales below.

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The table below breaks down sales of our main products by geographic region in 2009:

(*million)* Product	Total Reported	Europe Reported	Change at constant exchange rates (%)	United States Reported	Change at constant exchange rates (%)	Other countries Reported	Change at constant exchange rates (%)
Lantus®	3,080	767	+12.2%	1,909	+23.6%	404	+42.8%
Lovenox®	3,043	890	+13.7%	1,822	+5.3%	331	+14.8%
Plavix®	2,623	1,512	-10.4%	222	+28.5%	889	+19.3%
Taxotere®	2,177	928	+7.1%	827	+5.3%	422	+5.1%
Aprovel®/CoAprovel®	1,236	916	+2.6%	7		313	+8.6%
Eloxatine®	957	98	-52.4%	677	-37.2%	182	-1.6%
Apidra®	137	68	+40.0%	54	+27.5%	15	+87.5%
Multaq®	25			25			
Stilnox®/Ambien®/Myslee®	873	72	-3.9%	555	-4.8%	246	+9.1%
Allegra®	731	23	-20.0%	306	-15.9%	402	+13.9%
Copaxone®	467	454	+20.7%			13	-54.8%
Tritace®	429	298	-8.2%			131	-11.3%
Amaryl®	416	83	-6.4%	9	+33.3%	324	+7.2%
Depakine®	329	204	+2.8%			125	+15.7%
Xatral®	296	93	-28.9%	147	+16.0%	56	-10.8%
Actonel®	264	162	-25.0%			102	-2.7%
Nasacort®	220	36	-2.6%	158	-15.4%	26	0.0%

Flagship Products [(1)]

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.

Lovenox®, the leader in anti-thrombotics in the U.S., 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® 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® 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®/Ambien®/Myslee®** fell by 1.3% at constant exchange rates. In the United States, Ambien CR® reported growth of 0.9% at constant exchange rates, to 497 million. In Japan, net sales of Myslee®, the leading hypnotic on the market (source: IMS 2009 sales), totaled 194 million, an increase of 15.2% at constant exchange rates.

(1) Sales of Plavix® and Aprovel® are discussed below under Worldwide Presence of Plavix® and Aprovel® .

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Allegra® saw net sales fall by 2.6% at constant exchange rates in 2009 to 731 million, reflecting the arrival of Allegra® 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 U.S. 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®** 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® 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® 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®** (the first 5-in-1 pediatric combination vaccine against diphtheria, tetanus, pertussis, polio and *haemophilus influenzae* type b licensed in the United States 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®** (quadrivalent meningococcal meningitis vaccine) increased by 1.1% at constant exchange rates to 445 million.

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:

(*million)*	2009 Reported	2008 Reported	Change on a reported basis (%)	Change at constant exchange rates (%)
Influenza Vaccines* (*including Vaxigrip® and Fluzone®*))	1,062	736	+44.3%	+46.7%**
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 Endemic Vaccines	313	309	+1.3%	0.0%
Other Vaccines	196	177	+10.7%	+6.8%
Total Vaccines	**3,483**	**2,861**	**+21.7%**	**+19.2%**

* Seasonal and pandemic influenza vaccines.
** Change of -0.2% excluding pandemic flu (A(H1N1) and H5N1)

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

(million)	Total Reported	Europe Reported	Change at constant exchange rates (%)	United States Reported	Change at constant exchange rates (%)	Other countries Reported	Change at constant exchange rates (%)
Influenza Vaccines* (*including Vaxigrip® and Fluzone®*)	1,062	167	+80.9%	618	+36.2%	277	+55.7%
Polio/Pertussis/Hib Vaccines (*including Pentacel® and Pentaxim®*)	968	135	-12.5%	529	+56.8%	304	+5.2%
Meningitis/Pneumonia Vaccines (*including Menactra®*)	538	17	+63.6%	437	0.0%	84	+36.1%
Adult Booster Vaccines (*including Adacel®*)	406	62	+14.8%	310	-8.5%	34	+25.0%
Travel and Other Endemic Vaccines	313	27	-9.7%	69	-15.8%	217	+7.4%
Other Vaccines	196	40	-11.1%	135	+13.2%	21	+11.1%

* 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. Full-year net sales of Gardasil®, 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 three regions: Europe, the United States 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 (%)	Change on a constant structure basis and at constant exchange rates (%)
Europe	12,059	12,096	-0.3%	+3.2%	+0.3%
United States	9,426	8,609	+9.5%	+2.8%	+5.4%
Other countries	7,821	6,863	+14.0%	+12.1%	+9.1%
Total	**29,306**	**27,568**	**+6.3%**	**+5.3%**	**+4.0%**

In 2009, net sales in Europe grew by 0.3% on a constant structure basis and at constant exchange rates, reflecting the effect of the ongoing genericization of Eloxatine® and Plavix®. At constant exchange rates, growth in the region reached 3.2%, driven by Eastern Europe (34.9% growth at constant exchange rates) where Zentiva s sales have been consolidated since April 1, 2009.

In the United States, the end of commercialization of Copaxone® by sanofi-aventis effective April 1, 2008 and the genericization of Eloxatine® during the second half of 2009 slowed the pace of net sales growth to 2.8% (at constant exchange rates). Lantus® and Lovenox®, 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 the Other Countries region, net sales rose by 12.1% at constant exchange rates, due largely to the performance of the Vaccines business (up 20.8% at constant exchange rates) 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

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(up 28.8% at constant exchange rates), Russia (up 59.8% at constant exchange rates) and Japan. Net sales in Japan reached 1,844 million (up 10.7% at constant exchange rates), driven by the performances of Plavix®, Myslee® and Allegra®. 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.

In emerging markets (see definition under Item 4. Information on the Company B. Business Overview), net sales were 7,356 million, an increase of 19.0% at constant exchange rates.

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. Worldwide, these products are sold by sanofi-aventis and/or BMS under the terms of this agreement which is described in Financial Presentation of Alliances Alliance arrangements with Bristol-Myers Squibb above, with the exception of Plavix® in Japan which is outside the scope of the alliance.

The worldwide sales of these two products are an important indicator of the global market presence of these sanofi-aventis products, and we believe this information facilitates a financial statement user s understanding and analysis of our consolidated income statement, particularly in terms of understanding our overall profitability in relation to consolidated revenues, and also facilitates 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 investor to have a clearer understanding of trends in different line items of our income statement, in particular the line items Other revenues where we book royalties received on those sales (see Other Revenues); Share of profit/loss of associates (see Share of Profit/Loss of Associates) 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 minority interests (see Net Income Attributable to Minority Interests) where we book 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 2009 and 2008, by geographic region:

(million)	2009			2008			Change (%)
	sanofi-aventis [2]	BMS [3]	Total	sanofi-aventis [2]	BMS [3]	Total	
Plavix®/Iscover® [1]							
Europe	1,443	161	1,604	1,622	211	1,833	-12.5%
United States		4,026	4,026		3,351	3,351	+20.1%
Other countries	897	255	1,152	711	248	959	+20.1%
Total	**2,340**	**4,442**	**6,782**	**2,333**	**3,810**	**6,143**	**+10.4%**

(million)	2009			2008			Change (%)
	sanofi-aventis [5]	BMS [3]	Total	sanofi-aventis [5]	BMS [3]	Total	
Aprovel®/Avapro®/Karvea® [4]							

Europe	810	172	982	816	176	992	-1.0%
United States		524	524		499	499	+5.0%
Other countries	314	192	506	291	184	475	+6.5%
Total	**1,124**	**888**	**2,012**	**1,107**	**859**	**1,966**	**+2.3%**

(1) Plavix® is marketed under the trademarks Plavix® and Iscover®.
(2) Net sales of Plavix® consolidated by sanofi-aventis, excluding sales to BMS (311 million in 2009 and 282 million in 2008).
(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® and Karvea®.
(5) Net sales of Aprovel® consolidated by sanofi-aventis, excluding sales to BMS (113 million in 2009 and 94 million in 2008).

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Trends in worldwide sales of Plavix® and Aprovel® in 2009 and 2008 by geographic region are as follows (at constant exchange rates):

(million)	2009	2008	Change at constant exchange rates (%)
Plavix®/Iscover®			
Europe	1,604	1,833	-10.3%
United States	4,026	3,351	+12.8%
Other countries	1,152	959	+14.4%
Total	**6,782**	**6,143**	**+6.2%**

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