SANOFI-AVENTIS
Form 20-F
March 04, 2009
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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, 2008

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, 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, 2008 was:

Ordinary shares: 1,315,525,463

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, 2008.

Unless the context requires otherwise, the terms sanofi-aventis, the Company, the Group, we, our or us refer to sanofi-aventis and our 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®, Actonelcombi®, Optinate® and Acrel®, trademarks of Procter & Gamble Pharmaceuticals, Copaxone®, a trademark of Teva Pharmaceutical Industries, Exubera®, a trademark of Pfizer Products Inc., Mutagrip®, a trademark of Institut Pasteur, TroVax®, a trademark of Oxford BioMedica, Gardasil® and Rotateq®, trademarks of Merck & Co., Inc., Herceptin®, a trademark of Genentech, NanoCrystal®, a trademark of Elan Pharmaceuticals, Xyzal®, a trademark of UCB;

- 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, Arixtra® and Fraxiparine®, trademarks of GlaxoSmithKline, StarLink®, Liberty Link® and Liberty® trademarks of Bayer AG, Sabril®, a trademark of Ovation Pharmaceuticals in the United States; and

- other third party trademarks such as Cipro® in the United States and Aspirin®, trademarks of Bayer AG, Ivomec® , Eprinex®, Frontline®, Heartgard®, Vaxxitek®, Circovac® and Zactran, trademarks of Merial and Hexavac®, Repevax® and Revaxis® trademarks of Sanofi Pasteur MSD.

The data relative to market shares and ranking information presented in Item 4. Information on the Company B. Business Overview Markets Marketing and distribution is based on sales data from IMS Health MIDAS (IMS), retail and hospital, for calendar year 2008, 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 sales generated by the vaccines business, equating to the scope of our pharmaceutical operations;

(ii) adjustments to data for Germany, 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; and

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

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Data relative to market shares and ranking information presented herein for our vaccines business is 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 proxy statements, 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, adjusted net income, earnings per share, adjusted earnings per share, capital expenditures, 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;

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 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, 2008, 2007 and 2006 are included in Item 18 of this annual report.

The consolidated financial statements of sanofi-aventis for the years ended December 31, 2008, 2007 and 2006 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). The opening balance sheet as of the IFRS transition date (January 1, 2004) and the comparative financial statements for the year ended December 31, 2004 have been prepared in accordance with the same principles.

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, 2008	2007	2006	2005	2004
IFRS Income statement data					
Net sales	27,568	28,052	28,373	27,311	14,871
Gross profit	21,480	21,636	21,902	20,947	11,294
Operating income	4,394	5,911	4,828	2,888	2,426
Net income attributable to equity holders of the Company	3,851	5,263	4,006	2,258	1,986
Earnings per share: basic ( ) [a]	2.94	3.91	2.97	1.69	2.18
Earnings per share: diluted ( ) [b]	2.94	3.89	2.95	1.68	2.17
IFRS Balance sheet data					
Intangible assets and goodwill	43,423	46,381	52,210	60,463	61,567
Total assets	71,987	71,914	77,763	86,945	85,557
Outstanding share capital	2,611	2,657	2,701	2,686	2,668
Equity attributable to equity holders of the Company	44,866	44,542	45,600	46,128	40,810
Long term debt	4,173	3,734	4,499	4,750	8,654
Cash dividend paid per share ( ) [c]	2.20[d]	2.07	1.75	1.52	1.20
Cash dividend paid per share ($) [c] [e]	3.06[d]	3.02	2.31	1.80	1.62

[a] Based on the weighted average number of shares outstanding in each period used to compute basic earnings per share, equal to 1,309.3 million shares in 2008, 1,346.9 million shares in 2007, 1,346.8 million shares in 2006, 1,336.5 million shares in 2005, and 910.3 million shares in 2004.

[b] Based on the weighted average number of shares outstanding in each period used to compute diluted earnings per share, equal to 1,310.9 million shares in 2008, 1,353.9 million shares in 2007, 1,358.8 million shares in 2006, 1,346.5 million shares in 2005, and 914.8 million shares in 2004.

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

[d] Dividends for 2008 will be proposed for approval at the annual general meeting scheduled for April 17, 2009.

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

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EXCHANGE RATE INFORMATION

Exchange rate information

The following table sets forth, for the periods and dates indicated, certain information concerning the exchange rates for the euro from 2004 through February 2009 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.

	Period-end Rate	Average Rate [1]	High	Low
	(U.S. dollar per euro)			
2004	1.35	1.25	1.36	1.18
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
Last 6 months				
2008				
September	1.41	1.43	1.47	1.39
October	1.27	1.33	1.41	1.24
November	1.27	1.27	1.3	1.25
December	1.39	1.35	1.44	1.26
2009				
January	1.28	1.32	1.39	1.28
February	1.27	1.28	1.31	1.25

[1] The average of the Noon Buying Rates on the last business day of each month during the relevant period for year average, on each business day of the month for monthly average.

B. Capitalization and Indebtedness

N/A

C. Reasons for Offer and Use of Proceeds

N/A

D. Risk Factors

Important factors that could cause actual financial, business, research or operating results to differ materially from expectations are disclosed in this annual report, including without limitation the following risk factors 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.

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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 some 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. Our products could also be affected if a competitor s innovative drug 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 assets.

Through patent and other proprietary rights, we hold exclusivity rights for a number of our research-based products, and are involved in litigation worldwide to enforce these rights against generics and proposed generics. (See Item 8. Financial Information A. Consolidated Financial Statements and Other Financial Information Information on Legal or Arbitration Proceedings and Note D.22.b) to our consolidated financial statements included in this annual report at Item 18 for additional information.) However, these rights are limited in time and do not always provide effective protection for our products: competitors may successfully avoid our 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 and 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 or *a fortiori* the corresponding foreign 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, local variations in the patents and differences in national patent law and 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 could become subject to generic competition in the future. A few particularly significant products that may face the risk of generic competition in a major market as early as 2009 are described below:

Lovenox® may face generic competition in the United States following a decision by a U.S. court (upheld on appeal in May 2008) to the effect that our patent is unenforceable. While we have petitioned the U.S. Supreme Court to hear this case, there can be no assurance that it will do so or that the U.S. Supreme Court s ruling would change the outcome of this case. While 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, there currently is no stay in effect against FDA approval.

Plavix® (*clopidogrel bisulfate*) faces competition in Germany following a May 2008 decision by the German health authorities to approve a clopidogrel salt (*clopidogrel besylate*) different from the specific clopidogrel salt expressly claimed by our European patent. In addition, our data exclusivity protection in the European Union expired in July 2008, and we believe that competitors have filed marketing requests throughout Europe, which may lead to generic competition in a number of markets.

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 only filed patent infringement suits to oppose certain of these.

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Eloxatine® may face generic competition in the United States following the expiration of data protection in February 2008 and the submission of more than a dozen ANDAs relating to this product. While all ANDA filers are currently subject to regulatory 30-month stays against FDA approval as a result of our pending patent litigation, if the court were to render an unfavorable decision (including on summary judgment) in 2009, the regulatory stay would be lifted (the stay is currently expected to expire in August 2010).

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

Product liability is a significant business risk for us, particularly in the United States where product liability claims can be particularly costly. 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 drug 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. 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 Item 8. Financial Information A. Consolidated Financial Statements and Other Financial Information Information on Legal or Arbitration Proceedings), and there can be no assurance that the Group 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, 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, given the long time span required to evaluate risks that have actually materialized, 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 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, class action lawsuits and whistle blower litigation. See Item 8. Financial Information A. Consolidated Financial Statements and other Financial Information Information on Legal or Arbitration Proceedings and Note D.22.c) to our consolidated financial statements included at Item 18 of this annual report.

Because many of these cases allege substantial unquantified damages, may be subject to treble damages and frequently seek significant punitive damages and penalties, it is possible that any final determination of liability or settlement of these claims or investigations could have a material

adverse effect on our business, results of operations or financial condition.

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

The Group faces significant litigation and government investigations including litigation concerning product pricing, allegations of securities law violations, employment matters, patent and intellectual property disputes,

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and consumer law claims. In a similar vein, in the United States, committees of the Senate and House of Representatives are conducting a series of hearings concerning the FDA and the conditions under which a number of products, including Ketek®, were approved.

Unfavorable outcomes in pending litigation matters or in future litigation 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 Notes D.22.c) and D.22.d) to our consolidated financial statements included at Item 18 of this annual report.

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.

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. In 2008, we spent 4,575 million on research and development, amounting to approximately 16.6% of our net sales. See Item 4. Information on the Company B. Business Overview Pharmaceutical Research & Development and Vaccines Research and Development . There can be no assurance that any of these compounds will be proven safe or effective.

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, and during each stage there is a substantial risk that we will not achieve our goals and will have to abandon a product in which we have invested substantial amounts including in late stage development (Phase III). 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. In addition, obtaining regulatory marketing approval is not a guarantee that the product will achieve commercial success.

The patent protection that we are able to obtain for our products may also prove unsatisfactory (whether in terms of scope of coverage or expiration dates). 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.

As a complement to its portfolio of products in development, sanofi-aventis pursues a strategy of acquisitions, in-licensing and partnerships. The implementation of this strategy depends on our ability to identify business development opportunities at a reasonable cost and under acceptable conditions of financing. 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.

The regulatory environment is increasingly challenging for the pharmaceutical industry.

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

Health authorities and notably the U.S. FDA have imposed increasingly burdensome requirements on pharmaceutical companies in terms of the volume of data needed to demonstrate a product s efficacy and safety.

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These requirements have reduced the number of products that get approved. Marketed products are also subject to continual review even after regulatory approval. Later discovery of previously undetected problems may result in marketing restrictions or the suspension or withdrawal of the product, as well as an increased risk of litigation.

At the same time, as it is becoming increasingly difficult to bring innovative products to market for these reasons, government authorities are increasingly looking to facilitate generic competition to existing products through proposals to change existing patent and data exclusivity rules in major markets and, in the United States, add accelerated generic approval procedures for large-molecule biologicals.

To the extent new regulations raise the costs of obtaining and maintaining product approval, or limit the economic value of a new product to its inventor, the growth prospects of our industry and of our Company are diminished.

The European Commission s pharmaceutical sector inquiry may lead to significant legislative changes or other actions that adversely affect our business or results of operations.

On November 28, 2008, the European Commission s Directorate General for Competition published a preliminary report relating to competition in the European pharmaceutical sector following an inquiry that began in January 2008. In its report, the staff found that the number of novel medicines reaching the market has declined in recent years, and alleged that certain practices in the pharmaceutical sector tend to delay the market entry of less expensive generic medicines. As a result of this inquiry, in addition to possible actions against individual companies, the European Commission may decide to propose a number of significant revisions to the pharmaceutical industry s regulatory environment in Europe, which may effectively further limit the market exclusivity enjoyed by innovative products and thereby negatively affect our business and future results.

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. Changes in the pricing

environments in the United States market in particular could have a significant impact on our sales and results of operations. Risks in the United States include future revisions to health care reimbursement policies, possible cost control regulations, and possible unfavorable developments in coverage of prescription drugs by Medicare. See Item 4. Information on the Company B. Business Overview Markets Pricing & Reimbursement for a description of certain regulatory pricing systems that affect our Group.

Our results may also be adversely affected by parallel imports, a practice by which traders exploit price differentials among markets by purchasing in lower-priced markets for resale in higher-priced markets, especially in the European Union.

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 long lasting slowdown of the global economy or major national economies such as the United States 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

(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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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 failure of major players including wholesalers, 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 Procter & Gamble Pharmaceuticals 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 Markets Alliances. When we market our products through collaboration arrangements, we are subject to the risk that certain decisions, such as the establishment of budgets and promotion strategies, are subject to the control of our collaboration partners, and that deadlocks may adversely affect the activities conducted through the collaboration arrangements. For example, our alliances with BMS are subject to the operational management of BMS in some countries, including the United States. We cannot be certain that our partners will perform their obligations as expected. Further, our partners might pursue their own existing or alternative technologies or product candidates in preference to those being developed or marketed in collaboration with us.

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 for the 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 company 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.

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 our 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 at the most scrupulously selected suppliers. For example, in 2008 we recalled a limited number of batches of Lovenox® and depreciated 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

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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®. 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 products could harm our business.

The prescription drug supply has been increasingly challenged by 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, counterfeits 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, entailing substantial reputational and financial harm to the manufacturer of the authentic product.

Use of biologically derived ingredients may face patient resistance, 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. Most of these products cannot be made economically, if at all, with synthetic ingredients. 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.

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. While we seek to manage our exposure to client credit through such measures as the establishment of client credit profiles and credit limits, obtaining guarantees and insurance, and credit risk surveillance via tracking of payment times and late payments, it is not possible to eliminate this risk which 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 87% of our consolidated U.S. pharmaceutical sales were accounted for by just three wholesalers. 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.

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, actuarial

(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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data and experience, inflation trends, the level of benefits provided for by the plans, as well as changes in laws and regulations. Adverse changes of 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.

Environmental Risks of Our Industrial Activities

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

Pharmaceutical 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. For more detailed information on environmental issues, see Item 4. Information on the Company B. Business Overview Health, Safety and Environment (HSE).

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

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

- that we currently own or operate;
- that we formerly owned or operated; or
- where waste from our operations was disposed.

These environmental remediation obligations could significantly reduce our operating results. In particular, our accruals for these obligations may be insufficient if the assumptions underlying these accruals prove incorrect or if we are held responsible for additional, currently undiscovered contamination. Sanofi-aventis accrues reserves for remediation when our management believes the need is probable and that it is reasonably possible to estimate the cost. These judgments and estimates may later prove inaccurate, and any shortfalls could have a material adverse effect on our results of operations. See Item 4. Information on the Company B. Business Overview Health, Safety and Environment (HSE) for additional information regarding our environmental policies.

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 our predecessor companies, or our

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subsidiaries that we demerged, divested or may divest. We have disputes outstanding, for example, with Rhodia over environmental remediation at several 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.

Finally, 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 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.

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 2008, approximately 31% of our net sales were realized in the United States. While we incur expenses in those currencies, the impact of currency exchange rates on these expenses does not fully offset the impact of currency exchange rates on our revenues. As a result, currency exchange rate movements can have a considerable impact on our earnings. When deemed appropriate and when technically feasible, we enter into transactions to hedge our exposure to foreign exchange risks. These efforts, when undertaken, may fail to offset the effect of adverse currency exchange rate fluctuations on our results of operations or financial condition. 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, 2008, the Group s net debt amounted to 1.8 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 context of a market-wide liquidity crisis, the Group may be faced with reduced access to sources of financing, including under programs currently in place, or less favorable conditions. Were our sources of financing to be substantially reduced, we cannot guarantee that the Group would be in a position to refinance existing debt or incur new debt on terms that we would consider to be commercially reasonable if at all.

Risks Relating to an Investment in our Shares or ADSs

Foreign exchange fluctuations may adversely affect the U.S. dollar value of our ADSs and dividends (if any).

Holders of ADSs face exchange rate risk. Our ADSs trade in U.S. dollars and our shares trade in euros. The value of the ADSs and our shares could fluctuate as the exchange rates between these currencies fluctuate. If and when we do pay dividends, they would be denominated in euros.

Fluctuations in the exchange rate between the euro and the U.S. dollar will affect the U.S. dollar amounts received by owners of ADSs upon conversion by the depositary of cash dividends, if any. Moreover, these fluctuations may affect the U.S. dollar price of the ADSs on the New York Stock Exchange (NYSE), whether or not we pay dividends in addition to the amounts, if any, that a holder would receive upon our liquidation or upon the sale of assets, merger, tender offer or similar transactions denominated in euros or any foreign currency other than U.S. dollars.

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

At December 31, 2008, Total and L Oréal, our two largest shareholders, held approximately 11.29% and 8.99% of our issued share capital, respectively, accounting for approximately 18.27% and approximately 14.89%, 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 part of their respective holdings. Sales of a substantial number 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 2008, our net sales amounted to 27,568 million. Based on 2008 sales, we are the fourth largest pharmaceutical group in the world and the largest pharmaceutical group in Europe (source: IMS sales year end 2008; all available channels). 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: (i) pharmaceuticals and (ii) human vaccines through sanofi pasteur.

In our pharmaceutical activity, which generated net sales of 24,707 million in 2008, we specialize in six therapeutic areas:

Thrombosis: 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;

Cardiovascular: Our cardiovascular medicines include two major hypertension treatments: Aprovel® and Tritace®;

Metabolic Disorders: Our leading medicines in this area are related to diabetes. They include Lantus®, a long acting analog insulin which is a leading brand in the insulin market, and Amaryl®, an oral once-daily sulfonylurea;

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

Central Nervous System (CNS): Our major CNS medicines include Stilnox®/Ambien® CR, the world s leading insomnia 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 antihistamine, 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, including prescription drugs and products sold over the counter (OTC), making up our base business .

We are the world leader in the vaccines industry. Our net sales amounted to 2,861 million in 2008, 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, the latter in both hemispheres. Additionally, we manufacture pre-pandemic avian influenza vaccines (including H5N1 vaccines) as part of the global pandemic preparedness 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 United States in 2005), Decavac®, Repevax® and Revaxis®;

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

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 antivenoms. Key products include Imovax® Rabies, Verorab®, Typhim Vi®, Avaxim® and Vivaxim®.

In 2008, our vaccines activity was favorably influenced by the launch of Pentacel® and the growth of Menactra® and Adacel® in the United States and by the sales growth of Pentaxim® in the international region. Sanofi Pasteur also strengthened its leadership position in both seasonal and pre-pandemic influenza.

We have a strong commitment to research and development with 29 research centers.

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);

For our pharmaceutical activity, except where otherwise stated, all market share percentages and rankings are based on full-year 2008 sales figures from IMS Health MIDAS;

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 from our leading products sold directly and through alliances. As regards the products sold through our alliance with BMS, we also present the worldwide sales of Plavix® and Aprovel® whether consolidated by sanofi-aventis or by BMS. A definition of worldwide sales can be found in Item 5. Operating and Financial Review and Prospects Results of Operations .

A. History and Development of the Company

Sanofi-aventis was incorporated under the laws of France in 1994 as a *société anonyme*, a form of limited liability company, for a term of 99 years. We operate under the commercial name sanofi-aventis . Our registered office is located at 174, avenue de France, 75013 Paris, France, and

our main telephone number is +33 1 53 77 40 00. Our principal U.S. subsidiary s office is located at 55 Corporate Drive, Bridgewater, NJ 08807 ; Telephone: +1 (908) 981-5000.

We are present in more than 100 countries on five continents with more than 98,000 employees worldwide at year end 2008. 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 United States 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.

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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.

B. Business Overview

Strategy

As a leading player in the pharmaceutical industry (number 1 in Europe and number 4 in the world based on 2008 IMS sales) sanofi-aventis has core strengths in the field of healthcare: a global presence, market leadership in vaccines, major biological products (such as Lovenox® and Lantus®) and a strong and long-established presence in emerging markets, as well as a track record of adapting cost structures and a solid financial situation. However, although these are solid foundations, we, like most of our competitors, are faced with the foreseen competition from generics for some of our major products. Our environment is also subject to cost containment pressures from healthcare authorities, and increased regulatory barriers. Given the significant challenges facing the pharmaceutical industry, we need to develop new platforms for growth. Our response to these challenges is an ambitious one: to deliver sustainable growth, we need to transform ourselves into a diversified global healthcare leader.

This is why we initiated a wide-ranging transformation program at the end of 2008, focusing on three key themes:

Increasing innovation in Research & Development

At the end of 2008, we began a complete and objective review of our research portfolio, in order to reassess the allocation of resources. This review has already led to a rationalization of our portfolio and will be ongoing in the first half of 2009. In the future, we must focus our Research & Development (R&D) strategy on key technologies and diseases to better serve the needs of patients. Our internal R&D division needs to be organized to maximize flexibility and innovation, and some of our existing resources in R&D need to be reallocated to external collaborations. Finally, we will redefine the decision-making process in R&D so that new commercial potential and the scope for value creation are better integrated into our development choices. As part of this transformation and in response to the new industry environment, we have created two new positions: a Chief Medical Officer, who will closely monitor the benefit/risk balance in both marketed products and those in development; and a Scientific Advisor, who will contribute to R&D decision-making processes relating to both our pipeline and our strategy, and in particular the creation of alliances.

Adapting our structures to meet the challenges of the future

We intend to adapt our operating model, currently too focused on our traditional major markets, to reflect the diversity of our activities and our geographical reach. This means tailoring our strategy, structure and offering to each region s needs, so as to deliver the most appropriate solution to each patient. It also means combining our various activities, so as to address our customers needs more thoroughly and take best advantage of all local growth opportunities. Anticipating future changes in volumes and analyzing growth opportunities will enable us to realign our industrial capacity. Simplifying our organizational structures and operational processes will translate into a reduction of our general and administrative costs.

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Exploring external growth opportunities

Business development must be perfectly integrated in our overall strategy, and translate into disciplined acquisitions and alliances that build or strengthen the platforms for long-term growth that will create value for our shareholders. We have already taken the first steps in this direction through our alliance with Regeneron Pharmaceuticals, Inc (Regeneron), our acquisitions of Acambis Plc (Acambis), Symbion CP Holdings Pty Ltd (Symbion Consumer), and Zentiva N.V. (Zentiva). We are encouraging business development initiatives within operations in order to reinforce our regional approach. Our external research collaborations will be broadened to bring maximum creativity to R&D and hence deliver innovation to patients. The position of Chief Strategic Officer has been created at Executive Committee level to achieve this integrated approach to strategy and business development.

This transformation program has already led to the rollout of a number of initiatives, the conclusions of which will be implemented from mid-2009.

Pharmaceutical Products

Main Pharmaceutical Products

Within our pharmaceuticals business, we focus on six main therapeutic areas: thrombosis, cardiovascular, metabolic disorders, oncology, central nervous system and internal medicine.

The following table sets forth the net sales of our best selling pharmaceutical products for the year ended December 31, 2008. These products are major contributors to public health. 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 our products is material to our operations and is described at Patents, Intellectual Property and Other Rights Product Overview, 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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Therapeutic Area / Product Name	2008 Net Sales (million)	Drug Category / Main Areas of Use
Thrombosis		
Lovenox® (enoxaparin sodium)	2,738	Low molecular weight heparin Deep vein thrombosis
		Unstable angina / non-Q-Wave myocardial infarction
Plavix® (clopidogrel bisulfate)	2,616	Platelet adenosine disphosphate receptor antagonist Atherothrombosis
		Acute coronary syndrome with and without ST segment elevation
Cardiovascular		
Aprovel® (irbesartan)/CoAprovel®	1,202	Angiotensin II receptor antagonist Hypertension
Tritace® (ramipril)	513	Angiotensin Converting Enzyme Inhibitor Hypertension
		Congestive heart failure
		Nephropathy
Metabolic disorders		
Lantus® (insulin glargine)	2,450	Long-acting analog insulin Type 1 and 2 diabetes mellitus
Amaryl® (glimepiride)	387	Sulfonylurea Type 2 diabetes mellitus
Oncology		
Taxotere® (docetaxel)	2,033	Cytotoxic agent Breast cancer
		Non small cell lung cancer
		Prostate cancer
		Gastric cancer
		Head and Neck cancer
Eloxatine® (oxaliplatin)	1,348	Cytotoxic agent Colorectal cancer
Central Nervous System		
Stilnox®/Ambien®/Myslee® (zolpidem tartrate)	829	Hypnotic Sleep disorders
includes Ambien® CR	*475*	
Copaxone® (glatiramer acetate)	622	Non-interferon immunomodulating agent Multiple sclerosis
Depakine® (sodium valproate)	329	Anti-epileptic Epilepsy
Internal Medicine		
Respiratory/Allergy		
Allegra® (fexofenadine hydrochloride)	688	Antihistamine Allergic rhinitis
		Urticaria

Nasacort® (triamcinolone acetonide)	241	Local corticosteroid Allergic rhinitis
Urology		
Xatral® (alfuzosin hydrochloride)	331	Uroselective alpha1-blocker Benign prostatic hypertrophy
Osteoporosis		
Actonel® (risedronate sodium)	330	Biphosphonate Osteoporosis

Thrombosis

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®

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

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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 (DVT) and in acute coronary syndromes (ACS). It has become the product of reference in clinical trials for the development of new anticoagulants 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 medical patients.

The initial findings of the EXCLAIM trial had demonstrated the benefit of extended thromboprophylaxis in acutely ill medical patients with reduced mobility. Further analyses presented at the American Society of Hematology Congress in December 2008 have demonstrated that some patient populations, such as the elderly (aged 75 and above) or stroke patients, may potentially benefit more than the overall population from extended treatment.

Lovenox®/Clexane® was approved for marketing in Japan 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 January 2008 and in patients undergoing abdominal surgery in February 2009.

In the cardiovascular area, Lovenox® was approved in the United States in 2007 for the treatment of patients with ST-segment Elevation Myocardial Infarction (STEMI) based on the results of the ExTRACT-TIMI 25 trial, and since then has been approved in more than 40 countries worldwide for this indication.

Supporting the results of the ExTRACT PCI sub-study showing that Lovenox® can be safely used before and in the catheterization laboratory data from the STACKENOX trial were presented at the European Society of Cardiology meeting in September 2008. STACKENOX showed that using standard dosing of Lovenox® is sufficient to provide proper anticoagulation levels. It also provided new evidence against the practice of administering unfractionated heparin to patients who already received enoxaparin sodium, as it results in over-anticoagulation that may lead to excess bleeding as seen in trials like OASIS 5.

In terms of medical practice registries, GRACE (the Global Registry of Acute Coronary Events) has evaluated over 100,000 patients worldwide with acute coronary syndrome as of today and has led to the publication of more than 75 manuscripts in a variety of peer review medical journals. Furthermore, the GRACE Risk Score has been incorporated into various international guidelines on the treatment of patients with ACS, providing a valuable tool to physicians treating those patients.

Lovenox®/Clexane® is the leader in antithrombotics in the United States, Germany, France, Italy, Spain, and the United Kingdom (source: IMS 2008 sales, all available channels).

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 currently the only drug indicated for the secondary prevention of atherothrombosis regardless of the location of the arteries initially affected (heart, brain, lower limbs). This indication is supported by the results of the landmark CAPRIE trial, including almost 20,000 patients. CAPRIE demonstrated the superior efficacy of Plavix® over acetylsalicylic acid (ASA, the active ingredient of Aspirin®), with a comparable safety profile.

Following the significant results of the CURE, CLARITY and COMMIT clinical trials, Plavix® is now also indicated for the treatment of acute coronary syndrome with and without ST segment elevation (ACS; Q-wave and non-Q-wave myocardial infarction and unstable angina) 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.

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In addition to the 75mg tablet, a new Plavix® 300mg tablet was launched in over 15 countries during 2008. This new 300mg tablet reinforces Plavix® early use by simplifying its approved loading dose administration in patients with acute coronary syndrome (unstable angina, myocardial infraction). The 300mg tablet is bioequivalent to four 75 mg tablets of Plavix®.

The extensive clinical program for Plavix® including all completed, ongoing and planned studies, is one of the largest of its kind and has involved more than 100,000 patients overall. In addition, over 92 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.

The ongoing clinical trials that are designed to support the long-term value of Plavix® by providing complementary clinical data include:

- The ACTIVE study, which is intended to assess the value of Plavix® on top of ASA compared with ASA alone in patients with atrial fibrillation (who cannot take an oral anticoagulant) for the reduction of cardio-embolic and atherothrombotic events. This study has completed recruitment (14,000 patients included, currently in the follow-up phase). While one arm of the study ACTIVE-W was terminated early, the other two arms, ACTIVE-A and ACTIVE-I, are ongoing. The results of both ACTIVE-A and ACTIVE-I are expected in 2009;

- The CURRENT study, which aims to optimize the dosing regimen of clopidogrel bisulfate in 25,000 patients with ACS scheduled for percutaneous coronary intervention. A loading dose of 600 mg followed by 150 mg daily for 6 days then followed by 75 mg daily up to the end of the study (30 days) is compared to the currently approved regimen (300 mg loading dose followed by 75 mg daily). The recruitment started in 2006 and results are expected in 2009; and

- Following an FDA written request for pediatric data, the development of a pediatric indication for Plavix® in the United States is ongoing. The dose ranging Phase II (PICOLO study) has helped determine the right dose to be studied in Phase III (CLARINET). CLARINET is ongoing and results are expected in 2010. A pediatric investigational plan was approved in 2008 by the European Medicines Agency.

Plavix® is marketed in over 115 countries, including the United States, through our alliance with Bristol-Myers Squibb (BMS).

Sales of Plavix® in Japan are consolidated by sanofi-aventis and are outside the scope of our alliance with BMS. In Japan, a New Drug Application (NDA) for marketing authorization was approved in January 2006 for the reduction of recurrence after ischemic cerebrovascular disorder and launch took place in May 2006. In October 2007, the Japanese Health Authorities approved a new indication in cardiology for patients with Acute Coronary Syndrome for whom percutaneous coronary intervention is being planned.

Plavix® is the leading antiplatelet in the European and the U.S. markets (source: IMS 2008 sales, all available channels). Germany has been affected by competition from clopidogrel besylates since August 2008 in the monotherapy segment. The share of the German market by volume retained by Plavix®/Iscover® in December 2008 remains approximately 75% (source: IMS Pharmatrend, week of December 22, 2008).

Cardiovascular

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®

Aprovel® (irbesartan) belongs to the fastest growing class of antihypertensives, angiotensin II receptor antagonists. These highly effective antagonists act by blocking the effect of angiotensin, the hormone responsible for blood vessel contraction, thereby enabling blood pressure to return to normal. In addition to Aprovel®/Avapro®/Karvea®, we also market CoAprovel®/Avalide®/Karvezide®, a fixed dose combination of irbesartan

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and hydrochlorothiazide (HCTZ), a diuretic that increases the excretion of water by the kidneys and provides an additive 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® may be used in appropriate patients whose blood pressure is not adequately controlled on monotherapy, and as initial therapy in appropriate 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:

The i-PRESERVE study evaluated the effect of irbesartan in the treatment of heart failure with preserved ejection fraction (also called diastolic heart failure), a very specific disease for which there is no reference treatment. The results were published in November 2008 and were consistent with previous trials conducted in this patient population. Although the study did not meet its principal end point in terms of efficacy, i-PRESERVE confirmed the good safety profile of irbesartan in an already well-treated population.

ACTIVE-I evaluates the efficacy of Aprovel® combined with clopidogrel bisulfate (the active ingredient in Plavix®), in preventing complications in patients suffering from atrial fibrillation. We began this clinical program in 2003, with enrolment for the 10,000-patient study ongoing. Results are expected by late 2009.

Aprovel® and CoAprovel® are marketed in more than 80 countries, including the United States under the brand names Avapro® and Avalide®, respectively through an alliance with Bristol-Myers Squibb (BMS).

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.

In 2008, based on the total sales of Aprovel® /Avapro®/Karvea® and CoAprovel®/Avalide®/Karvezide®, our main markets are Europe and the United States, where we rank second and fourth respectively among the angiotensin II receptor antagonists in the hypertension market (source: IMS, 2008 sales).

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, heart attack and death in these patients and has the broadest spectrum of indications among ACE inhibitors for the treatment of cardiovascular disease.

The most recent European Society of Hypertension (ESH) / European Society of Cardiology (ESC) guidelines on the management of hypertension have highlighted the importance of taking global cardiovascular risk into account 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.

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Tritace® (ramipril) is available in tablets and capsules. It is marketed in over 70 countries. We have no rights on this product in the United States. Launches in several countries in Eastern Europe, the Middle-East and Asia are scheduled in 2009.

The three leading countries for sales of Tritace® in 2008 were Italy, Poland and Canada (source: IMS, 2008 sales). Generic ramipril became available in Italy in 2008, negatively affecting our sales there.

Metabolic Disorders

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 population aging. Our principal products are Lantus®, an insulin analog, and Amaryl®, a sulfonylurea.

Lantus®

Lantus® (insulin glargine) is a long-acting basal insulin analog, 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 (T2DM), 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 (T1DM).

Lantus® can be administered subcutaneously thanks to syringes or specific pens including Lantus® SoloSTAR®. Lantus® SoloSTAR® is a pre-filled disposable pen available in over 50 countries worldwide. It is the only disposable pen that combines the following advantages; 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.

Lantus®, the number-one prescribed insulin in the world in both sales and units (source: IMS, 2008 sales), is the only once-daily, 24-hour duration of action, peakless basal insulin.

The uniqueness of the Lantus® profile was confirmed in a direct comparison to detemir, another basal insulin analog, where Lantus® was shown to have activity levels more than 4 times greater than detemir during the period from 12 to 24 hours after administration. The same study showed a marked and highly significant difference in terms of duration of action: Lantus® showed a 24-hour coverage whereas detemir had a duration of action of only 17.5 hours. Indeed, a large clinical study confirmed that, while Lantus® is effective once a day, 55% of patients need detemir twice daily. Moreover, in this study Lantus® patients used a 40% smaller dose and had 3 times fewer injection site reactions.

The Lantus® profile allows a once-daily regimen that can be taken at any time (albeit at the same time every day) with titration under safer conditions and less hypoglycemia than with the basal human insulin NPH. Patients can titrate Lantus® easily and safely toward Fasting Plasma Glucose target thanks to the Lantus® profile. The results in terms of glycemic control are particularly consistent with Lantus® given once-a-day and properly titrated: *e.g.,* the final mean A1C (HbA1c, a measure indicating good control of long-term blood sugar levels) on Lantus® ranged from 6.9% to 7.2% in seven studies where aggressive titration was performed and strict monitoring was used.

In 2008, the American Diabetes Association (ADA) and European Association for the Study of Diabetes (EASD) released the updated treatment recommendations for type 2 diabetes. Designed by a team of diabetes experts, the updated recommendations provide healthcare professionals with a consensus algorithm that further establishes 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 new treatment recommendations reinforce the timely use of basal insulin as a Core Therapy for type 2 Diabetes.

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A number of controlled and randomized studies have investigated the efficacy and safety of Lantus® plus oral antidiabetic agents (OADs) in type 2 diabetes mellitus:

- The recently published TULIP study demonstrated the advantage of prescribing Lantus® as soon as patients glycemic targets are not achieved with diet, exercise and oral medications alone, bringing them below the recommended glycemic goal of 7%;

- A recent meta-analysis of 5 studies comparing Lantus® to NPH, confirmed a lower rate of all nocturnal hypoglycemia including severe hypoglycemia with Lantus® as compared to NPH in patients with type 2 diabetes;

- The APOLLO study published in 2008 in The Lancet compared two strategies for insulin initiation in patients with type 2 diabetes after OAD failure: a prandial versus a basal insulin strategy with Lantus®. APOLLO showed that after OAD failure in type 2 patients Lantus® reduces A1C to target with fewer hypoglycemic events, fewer injections and blood glucose monitoring than with a prandial insulin strategy;

- The INITIATE study showed that Lantus® is an easy and effective method of insulin initiation in patients with type 2 diabetes on OADs. In this study, within 24 weeks, Lantus® lowered A1C by 2% to reach a mean A1C of 6.8-6.9% with a concomitant treatment satisfaction improvement;

- The SCHREIBER study, an observational study of everyday practice conducted in more than 12,000 patients, showed that Lantus®, when added to oral diabetes medications, brings the patients to a target A1C of 7.0% after an average 9-month period. This glycemic control is sustained in the long term, 32 months after Lantus® initiation. In addition, the neutral effect on weight observed at 9 months was confirmed at 32 months; and

- 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 with no excess in hypoglycaemia rate in a population of advanced type 2 diabetes patients.

Several studies presented in 2008 demonstrated the advantages of Lantus® in a real-life setting compared to other basal insulins:

- Lantus® is more effective at lowering A1C than detemir and provides cost savings (THIN Study);

- Lantus® is more effective at lowering A1C, results in a lower rate of hypoglycemia, and reduces total healthcare cost compared to NPH (ROLE Study);

- Lantus® results in better patient satisfaction than NPH (LIVE-DE Study); and

- Patients who failed to achieve glycemic goals on NPH significantly improve their A1C after they are switched to Lantus®. They also had less hypoglycemia and improved treatment satisfaction (LAUREL Spain).

Sanofi-aventis has set up a comprehensive clinical program to evaluate the acute and long-term effect of Lantus® on cardiovascular outcomes. As part of this program, the INTENSIVE trial in patients with STEMI and the ORIGIN morbidity/mortality trial in high-risk dysglycemic patients are still ongoing and results are expected in 2012.

Lantus® is available in over 70 countries worldwide.

The three leading countries for sales of Lantus® in 2008 are the United States, Germany and France (source: IMS 2008 sales).

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 glycaemic 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.

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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 American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) recommendations for type 2 diabetes were updated in 2008: they further establish the combination of metformin and second generation sulfonylureas such as Amaryl® as a one of the two preferred second-line treatment options for people with diabetes who are unable to achieve glycemic control targets with lifestyle intervention and metformin alone. The second recommanded option is to add to metformin a basal insulin, such as Lantus®.

The combination of metformin (which reduces hepatic glucose production and improves insulin resistance) with a sulfonylurea (which stimulates insulin secretion) is the rational combination for counteracting the two defects seen in type 2 diabetes. It is the most prescribed combination of diabetes drugs worldwide. Amaryl M®, a fixed-dose combination of glimepiride plus metformin in a single presentation was launched in 2007. The fixed dose treatment is more efficacious 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 2008, Amaryl M® was launched in India, Mexico and Brazil among other countries.

Our leading market for Amaryl® is Japan, where it is the leading oral antidiabetes product by volume (source: IMS 2008 sales).

Acomplia®

Acomplia® (rimonabant) is a selective CB-1 receptor blocker developed in the treatment of obese or overweight patients with associated cardiometabolic risk factors such as type 2 diabetes or dyslipidemia. It had been marketed in Europe and in certain other countries, but in 2008 was withdrawn from all selling and marketing.

In October 2008, the European Medicines Agency (EMEA) recommended the temporary suspension of the marketing authorization of Acomplia® for the approved indication of overweight and obese patients. Sanofi-aventis subsequently definitively stopped selling and marketing Acomplia® in all countries concerned. The Group has filed to withdraw marketing authorizations worldwide, and in January 2009, the European Union withdrew the marketing authorization.

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.

In breast cancer, Taxotere® in combination with carboplatin and Herceptin® (TCH) was approved by the FDA in early stage breast cancer in May 2008. This combination, which presents a better safety profile than the anthracycline-based treatment, allows the treatment of a larger number of patients with Taxotere®. The TCH treatment combination is now a standard of care in United States for patients with early stage breast cancer, HER2 positive and node positive. In Europe too, Taxotere®-based treatments excluding anthracycline are prescribed to an increasing number of patients with early stage localized breast cancer.

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Taxotere® was approved in September 2008 by the Japanese Ministry of Health, Labor and Welfare (MHLW) following a supplemental New Drug Application (sNDA) for a new indication as a treatment of metastatic hormone refractory prostate cancer. Only a limited number of drugs with health insurance coverage are used to treat mHRPC in Japan. For this reason, Japanese urologists quickly recognized Taxotere® as the standard of care in this indication. In the United States and Europe, Taxotere® is also considered as the standard treatment in this indication.

Important new results of clinical studies on Taxotere® presented in 2008, in major international oncology conferences, should lead to a more frequent use of Taxotere® for patients with breast, prostate or head and neck cancers:

- The GEICAM 9805 trial, including 1,100 patients with node negative early stage breast cancer, demonstrated a significant survival benefit in favor of the Taxotere® regimen compared to a fluorouracil-based regimen. Efficacy results were presented during the 44th annual meeting of the American Society of Clinical Oncology (ASCO). Those new data will be part of the EMEA and FDA dossier planned to be filed in the first quarter of 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.

- For patients with androgen-independent (hormone-refractory) metastatic prostate cancer, the results of the Triade retrospective study presented at ASCO demonstrated that re-treatment with Taxotere® after a first-line treatment with Taxotere® is feasible and efficient.

- The first clinical trial comparing the Taxotere®-based induction treatment with a treatment without induction for patients with locally advanced head and neck cancer was presented at the 44th ASCO meeting. An induction treatment is aimed at reducing the tumor size before a chemo-radiotherapy. The results demonstrated significant efficacy results on the primary endpoint in favor of the Taxotere®-based induction compared to chemo-radiotherapy alone. This could make the induction-based treatment the new standard of care in this indication. The results of the clinical trial have been submitted to the Journal of Clinical Oncology with an expected publication date in the first half of 2009.

The top four countries contributing to the sales of Taxotere® in 2008 were the United States, France, Germany and Japan (source: IMS, 2008 sales).

Eloxatine®

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

Eloxatine® is indicated in combination with 5-fluorouracil and folinic acid in adjuvant treatment of stage III colon cancer patients who have undergone complete resection of the primary tumor and for the treatment of advanced carcinoma of the colon or rectum (metastatic colorectal cancer).

The development of Eloxatine® has led to major progress in the treatment of metastatic colorectal cancer. Thanks to its demonstrated ability to reduce the size and number of liver metastases, Eloxatine® increases the chances of having complete surgical removal of liver metastases and has given the hope of a potential cure in a significant proportion of patients with initially unresectable liver metastases. Furthermore, in patients with resectable liver only metastases from colorectal cancer, the results of the EPOC study demonstrated that peri-operative chemotherapy with Eloxatine® given in combination with 5-fluorouracil/folinic acid leucovorin (the FOLFOX regimen) significantly reduced the risk of relapse compared to surgery alone.

Due to its consistently high and sustained efficacy in treating metastatic colorectal cancer, the FOLFOX regimen is a mainstay treatment of metastatic colorectal cancer in the United States, Europe and certain countries in the Asia-Pacific region.

Eloxatine® has been developed for adjuvant treatment of colon cancer. The 6-year survival analysis of the landmark MOSAIC study presented at the American Society of Clinical Oncology meeting in 2007 showed that FOLFOX significantly improved the overall survival in Stage III colon cancer surgically resected. In May 2008, following the publication of the final results of the study, the FDA approved the inclusion of six-year Overall

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Survival analysis and five-year Disease Free Survival data for stage III colon cancer patients treated following surgery to remove the primary tumor in the Eloxatine® Prescribing Information.

FOLFOX is now the standard treatment for stage III colon cancer patients who have undergone complete resection of the primary tumor.

Following the end of the Eloxatine® European regulatory data exclusivity in April 2006, a number of oxaliplatin generics have received marketing authorization and have now been launched throughout Europe.

Eloxatine® is in-licensed from Debiopharm and is marketed in more than 70 countries worldwide. The three leading countries in for sales of Eloxatine® in 2008 were the United States, France and Canada (source: IMS, 2008 sales).

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 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 awake 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.

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. Myslee® has been copromoted jointly with Astellas since 2006. We launched Ambien® CR in the United Sates in September 2005.

The top three markets for Stilnox® (both immediate and controlled release formulations) are the United States, Japan and Italy (based on 2008 net sales).

Generic zolpidem tartrate has been available in France since 2004. In the United States, generics of the immediate release formulation of Ambien® have been available since 2007.

Copaxone®

Copaxone® (glatiramer acetate) is an 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.

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Recent results of the PreCISe study have demonstrated that Copaxone® reduces the risk of developing confirmed multiple sclerosis in patients having Clinical Isolated Syndrome (CIS) by 45% as compared to a placebo. In February 2009 the Medicines and Healthcare products Regulatory Agency (MHRA) approved an expanded label for Copaxone® to include the treatment of patients with CIS suggestive of multiple sclerosis (MS). This approval includes 24 EU member countries that take part in the MHRA mutual recognition procedure . Applications have been submitted to national Health Authorities of other European countries, including France and Switzerland. Approval of an expanded label for Copaxone® to include the treatment of CIS patients was also provided by the Australian Health Authority (the Therapeutic Goods Administration) in December 2008.

The three leading countries for Copaxone® are the United States, Germany, and France (based on 2008 net sales).

Copaxone® is in-licensed from Teva and marketed via our agreement with that company. Teva assumed the Copaxone® business, including sales of the product in the United States and Canada, on March 31, 2008. Under the terms of our agreement, the Copaxone® business in other countries will be transferred to Teva over a period running from Q4 2009 to Q1 2012 at the latest, depending on the country. Additional details on this agreement can be found in Alliances below.

Depakine®

Depakine® (sodium valproate) is a broad-spectrum anti-epileptic that has been prescribed for more than 40 years. Numerous clinical trials, as well as 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. Valproate is recommended as a first-line treatment in these indications by international guidelines such as the guidelines of the American Psychiatric Association, the Canadian Network for Mood and Anxiety Treatments and the U.K. NICE Guidance.

We provide a wide range of formulations of Depakine® which permits its adaptation 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® are the United Kingdom, France and Italy (based on 2008 net sales).

Internal Medicine

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

Respiratory/Allergy

Allegra®/Telfast®

Allegra® (fexofenadine hydrochloride) is an effective, long-lasting (12- and 24-hour) non-sedating prescription antihistamine for the treatment of seasonal allergic rhinitis (hay fever) and for the treatment of uncomplicated skin manifestations of chronic idiopathic urticaria (hives). It offers patients significant relief from allergy symptoms without causing drowsiness.

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

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

Allegra® s largest market is Japan (based on 2008 net sales). Allegra-D® 12-Hour and Allegra-D® 24-Hour s biggest market is the United States (based on 2008 net sales).

The single-entity formulation of Allegra® already faces generic competition in its major markets outside Japan. In settlement of patent litigation, Barr has been granted a license to sell a generic Allegra®D-12 Hours in the United States starting in November 2009.

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. First launched in 1996, 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.

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 2 and 5 years from the FDA in September 2008.

Our leading markets for Nasacort®AQ Spray are the United States, France and Turkey (based on 2008 net sales).

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.

Urology

Xatral®/Uroxatral®

Xatral® (alfuzosin) 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 unique alpha1-blocker indicated as an adjunctive therapy with catheterization for acute urinary retention (AUR), 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.

The benefits of Xatral® on AUR demonstrated with the ALFAUR study have been confirmed by the largest international registry ever conducted on the management of AUR, Reten-World. Final results were based on 6,074 patients catheterized for AUR associated with BPH; demonstrating that a trial without catheter is now the standard of care worldwide (78% of cases) and that 86% of patients received an alpha1-blocker (Xatral® in seven case out of ten) at the time of catheter removal. The survey also confirmed that return to normal voiding was significantly higher in patients who received an alpha1-blocker (mainly Xatral®) at the time of catheter removal.

The ALTESS study had shown that Xatral® significantly reduced the risk of overall BPH progression. The long term results of the ALF-ONE real life practice study were published in April 2008. The study, which enrolled some 700 patients treated with Xatral® over a three-year period , confirmed its efficacy and safety and showed that patients experiencing BPH progression could be rapidly identified as they are in fact not responding to Xatral® treatment.

Lastly, 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 results of the Phase III clinical trial undertaken as part of the development of Xatral® in Japan will be discussed with the health authorities as part of a preliminary consultation in 2009.

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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.

Over four billion treatment days of alfuzosin have been prescribed worldwide since launch. The three leading countries for sales of Xatral® in 2008 were the United States, Italy and France (based on 2008 net sales). Generic alfuzosin became available in Italy in 2008, negatively affecting our sales there.

Osteoporosis

Actonel®/Optinate®/Acrel®

Actonel® (risedronate sodium) belongs to the bisphosphonate class. The bisphosphonates are antiresorptive treatments that inhibit osteoclast-mediated bone resorption and therefore help to prevent osteoporotic fractures.

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

Actonel® is available in various formulations (tablets and sachets) and dosages to better fit patients needs:

Actonel® 5 mg daily is indicated for the prevention of postmenopausal osteoporosis (PMO) in Europe and for the treatment of PMO and glucocorticoid-induced osteoporosis in Europe and the United States. In the United States, it is indicated for patients either initiating or continuing systemic glucocorticoid treatment (daily dosage of 7.5 mg or more of prednisone or equivalent) for chronic diseases.

Actonel® 35 mg once-a-week is indicated for treatment of this disease and for treatment of osteoporosis in men in both Europe and the United States, and for prevention of PMO in the United States.

Actonel® 30 mg is approved for the treatment of Paget s disease, a rare bone disorder.

Actonel® 75 mg, already available in the United States, was launched in France and Italy in September 2008. Actonel® 75 mg is a monthly treatment dosed on two consecutive days during the month, for the treatment of PMO.

Actonel® 150 mg was launched in the United States in June 2008 for the treatment of PMO. Recent year-2 results confirmed that 150 mg Actonel® given once-a-month was overall similar to 5 mg daily Actonel® in both efficacy and safety/tolerability when used in the treatment of postmenopausal osteoporosis.

Actonelcombi®, the combination of Actonel® 35 mg and calcium/vitamin D pouch form was launched in France in January 2008.

Actonel® is in-licensed from Procter & Gamble Pharmaceuticals (P&G). It is marketed by sanofi-aventis and P&G in more than 75 countries through the Alliance for Better Bone Health . Additional details on this alliance can be found in Alliances below. In Japan, Actonel® is marketed by Eisai.

The top four markets for Actonel® are the United States, France, Canada and Spain (source: IMS, 2008 sales, all available channels).

Other Pharmaceutical Products

The global portfolio of sanofi-aventis comprises a wide range of other pharmaceutical products, including prescription drugs and products sold over the counter (OTC), making up our base business . These products represent almost one third of the Group s worldwide pharmaceutical net sales (32.6% in 2008) and account for more than 57% of pharmaceutical net sales in the five BRIC-M countries (Brazil, Russia, India, China and Mexico) with growth of some 13% in 2008 (comparable data).

These products account for a significant share of our sales in some emerging, fast growing markets, in particular thanks to the so-called local star products, whose penetration in specific national markets is very deep, and also to tail products whose long presence on the market, effectiveness and safety has induced strong brand recognition by healthcare professionals and patients.

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We are already active on the market for generic drugs through our brand Winthrop®, which combines the generic promotion of our own mature molecules together with a broad-based portfolio of over 300 generic molecules originating from other laboratories. We seek to enhance our generic business through the acquisition of a controlling interest in Zentiva N.V. scheduled to close on March 11, 2009. Zentiva N.V. is a branded generic group of which we already own 24.9%, with products tailored to the Eastern and Central Europe markets. See also Item 7. Major Shareholders and Related Party Transactions B. Related Party Transactions and Note D.21. to our consolidated financial statements included at Item 18 of this annual report.

With over 2% market share based on 2008 sales of 1,415 million (an increase of 5.3% on a comparable basis), sanofi-aventis ranks sixth (source: Nicholas Hall, DB6 2007 MSP, based on owner perimeter) in the world OTC market. Our portfolio includes well known brands, whose aggregate sales accounted for 44% of our OTC sales in 2008 and are expected to continue growing substantially. In 2008, we also acquired Symbion Consumer, the Australian leader in nutraceuticals (vitamins, minerals and food supplements) and OTC brands and intend to offer this portfolio internationally.

Vaccines Products

Sanofi Pasteur is a fully integrated vaccine division offering the broadest range of vaccines in the industry. In 2008, sanofi pasteur immunized over 500 million people against 20 serious diseases and generated net sales of 2,861 million. Sales were favorably impacted by the strong growth in markets outside of North America and Europe, the launch of Pentacel® in the United States in 2008 and the continued growth of Adacel® and Menactra® in the same market. Sales growth was also due to an uptake of Pentaxim® sales in the international region, and the successful seasonal influenza vaccine campaigns.

Sanofi Pasteur is the world leader in the vaccine industry. It holds a leading position in most countries. In the United States and Canada, sanofi pasteur is the market leader in the segments where we compete.

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 in particular in France. In 2008, net sales of Sanofi Pasteur MSD, which are accounted for using the equity method, amounted to 1,272 million.

Sanofi Pasteur has established a leading position in Latin America. It has also been expanding in Asia, particularly in China and India, and is very active in international publicly-funded markets. We also have a significant activity in other developed, middle income and emerging markets throughout the world.

The table below details net sales of our Vaccines activity by range of products:

(*million)*	**2008 Net Sales**
Pediatric Combination and Poliomyelitis Vaccines	768
Influenza Vaccines *	736
Meningitis/Pneumonia Vaccines	472
Adult and Adolescent Booster Vaccines	399

Travel and Endemic Vaccines	309
Other Vaccines	177
Total Human Vaccines	**2,861**

* 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. In 2008, the

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FDA licensed Daptacel® vaccine for the fifth consecutive dose in the pediatric DTaP immunization series. 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 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®, which is a vaccine protecting against five diseases (pertussis, diphtheria, tetanus, polio and *Haemophilus influenzae* type b), launched in the United States in 2008, is approved in ten countries and has been the standard for preventive care in Canada since its launch in 1997.

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). 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. The worldwide polio eradication initiative of 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, Oral Monovalent 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 acellular-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. In 2008, eIPV was launched in Russia following the decision by the Russian authorities to choose the inactivated polio vaccine from sanofi pasteur for primary immunization of all infants. eIPV is the vaccine of choice for post-eradication polio immunization programs in the Russian federation.

Influenza vaccines

Sanofi Pasteur is the 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 production reached more than 170 million doses in 2008 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 and wider government immunization recommendations. Given the awareness of a potential influenza pandemic amongst health authorities, medical professionals and the public at large, the demand for influenza vaccines has increased in general.

In recent years, influenza vaccine demand has experienced strong growth in many other countries, particularly in China, South Korea 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 increased demand. In November 2007, sanofi pasteur signed an agreement with the Chinese authorities for a project to build an influenza vaccine facility in Shenzhen (Guangdong Province) with the goal of producing influenza vaccines for the Chinese market by 2012. The foundation stone 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. The building of the plant is planned to start in 2009.

In April 2007, sanofi pasteur received the first U.S. license for a vaccine against avian influenza in humans, marking an important milestone in pandemic preparedness. The licensure of this vaccine was based on a clinical trial conducted by the National Institute of Allergy and Infectious Diseases.

In April 2008, the U.S. Department of Health and Human Services (HHS) accepted H5N1 bulk vaccine antigen to produce approximately 38.5 million doses of vaccine to protect against a new strain of avian influenza. Sanofi Pasteur has a multi-year contract with HHS as part of its pandemic program, and received a payment of $192.5 million for acceptance of the bulk vaccine lot.

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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, in particular the convenience and the 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 territory for the prevention of seasonal influenza in both the adult (aged 18 and over) and elderly (aged 60 and over) populations.

Adult and Adolescent Boosters

The incidence of pertussis (whooping cough) is on the rise globally, affecting children, adolescents and adults. 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 been the standard of care in Canada since 2004, where most provinces provide routine adolescent immunization. This product plays an important role in efforts to better control pertussis, not only by preventing the disease in adolescents and adults but also by breaking the cycle of transmission to infants too young to be immunized or only partially vaccinated.

Meningitis and pneumonia vaccines

Sanofi Pasteur is at the forefront of developing vaccines to prevent meningitis and introduced the first conjugate quadrivalent vaccine against meningococcal meningitis, arguably the deadliest form of meningitis in the world. In 2008, 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, FDA granted sanofi pasteur licensure to expand the indication of Menactra® to children 2 years through 10 years of age. Menactra® is now indicated for people aged 2-55 years in the United States as well as in Canada. Additional submissions are expected during the coming years in various parts of the world. 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 antivenoms. These vaccines are used in endemic settings in the developing world and are the basis for important partnerships with governments and organizations such as UNICEF. These vaccines are also used by military and travelers to endemic areas. As the global market leader in the majority of these vaccine markets, sanofi pasteur s Travel/Endemic activity has exhibited stable growth.

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 for developing a vaccine stockpile.

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

Pharmaceutical Research & Development

The objective of our Research & Development (R&D) organization for pharmaceutical activities is to discover, develop, register and launch worldwide highly innovative compounds answering major unmet medical needs.

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Global and focused organizations: Discovery and Development

Discovery Research

In 2008, Discovery Research continued to enrich sanofi-aventis Development s portfolio with a pipeline of high quality, innovative drugs with the potential to fulfill unmet medical needs or provide improved treatments for patients. In this respect 15 new drug substances (small molecules or bio-therapeutics) entered into development.

The majority of these 2008 development entries are innovative in nature with 8 out of 15 representing first-in-class products.

The expertise of our scientists is developed in 6 major therapeutic areas: Metabolic Disorders, Cardiovascular Diseases, Thrombosis, Central Nervous System Diseases (neurology and psychiatry), Internal Medicine and Oncology. Our research activities currently target 12 out of the 16 diseases/conditions identified as demonstrating pharmaceutical gaps according to the World Health Organization.

In 2008, we strengthened several key areas of innovation such as:

- Orphan G protein coupled receptors through dedication of biological and chemistry resources from our Strasbourg (France) site, in order to increase the efficiency of the selection and optimization of innovative tool-compounds, agonist or antagonist of these receptors, for in vitro / in vivo evaluation.

- The search for novel anti-infectives through formalization of the organization and ramping up of scouting for external opportunities.

Five of our new entries in preclinical development from 2008 belong to the bio-therapeutics: two originated purely from internal efforts and three from outside collaborations:

Opening our organization to the outside world

- Reinforcement of the interactions between Discovery and Partnership & Innovation led to the monthly screening of about twenty external opportunities at various stages of advancement and to the selection on a yearly basis of about five to ten of them for in-depth evaluation and negotiations for putative in-licensing.

- Setting up an organization in China to boost our network of collaborations with small biotech companies, with public laboratories and research institutes. A team in charge of the identification of options and coordination of our activities has been created with local representatives based in Beijing and Paris.

A major agreement has been signed with the Institutes for Biological Sciences of Shanghai in order to discover innovative drugs for the treatment of neurological disorders, Diabetes and Cancer.

Sanofi-aventis has also signed a collaboration agreement with the University of Baltimore (Johns Hopkins School of Medicine, Maryland, United States) for the discovery of novel treatments for respiratory illnesses (e.g. asthma, Chronic Obstructive Pulmonary Disease), from original target identification new evaluation methodologies and biomarkers selection.

New operating models

We have been rationalizing our organization and interfaces in order to increase productivity in Research. For instance:

Reinforcement of interactions at the interface between Discovery and Preclinical/clinical Development has enabled us to reach ambitious objectives in terms of developability of bio-therapeutics with the aim of shortening development times. A number of joint assessments will be prepared by Research and Development in order to address early on any potential issues related to resources, means and technologies to produce and purify monoclonal antibodies and to better anticipate the entry of these products into development.

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A solid portfolio of bio-therapeutics programs has been created with the objective to enter three to five candidates of biological type (such as therapeutic protein, monoclonal antibodies or protein trap) into preclinical development per year originating either from external collaborations/in licensing or from internal efforts.

In conclusion, the sanofi-aventis Discovery Research function is adapting to the targeted diversification objective of the Company towards bio-therapeutics approaches making full use of existing internal competencies. Our internal efforts are significantly complemented by a number of external opportunities. In 2008, Discovery Research has continued to improve its interfaces with development in order to improve the quality of results and dossiers in full alignment with patient needs and regulatory requirements.

Development

Sanofi-aventis development relies on a strong matrix organization that leads and coordinates the efforts and expertise of representatives from all functions, and at all stages of development, from preclinical to marketing.

Most clinical trials are monitored through the sanofi-aventis internal Clinical Research Units (CRU) network which is deployed in more than 40 countries on the five continents to ensure best patient follow-up worldwide. This international dimension allows sanofi-aventis to study global and local diseases, to meet the expectations of local scientists, to have access to cutting-edge research and, in some countries, to fulfill a local regulatory prerequisite to obtain marketing authorization.

Sanofi-aventis has expanded its development presence in China. After the creation of a Clinical Research Unit in Shanghai in 2005, a state-of-the-art self-sufficient Biometrics Center was opened in Beijing in 2008. This center is devoted to study design, data management and statistical analysis of global and local Phase I to IV clinical trials, and will sustain the rapid growth of the Group Research & Development and support registration dossiers in China.

Sanofi-aventis is maintaining its efforts for high quality standards and ensuring best patient safety:

The majority of clinical trials started in 2008 use electronic data capture; this new technology gives development teams quicker access to patient clinical data, allows better study management, tight patient safety follow-up and helps to improve the quality of clinical data, while meeting time compression objectives in the conduct of the studies.

Most Phase II-III clinical trials are monitored by an independent external DMC (Data Monitoring Committee), whose members are selected for their expertise in the clinical, methodological, statistical and ethics fields. The DMC s role and responsibilities are described in a predefined charter prepared in collaboration with sanofi-aventis. The DMC s mission is to review on a regular basis the efficacy and safety data collected during the trial and to propose any appropriate measure to ensure the safety of the patients included in the study.

An internal sanofi-aventis advisory committee was established in 2008 to evaluate the profile of the drug-candidates in term of benefit/risk balance throughout the life of the molecules in development.

Clinical trials as well as the systems and processes involved in these trials are regularly audited by the Scientific Quality department which is independent from Development.

Special attention is paid to the training of both sanofi-aventis employees involved in the conduct of clinical trials (Internal Procedures, Good Clinical Practice, Regulatory requirements) and staff working in clinical investigation sites.

Sanofi-aventis continues to commit to disseminate clinical information in a transparent manner (in accordance with the Joint Position Statement issued by the Pharmaceutical Industry associations in January 2005) by disclosing protocol summaries of new and ongoing clinical studies on the publicly available website www.clinicaltrials.gov as well as posting non-exploratory clinical trial results, whether positive or not, on the public site www.clinicalstudyresults.org within a year of the launch of the product or of the end of the study for already marketed product.

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Portfolio

The research and development process generally takes from 10 to 15 years from discovery to initial product launch and is conducted in various stages. During the preclinical stage, research scientists perform pharmacology and toxicology studies on various animal models. Before testing on humans, an application for the compound must be filed with and approved by the regulatory authorities. Trials in humans are performed in different clinical phases to demonstrate the safety (Phase I), the proof of concept (Phase IIa) and efficacy (Phase IIb and Phase III) of a new compound.

Together, Phases IIb and III typically take from three to five years to complete. Thereafter, an application containing all data for the proposed drug is sent to regulatory authorities for approval, which may take from an additional six months to two years or longer. There are two further types of clinical trials: one called Phase IIIb, where additional indications are sought for a marketed product; and one called Phase IV trials, which are generally carried out after product launch to continue to monitor the efficacy and safety of a new drug.

R&D portfolio

The table below shows the most advanced drugs of our portfolio.

	Phase I	Phase II	Phase III	Registration
Metabolic Disorders	AVE0897		AVE0010	
Cardiovascular	SAR351034 SAR407899	Celivarone	AVE5530 XRP0038	Multaq®
Thrombosis	SSR128428	Otamixaban	AVE5026 Idraparinux/ Idrabiotaparinux	
Central	AVE0118 SSR103800	Ataciguat Nerispirdine	Teriflunomide Saredutant	Ciltyri®
Nervous	SAR115740 SSR125543	AVE0657 AVE1625		
System	SAR501788	SSR180575 SSR411298		
Internal	AVE0675 SAR21609	Ferroquine SAR97276		
Medicine	SAR153191 SAR389644			
	SAR3419 SSR97225	AVE1642	Aflibercept Alvocidib	
Oncology			Carbazitaxel Larotaxel Xaliproden AVE8062 TroVax®	

Sanofi-aventis Research and Development is undertaking the clinical development of 42 new compounds, in six therapeutic areas (these figures do not include the vaccines portfolio, please refer to Vaccines Research and Development below).

Sanofi-aventis is gearing up to:

bring to the market, in the short and mid-term, a large number of differentiated medicines, fitting in our therapeutic axes of expertise;

develop products for future growth, using the synergies between small molecules, vaccines and biotherapeutics;

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strengthen internal, but also external growth, taking advantage of our expertise and track record in alliances; and

adapt to the environment, develop scenarios and anticipate changes, mainly in medical needs and in the evaluation of health costs versus the benefits provided.

Sanofi-Aventis Research and Development Achievements in 2008

The dynamics of the sanofi-aventis portfolio are illustrated through the R&D achievements and projects highlights in 2008.

In 2008, 15 new compounds entered preclinical development (see Global and focused organizations: Discovery and Development Discovery Research above).

In 2008, several partnerships were initiated (see Principal Partnerships below). With Dyax Corp. an agreement was signed granting sanofi-aventis an exclusive worldwide license for the development and commercialization of a fully human monoclonal antibody SAR161578/DX2240, as well as a worldwide non exclusive license to Dyax Corp s proprietary antibody Phage display technology.

In 2008, seven compounds entered Phase I, while five projects entered Phase II and seven Phase III programs were initiated. For Japan, where regulatory authorities require local studies, two Phase I and one Phase III development programs have been initiated (Compounds having progressed in a new phase and being terminated subsequently were not counted).

Two NDAs for new chemical entities were submitted in the United States and in Europe: Multaq® (dronedarone), an antiarrhythmic drug in atrial fibrillation, and Ciltyri® (eplivanserin), a 5-HT2A antagonist in insomnia.

In Japan, the Fasturtec® dossier was submitted in February 2008 for hyperuricemia. One JNDA was submitted in 2008 for Lovenox® in VTE prevention after abdominal surgery.

Several sNDAs were granted in the United States and Europe in 2008 to major products like Apidra®, Actonel®, Plavix® or Lantus®.

In Japan, a new indication was approved for Taxotere® injection for the treatment of patients with prostate cancer having progressed or relapsed prostate cancer after surgical or medical castration. In April 2008, Aprovel® (irbesartan) received its first approval from the Japanese Health Authorities in the treatment of hypertension.

A full review of the Research and Development portfolio has been initiated in order to reassess the allocation of resources and distribute them to the projects with the highest potential in the currently prevailing healthcare environment. Consequently, a number of projects have been discontinued either on the basis of an unsatisfactory benefit/risk ratio or inadequate additional clinical benefit, or because of the expected

sub-optimal return on investment. This review will continue through April 2009.

The following programs were halted in 2008:

Cardiovascular: **Ilepatril** (AVE7688**,** vasopeptidase inhibitor, uncontrolled or resistant hypertension, chronic kidney disease stage 3; Phase IIB). Development was stopped based on an unfavorable expected benefit/risk ratio as compared to current and potential future therapies. **SL65.0472** (5-HT1B/5-HT2A antagonist, peripheral artery disease; Phase IIb). Development was stopped following results of the MASCOT Phase IIb study which showed no significant difference of the investigational drug compared to placebo and cilostazol.

Metabolism: the clinical development program relating to **Acomplia®** (rimonabant), a CB-1 antagonist, was discontinued in all indications following the European Medicines Agency recommendation to suspend the marketing authorization for the approved indication of overweight and obese patients. **AVE2268**, an SGLT-2 inhibitor which was developed for Type 2 diabetes mellitus was discontinued because of lack of competitiveness. A sustained release injectable form of **AVE0010** in Type 2 diabetes mellitus was discontinued because of lack of competitiveness.

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Oncology: **S-1** (oral fluropyrimidine, gastric and colorectal cancer; Phase III) rights were returned to Taiho Pharmaceuticals in July 2008 following negative results from Phase III in metastatic gastric cancer. The development of **larotaxel** and **carbazitaxel** has been discontinued in the treatment of breast cancer indication. Development in other indications is ongoing.

CNS: **Amibegron** (SR58611, beta-3 agonist; Phase III) in Major Depressive Disorders (MDD) in monotherapy and in combination with SSRI and **SSR149415** (V1b antagonist; Phase IIB) in MDD and General Anxiety Disorders (GAD) were discontinued due to an unfavorable product profile. **Surinabant** (SR147778, CB-1 receptor antagonist) was discontinued after a Phase IIb study in smoking cessation did not achieve statistically significant results. **Volinanserin** (M100907, 5-HT2A antagonist, insomnia Phase III) developed in sleep maintenance insomnia, was stopped after the results of the Phase III study for insufficient efficacy.

Internal Medicine: **Aquilda®** (Satavaptan, SR121463, vasopressin V2 receptor antagonist, dilutional hyponatremia; cirrhotic ascites). Based upon the recommendation of the DSMB (Data and Safety Monitoring Board) to stop the Phase III program on cirrhotic ascites and the subsequent reassessment of the overall viability of the project, the development was discontinued. **SSR240600** (NK1 antagonist overactive bladder/urge urinary incontinence; Phase IIb). The project was stopped, following the outcome of the dose ranging study (insufficient expected benefit/risk ratio).

Project Highlights

Our main compounds currently in clinical development Phase IIb or III are described in the paragraphs below.

Life Cycle Management (LCM) development programs for our marketed pharmaceutical products are described above in Pharmaceutical Products .

Thrombosis

The following compounds are currently in later-stage development in thrombosis:

Idraparinux sodium (SR34006, long acting pentasaccharide, indirect factor Xa inhibitor, thromboembolic events; Phase III). Idraparinux sodium is a synthetic pentasaccharide evaluated in the long-term treatment of thromboembolic events in patients suffering from deep-vein thrombosis (DVT) or pulmonary embolism (PE) (the VAN GOGH Phase III program) and in the prevention of thromboembolic events associated with atrial fibrillation (AMADEUS study). The results of the VAN GOGH program and of the AMADEUS study were published in The New England Journal of Medicine (September 2007) and in The Lancet (January 2008), respectively. All the data generated with idraparinux sodium will be used to support registration of idrabiotaparinux sodium (see below).

Idrabiotaparinux sodium (SSR126517, neutralizable long acting pentasaccharide, indirect factor Xa inhibitor, thromboembolic events; Phase III). SSR126517 is a long-acting synthetic pentasaccharide, with the same structure and the same pharmacological activity as idraparinux sodium. However, the addition of a biotin hook to the pentasaccharide structure allows neutralization following the infusion of avidin. This unique profile potentially provides SSR126517 with a competitive advantage over current oral anticoagulants. The clinical development program was designed to bridge clinical results obtained with idraparinux to those with idrabiotaparinux. The results of the bioequipotency study in patients with DVT (EQUINOX) were presented at the Annual Meeting of the American Society of Hematology (ASH) in December 2008. They showed a

similar PD profile between idraparinux and idrabiotaparinux, an efficient neutralization of idrabiotaparinux by avidin and a comparable efficacy / safety profile of idraparinux and idrabiotaparinux.

The safety and efficacy study in patients with PE (CASSIOPEA) and the Phase III trial to demonstrate the efficacy of idrabiotaparinux in the prevention of stroke in atrial fibrillation patients (BOREALIS) are ongoing.

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AVE5026 (indirect factor Xa/IIa inhibitor, prevention of VTE; Phase III). AVE5026 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 low-molecular-weight heparins (LMWHs). This once-a-day anti-thrombotic agent has a 100% bioavailability and is not anticipated to have drug interaction. It is being developed primarily in the primary prevention of venous thromboembolic events in patients undergoing knee replacement surgery, hip replacement surgery or hip fracture surgery as well as in patients undergoing abdominal surgery and in cancer patients undergoing chemotherapy according to the original plans. Regarding the medical indications for AVE 5026, it was decided to currently proceed only with those that target oncology patients.

Otamixaban (XRP0673, direct factor Xa inhibitor, acute coronary syndrome; Phase IIb). Otamixaban is an injectable, selective direct inhibitor of coagulation factor Xa. It is a synthetic small molecule. It has predictable pharmacokinetic and pharmacodynamic properties with low variability. Otamixaban exhibits a fast on- and off-set of action. SEPIA-PCI, a Phase IIa study in patients undergoing elective PCI, showed a good safety profile with predictable and dose-proportional anticoagulant activity. SEPIA-ACS, a Phase IIb study in acute coronary syndrome, is currently ongoing.

Cardiovascular

Certain of our principal compounds in the field of cardiovascular medicine currently in Phase II or Phase III clinical trials are described below.

Multaq® (dronedarone, SR33589, atrial fibrillation; submitted). The results of the ATHENA trial showed a statistically significant 24% reduction of cardiovascular hospitalization or death in patients with atrial fibrillation (AF). In addition, a decreased risk of stroke by 34% in patients with AF already adequately treated by antithrombotic therapy was demonstrated. In ATHENA, dronedarone significantly reduced the total number of hospital nights by 28% and decreased by 35% the total length of time spent in hospital for cardiovascular reasons. DIONYSOS study results showed the respective profiles of dronedarone and amiodarone: in the primary endpoint, atrial fibrillation after electrical cardioversion occurred in 36.5% of patients in the dronedarone arm versus 24.3% of patients in the amiodarone arm. However, in the dronedarone arm less thyroid events (2 versus 15), neurological events (3 versus 17) and premature study drug discontinuation due to any adverse events (13 versus 28) were observed. The FDA granted a priority review status for the use of Multaq® in patients with AF in August 2008. In November 2008, the FDA informed sanofi-aventis that they intended to discuss the Multaq® (dronedarone) application at the Cardio-Renal Advisory Committee on March 18, 2009.

Celivarone (SSR149744, antiarrhythmic; Phase IIb). Following the results of the ICARIOS trial, which demonstrated celivarone s effects on reducing the firing rate of implantable cardioverter/defibrillator (ICD) by 46% for either ventricular tachycardia or fibrillation versus placebo, the development of celivarone was stopped in atrial fibrillation. Its future development will depend on the outcome of the Multaq® Advisory Committee on March 18, 2009.

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. A Phase III program (TAMARIS study) is currently ongoing. The primary objective is to demonstrate the safety and effectiveness of XRP0038 in the prevention of major amputations in critical limb ischemia patients. Submission is planned for end of 2010.

Metabolic Disorders

Our main compounds currently in clinical development Phase II or III for metabolic disorders are described below.

The **AVE1625** (CB1 antagonist) development program in metabolism is discontinued and the development is focused in CNS indications (see Central Nervous System , below).

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AVE0010 (GLP-1 agonist, type 2 diabetes mellitus; Phase III). In Phase IIb, once-a-day dosing with AVE0010 was shown to be effective in lowering blood sugar and decreasing body-weight with a good tolerability. A Phase III program in patients with type 2 diabetes mellitus was initiated during the second quarter of 2008. Completion of this program is projected for 2010 (AVE0010 was licensed-in from Zealand Pharma A/S).

AVE5530 (Cholesterol absorption inhibitor, hypercholesterolemia; Phase III). In a Phase II study, AVE5530 demonstrated that it decreased LDL-C (Low Density Lipoproteins-Cholesterol) in patients with hypercholesterolemia. The Phase III program (four studies) was initiated in 2008 with two doses of AVE5530 (25 mg and 50 mg) once daily.

Oncology

The sanofi-aventis oncology portfolio represents a broad spectrum of novel agents with a variety of mechanisms of action for treating cancer and/or cancer side-effects, including cytotoxic agents, antimitotic agents, anti-angiogenic agents, antivascular agents, monoclonal antibodies, and cancer vaccines as well as supportive care therapies. Our principal compounds in the field of oncology currently in clinical trials are described below.

Xaliproden (SR57746, neurotrophic, chemotherapy-induced neuropathy; Phase III). Xaliproden is an orally active neurotrophic agent which is currently being studied in Phase III trials for the treatment of chemotherapy-induced neuropathy with a go/no go decision for regulatory submissions anticipated in the second half of 2009.

Larotaxel (XRP9881, taxoid, pancreas and bladder cancers; Phase III). XRP9881 is a taxane derivative that has been designed to overcome resistance to existing taxanes, docetaxel and paclitaxel. Larotaxel in monotherapy has shown to be active in tumors progressing after anthracycline/taxane therapy (metastatic breast cancer, Phase II). Based on the results of Phase III in second-line pancreas cancer, regulatory submissions are planned in the United States and in Europe in June 2010. A Phase III in first-line bladder cancer in combination with cisplatin was initiated at end 2007 and is ongoing.

Carbazitaxel (XRP6258, taxoid, prostate cancer; Phase III). XRP6258 is a new taxane derivative. XRP6258 has shown to be active in tumors progressing after taxane therapy (metastatic BC, Ph II). A Phase III study in hormone resistant prostate cancer after failure of Taxotere® is ongoing, with data expected in 2009.

Alvocidib (flavopiridol, HMR1275, 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 on going in Europe and the United States. Additional studies will be exploring the potential benefit of alvocidib in various other hematological malignancies.

Aflibercept (VEGF Trap, AVE0005, anti-angiogenesis agent; solid tumors; Phase III). VEGF (Vascular Endothelial Growth Factor) Trap is being developed under an alliance with Regeneron Pharmaceuticals. VEGF Trap is a novel anti-angiogenesis agent that acts as a decoy receptor or Trap for circulating VEGF. Four 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), in second line non-small cell lung cancer (with Taxotere®), in second line metastatic colorectal cancer (with FOLFIRI) and in first line metastatic pancreas cancer (with gemcitabine). 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. Registration in refractory ovarian cancer as single agent was cancelled as the results, although demonstrating biological activity, are unlikely to meet regulatory requirements.

TroVax® (advanced renal cell cancer, Phase III) is a cancer therapeutic vaccine in-licensed in March 2007 from Oxford BioMedica targeting a broad spectrum Tumor-Associated Antigen called

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5T4, which is broadly distributed throughout a wide range of solid tumors. In Phase II studies, TroVax® has been shown to induce a strong immune humoral and cellular response, both as single agent and in combination with immunotherapy (renal cancer) and chemotherapy (metastatic colorectal cancer). TroVax® is being evaluated in a Phase III study in advanced renal cell carcinoma patients (TRIST). However, following its fourth interim review of the data, the DMC (Data Monitoring Committee) advised that TroVax®, administered according to the protocol, will not meet the predefined primary efficacy endpoint, and therefore recommended to discontinue further vaccinations but continue follow-up of patients.

AVE8062 (combretastatin derivative) is a new antivascular licensed from Ajinomoto. Single agent and combination studies with cisplatin, docetaxel and oxaliplatin have been conducted with AVE8062 over recent years. In these studies, AVE8062 has been shown to dramatically decrease the tumor blood flow, resulting in anti-tumor efficacy, mainly in combination. At the recommended dose, AVE8062 appears to be well tolerated. Based on these data, a Phase III in sarcoma in combination with cisplatin has been initiated in 2008.

AVE1642 is an anti-IGF1R monoclonal antibody developed in collaboration with ImmunoGen. Single agent and combination studies with docetaxel have confirmed the good tolerance of the drug as well as encouraging signs of activity, mainly in combination. Further combinations with other anticancer agents are being explored. Based on these encouraging data, a randomized Phase II study in combination with fulvestrant in women with hormone sensitive breast cancer has been initiated.

Central Nervous System

Certain of our principal compounds in the Central Nervous System field currently in Phase II or III clinical trials are described below.

Teriflunomide (HMR1726, immunomodulator, multiple sclerosis; Phase III). Teriflunomide is an orally active dihydroorotate dehydrogenase inhibitor. An international Phase III development program is progressing in multiple sclerosis.

Saredutant (SR48968, NK2 antagonist, depression, anxiety; Phase III). Saredutant is a non-peptide selective antagonist of the human brain NK2 receptors developed for the treatment of major depressive disorders (MDD). Five short-term Phase III studies demonstrated an overall statistically significant efficacy versus placebo. In the long-term efficacy trial, benefit of continuing saredutant for one year in responders to an initial 3-month saredutant course was not demonstrated. The decision on submitting saredutant for regulatory approval will depend on the results of the two ongoing trials, assessing the product in combination with two selective serotonin reuptake inhibitors (SSRIs), which are due to be completed in the first half of 2009.

Ciltyri® (eplivanserin (SR46349), 5-HT2A antagonist, insomnia; submitted). Ciltyri® is a new non-sedative sleep agent developed for the treatment of chronic insomnia characterized by difficulties with sleep maintenance. A large world-wide Phase III program was completed which included more than 2,700 patients. At 5mg /day Ciltyri® improves sleep maintenance by decreasing the wake time after sleep onset and the number of nocturnal awakenings and improving the quality of sleep/refreshing quality of sleep. Ciltyri® is overall well tolerated and, unlike other available sedative sleep agents is devoid of next-day residual effects. The registration dossier was filed in the United States and Europe in late 2008.

AVE1625 (CB1 antagonist, schizophrenia; Phase IIb). AVE1625 is an oral selective and potent antagonist of cannabinoid receptors. A Phase II development program for cognitive impairment in schizophrenia is ongoing.

Ataciguat (HMR1766**,** NO-independent activator of soluble guanylate cyclase; Phase IIb). The Phase IIb study (ACCELA) was completed. The results of this study did not show a significant difference of HMR1766 compared to placebo or cilostazol in patients with intermittent claudication, Fontaine classification stage II. A clinical investigation in patients with neuropathic pain is ongoing.

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Nerispirdine (HP184 K+ and Na+ Channel Blocker, symptomatic treatment for MS; Phase II) initiated the Phase II program for symptomatic treatment of all forms of multiple sclerosis (MS).

SSR411298 (FAAH inhibitor; Phase II). A dose finding study has been initiated in 2008 in Major Depressive Disorders in elderly patients.

Internal Medicine

Our principal compounds in the field of Internal Medicine currently in late-phase clinical trials are described below.

Ferroquine (SSR97193, 4-aminoquinoline, malaria; Phase II). Ferroquine is a new 4-aminoquinoline which is being developed for the treatment of acute uncomplicated *Plasmodium falciparum* malaria in combination with another antimalarial (artesunate, an artemisinine derivative). A Phase II study aimed at evaluating the safety and activity of the association in adult African patients has just been completed. Further evaluation of the drug s therapeutic potential in children (the most at risk for the disease) is planned to start in 2009.

Besides ferroquine, one other antimalarial drug with an innovative mechanism of action is currently in development. **SAR97276** is developed for the treatment of severe *Plasmodium falciparum* malaria in adults and children. Phase II started in 2008 in Africa.

These projects are part of the global commitment of sanofi-aventis to fight against neglected diseases which heavily impact the developing world.

Principal Partnerships

Through partnerships and alliances established with biotechnology firms and other pharmaceutical groups, sanofi-aventis is able to access new technology and to extend or strengthen existing areas of research. Further to those already mentioned, some examples are described below.

Discovery Research

Two types of partnerships are being used to enhance Discovery Research:

Technological partnerships giving sanofi-aventis teams access to new technology and extending their research and skills areas. The following are examples of such partnerships:

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Elan (Dublin, Ireland): license for NanoCrystal® formulation technology, which can enable formulation and improve compound activity and final product characteristics.

- **Critical Path Institute** (Tucson, Arizona, United States): sanofi-aventis is a member of the Predictive Safety Testing Consortium (PSTC), which aims at identifying and developing methods for testing drug safety.

- **Dyax Corp**. (Cambridge, Massachusetts, United States): see sanofi-aventis Research and Development Achievements in 2008 above.

- **dScreen Consortium**: founded with the assistance of the Alsace Biovalley cluster (France), sanofi-aventis launched in September 2008 a research initiative conducted with Raindance Technologies (Lexington, Massachusetts, United States) and Louis Pasteur University (Strasbourg, France) to develop the new generation of High-Throughput Screening (HTS) for drug discovery applications.

Partnerships on innovative products, to maximize opportunities of exploring new leads in our therapeutic areas of excellence. The following are examples of such partnerships:

- **Immunogen** (Cambridge, Massachusetts, United States): identifying and developing naked antibodies or immuno-conjugates (monoclonal antibodies associated with an anticancer agent) in oncology. On the technology side, sanofi-aventis has licensed the rights to Immunogen s proprietary resurfacing technology to humanize antibodies. The research collaboration ended on August 31, 2008, but compounds are still in the development portfolio.

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- **Regeneron Pharmaceuticals, Inc.** (Tarrytown, New York, United States): very active, global, strategic collaboration agreement (signed in 2007) to discover, develop, and commercialize fully-human therapeutic antibodies. In 2008, two antibodies entered into preclinical development (see also Discovery Research).

- **Institute of Hematology and Blood Diseases Hospital, Chinese Academy of Medical Sciences** (Tianjin, China): the purpose of the agreement is the isolation of acute myeloid leukemia stem cells and the generation of monoclonal antibodies against these cells with the aim to capitalize on the increasing evidence of the role of cancer-stem cells. Such antibodies would serve as valuable vectors to study these rare cells and may become the basis for new therapeutic strategies.

- **Coley** (Wellesley, Massachusetts, United States): global license and collaboration agreement on research into CpG (Cytosine phospodiester Guanine) oligonucleotides, which act as immunomodulators, for the treatment of certain respiratory disorders.

- **Mitsubishi Pharmaceutical Corp.** (Tokyo, Japan): identifying and developing new protective agents for the treatment of neurodegenerative diseases.

- **Genfit** (Lille, France): collaboration covering several projects, particularly pharmacological characterization and selection of the best drug candidates of sanofi-aventis to act on an innovative target involved in metabolic and inflammatory mechanisms and launch of a new program based on a new target involved in inflammatory diseases.

- **INSERM/Innogenetics** (through affiliate INSERM Transfert, Paris, France and Gent, Belgium): collaboration that will make it possible to study the role of specific forms of the key Alzheimer protein amyloid beta, and to discover new therapeutic avenues for Alzheimer s disease.

- **Global Alliance for TB drug Development**: collaboration agreement to accelerate the discovery, development and clinical use of drugs against tuberculosis.

As part of the Impact Malaria program, three cooperative programs were continued in 2006. Ferroquine, co-developed with the *Université Scientifique et Technique de Lille* (France), is currently in Phase IIb of clinical development.

In the same field, sanofi-aventis and **Medicines for Malaria Ventures** (Geneva, Switzerland) have entered into a collaboration to fight malaria. Sanofi-aventis will share information with MMV on its malaria drugs portfolio, and will define specific collaborative actions for development of the portfolio projects.

Sanofi-aventis is engaged in numerous partnerships with academic institutions: such as INSERM, CNRS, CEA or Institut Pasteur in France, Frankfurt University in Germany, Rockefeller University in the United States.

License and development agreements

Regeneron Pharmaceuticals, Inc. (Tarrytown, New York, United States): joint development of a recombinant fusion protein, the VEGF Trap (AVE005), that produces soluble decoy-receptors which bind to VEGF (Vascular Endothelial Growth Factor), stopping it from stimulating the natural VEGF receptor and thus preventing angiogenesis. The VEGF Trap has now entered Phase III of

clinical development.

Zealand: AVE0010 is a glucagon-like peptide 1, or GLP-1 , receptor agonist, currently in Phase III clinical trials, intended to treat type 2 diabetes.

Ajinomoto: AVE8062 is an antivascular agent for the treatment of solid tumors, currently in Phase III clinical trials.

Oxford BioMedica (Oxford, United Kingdom): exclusive global licensing agreement to develop and commercialize TroVax®, an immunotherapy product for the treatment and prevention of cancers. Based on the broad distribution of the 5T4 tumor antigen, TroVax® has potential application in a wide range of solid tumors, including renal, colorectal, lung, breast and prostate cancer. The compound is in Phase III.

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Dyax Corp (Cambridge, Massachusetts, United States): as part of the strategic antibody collaboration, sanofi-aventis has been granted an exclusive global license for the development and commercialization of DX-2240, a fully human monoclonal antibody that targets the Tie-1 receptor on tumor blood vessels and has therapeutic potential in numerous oncology indications.

Novozymes (Bagsvaerd, Denmark): a global licensing and collaboration agreement was signed in December 2008, for the development and marketing of a potential new antibiotic (plectazin NZ2114).

Partnerships for access to medicines

Sanofi-aventis works in partnership with the World Health Organization (WHO) in several fields, in particular in neglected tropical diseases. Initiated in 2001 to combat sleeping sickness, this partnership was renewed in 2006 for an additional five years to include leishmaniasis, Buruli ulcer and Chagas disease. In close liaison with the WHO, sanofi-aventis is implementing an innovative pharmacovigilance program on antimalarial drugs in Sub Saharan Africa with the support of MMV (Medicines for Malaria Venture) and DNDi (Drugs for Neglected Diseases initiative).

Sanofi-aventis is also involved in partnerships with several organizations actively supported by the Bill & Melinda Gates Foundation, such as the Global Alliance for Vaccines and Immunization, Medicines for Malaria Venture (for antimalarial drugs) and the Global Alliance for TB Drug Development (for antituberculosis drugs).

Vaccines Research and Development

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

Sanofi Pasteur R&D Pipeline

The sanofi pasteur R&D portfolio includes 22 vaccines currently in advanced development as shown in the table below.

Phase I	Phase IIa	Phase IIb	Phase III	Submitted
Meninge A,C,Y,W conj.	**Flu [1] Cell Culture**	**DTP-HepB-**	**Hexaxim**	**Emerflu EU**
2nd generation	New production method	**Polio-Hib [1]**	DTP-HepB-	Pandemic flu H5N1
Meningitis in infants			Polio-Hib [1]	
	West Nile	**ACAM C. diff**		
Pneumo	Prevention of disease	Prevention of C. difficile associated diarrhea (CDAD)	**Unifive**	
Meningitis & pneumonia			DTP-HepB-Hib [1]	

in infants

(Monovalent)

Tuberculosis

Prevention of disease

Flu Pandemia

Low dose

ACAM-Flu-A

Broad protection against

influenza A strains

Rabies

mAb post exposure

prophylaxis

Melanoma

Tumor antigen

administered

through viral vector

Treatment of

stage III & IV

Dengue

Mild-to-severe

dengue fever

Pediacel® EU

DTP-Polio-Hib [(1)]

ADACEL®

DTP[(1)] 4-6 years

Menactra®

Menactra Infant/Toddler

9-12 months

Flu[(1)] Micro-injection

New method of delivery U.S.

IMOJEV

Japanese encephalitis

Prevention of infection

HIV (Thailand)

Prevention of

infection

Proof of concept

Flu

New formulation U.S.

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

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Project highlights

Influenza

To sustain our global leadership in the development of influenza vaccine, our Research & Development efforts are focused on innovative approaches for assessing new formulations and alternate delivery systems as well as diversifying our flu manufacturing technologies for increased vaccine efficacy, acceptance or both. We remain actively engaged in pandemic preparedness activities.

A new formulation (increased dosage) was developed with the aim of improving vaccine effectiveness in the elderly population. The elderly experience a progressive reduction in their immune system with increasing age as well as reduced antibody responses to inactivated virus vaccines. Results from a recent Phase III influenza vaccine study with 4,000 participants demonstrated increased immune responses among adults 65 years of age and older who received a high-dose influenza vaccine as compared to those that received the standard inactivated vaccine formulation used for the 2006-2007 season. Following an agreement with the Center for Biologics Evaluation and Research (CBER) of the FDA on the registration strategy, this formulation will be submitted for approval in the next few months.

To assess whether vaccine efficacy could be enhanced by using a new delivery system, clinical evaluation continued in 2008 with the novel microinjection system (micro-needles used to deliver vaccine to the dermal layer of the skin) that was developed in collaboration with Becton Dickinson. The data from the Phase III trial in Europe involving 7,000 adults or elderly participants evaluated the safety of the system and its ability to generate an immune response that meets all criteria required by the European Medicines Agency (EMEA). A full submission with an updated common technical document (CTD) was sent to the EMEA in November 2008. In December 2008, Intanza®/IDflu®, the first influenza vaccine delivered by intradermal (ID) microinjection, received a positive opinion from Europe s Committee for Medicinal Products for Human Use (CHMP), the scientific committee of EMEA. On February 26, 2009 the European Commission granted marketing authorization for INTANZA®/IDflu® for the prevention of seasonal influenza in both the adult and elderly populations. This represents a key step towards recognition of the ID route as an alternative for vaccine administration. Enrollment in the Phase III trial in the United States has been completed.

As part of an initiative to diversify flu vaccine manufacturing technologies, a cell culture based process is being developed in partnership with Crucell and Lonza. The project has been carried out under contract with the U.S. government. Results of a Phase II clinical study showed that the product appears to be safe and immunogenic. The results also highlighted opportunities to further improve the process. This is ongoing.

ACAM-Flu-A Phase I has been completed to evaluate the ability to elicit Flu M2-specific responses. This project is a recombinant form of M2 protein as an adjunct to trivalent vaccine.

Pandemic Preparedness Efforts in pandemic preparedness continued in 2008 with dose sparing initiatives using a proprietary adjuvant. Building on the promising results from the Phase I study in healthy adults where vaccine doses as low as 1.9 µg of an H5N1 vaccine formulated with a proprietary adjuvant reached the 70% seroprotection threshold accompanied by a significant increase in cross reactivity with variant H5 viruses, preparations have been underway in 2008 for a Phase II/III study to be initiated in 2009. Results of a subsequent Phase I study (antigen and adjuvant dose ranging in adults) in 2008 allowed the antigen and adjuvant dose selection for the Phase II/III study. Progress has also been made in scaling up the proprietary adjuvant. These efforts continue to support increased stockpiling and response capabilities.

Pediatric Combination & Adolescent/Adult Booster Vaccines

A number of pediatric vaccines are in 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.

Pentacel® The FDA granted a license in June 2008 and the product was launched later that year.

Pediacel® Clinical trials continued throughout 2008. All clinical results for the CTD are now available to support licensure in the rest of Europe of this pentavalent pediatric vaccine that is the

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standard of care in the United Kingdom and Netherlands for protecting against diphtheria, tetanus, pertussis, polio and *Haemophilus influenzae* type b disease. Our first Pediatric Investigation Plan submission received a positive response from the Pediatric Committee of the EMEA, with no additional studies required.

Unifive® and Hexaxim® two multivalent (one pentavalent and one hexavalent) pediatric vaccines aimed specifically at the international zone are in development. Multiple Phase III trials have continued in several countries.

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 2008, efforts remained focused on expanding its area of licensure and on extending its indications primarily the pre-school booster indication in countries where the product is already marketed.

Meningitis Program

Neisseria meningitidis has been a leading cause of meningitis in the United States, Europe and elsewhere, striking the very young as well as adolescents. Five serogroups contribute to the vast majority of the incidences of the disease worldwide: A, C, W-135, Y and B. A polysaccharide vaccine comprised of serogroups A, C, W-135 and Y, Menomune®, has proven its efficacy for many years. In 2005, the first ever quadrivalent conjugate-based vaccine, Menactra®, was licensed in the United States for indications against invasive meningococcal diseases in patients aged 11-55 years. As a conjugate vaccine, Menactra® provides longer immunity than the polysaccharide vaccine. The primary focus of several ongoing projects related to Menactra® is to decrease the age at which one can first receive this vaccine. As part of this objective, Menactra® was licensed in Canada for ages 2-55 years in 2006 and a supplement to the U.S. Menactra® license lowering the minimum recommended age and effectively broadening the age range to 2-55 years, was approved by the FDA in 2007. In February 2008, the Advisory Committee on Immunization Practices (ACIP) recommended Menactra® for high risk 2-10 year olds. Additional international license submissions will occur in the near future.

Menactra® Infant/Toddler (9-12 months) this project is aimed at lowering the age of administration below twelve months of age. Phase III clinical studies continued in 2008 and are at various stages of advancement.

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.

Meninge B The MenB project is aimed at preventing severe disease in infants and young adults. This project is entering development following progress from in-house and partnered discovery efforts.

Pneumococcal Vaccine Program

Streptococcus pneumoniae is the leading etiological agent of severe infections such as pneumonia, septicemia, meningitis and otitis media and causes over 3 million deaths per year worldwide, of which one million are children. Antimicrobial resistance in *Streptococcus pneumoniae* has complicated the treatment of pneumococcal disease and further emphasized the need for vaccination to prevent large-scale morbidity and mortality.

Sanofi Pasteur is focused on the development of a protein-based pneumococcal vaccine. This approach should result in a vaccine with superior serotype coverage as compared to current polysaccharide or conjugate based vaccines. Data from early clinical trials and supportive

epidemiological studies have provided strong support for a protein-based approach. Antigens for the multivalent vaccine formulation have been selected for further development and clinical evaluation.

Rabies Vaccine

The Vero serum-free improvement of our current Verorab® rabies vaccine will provide a worldwide, single rabies vaccine as a follow-up to our current vaccine offerings.

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Rabies mAb Post Exposure Prophylaxis In January 2008, we announced the signature of an exclusive collaboration and commercialization agreement with Crucell for their combination of two rabies monoclonal antibodies (MoABs) which will be used in association with the rabies vaccine for post-exposure prophylaxis. Based on the successful results of the Phase I studies, a Phase II study in adolescents and children in the Philippines completed enrollment in 2008. Additional Phase II studies are planned.

New Vaccine Targets

Dengue Dengue fever is of growing epidemiological importance due to global socio-climatic changes, and 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 were tested to develop a vaccine covering the four viral serotypes of dengue fever in order to prevent this disease and its severe complications (hemorrhagic fever). Results of a Phase II clinical trial of adults in the United States demonstrated proof of concept of the lead vaccine candidate that is based on the ChimeriVax technology. Administration of the quadrivalent candidate vaccine against dengue fever promoted neutralizing antibodies against the four serotypes responsible for dengue fever. Expanded Phase II studies are ongoing in endemic areas in adults as well as children. 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 the pediatric endemic population through disease burden evaluation, vaccine advocacy and vaccine access. In February 2009, the sanofi pasteur dengue vaccine entered into a pediatric clinical study in Thailand.

IMOJEV The ChimeriVax technology was further leveraged to develop a vaccine for protection against infection with 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. Positive Phase III results were obtained in adults. Extension of clinical testing (Phase IIb) in children and toddlers (12-24 months) occurred in 2008. In addition, recruitment for the Phase III bridging trial for the Thai licensing was completed.

West Nile virus Further extension of the ChimeriVax technology included the development of a West Nile virus vaccine. The West Nile virus vaccine was safe and immunogenic in Phase II studies.

Malaria The malaria vaccine project remained in the preclinical stage in 2008 with selected antigens from the malaria partnership network and vaccine adjuvant technology developed in-house.

Chlamydia trachomatis *Chlamydia trachomatis* is the most commonly reported sexually transmitted bacterial pathogen and produces serious morbidity and long-term sequellae, especially in women. Chlamydia-host immunobiology is characterized by acute infection followed by immunity or by persistent infection that is associated with tissue damage and disease sequellae. The *Chlamydia trachomatis* project goal is to develop a recombinant protein vaccine for prophylactic vaccination against the *Chlamydia trachomatis* sexually transmitted infection. The target population is pre-sexually active women who are between 11 and 14 years of age. The project continued in the preclinical stage in 2008 as the composition of the candidate prototype vaccine for further clinical development was identified.

Cytomegalovirus (CMV) Results from a proof of concept study in women of child-bearing age suggest a glycoprotein B vaccine has the potential to prevent maternal and congenital infection by cytomegalovirus. However, the durability of protection appears short-lived. Subsequent formulations will be studied to look to enhance breadth and durability of vaccine protection.

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 currently in a clinical Phase I trial. A previous study in adults indicated the candidate SSI sub-unit vaccine to be safe and immunogenic. Multiple Phase I clinical trials are currently ongoing

using the SSI recombinant protein-based vaccine. If the development is successful, sanofi pasteur would manufacture and commercialize the vaccine. An effective vaccine is urgently needed as tuberculosis is estimated to cause the death of two million people worldwide each year.

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Melanoma The candidate vaccine of sanofi pasteur uses the ALVAC technology to deliver multiple tumor associate antigen to the immune system. A Phase II study was initiated in 2008. Recruitment of subjects will continue into 2009.

HIV A recombinant canarypox vaccine, ALVAC-HIV, is currently in Phase III in Thailand. The trial is a collaboration between the U.S. Army, the National Institute of Allergy and Infectious Diseases of the NIH, the Ministry of Public Health of Thailand, sanofi pasteur and Vaxgen. The vaccination phase was completed in July 2006. Following a safety and effectiveness assessment in mid 2008, the Data and Safety Monitoring Board recommended that the trial continue. Final study analysis is scheduled for mid 2009.

ACAM-Cdiff Phase II started in February 2009. *Clostridium difficile* is the leading cause of infectious diarrhea in hospitals, in the adult and particularly elderly population. The epidemiology of the *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. The disease burden cost is estimated to be over $3 billion in both the United States and the European Union. ACAM-Cdiff is a toxoid-based vaccine for the primary prevention of *C.difficile* associated with diarrhea. *C.difficile* is a major public health concern in North America and Europe. There is currently no vaccine available.

Animal Health: Merial

Merial, a joint venture in which we and Merck & Co. Inc. each hold 50%, 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 2008 amounted to $2,643 million.

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. The company 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 2008, the patent protecting fipronil, the active ingredient of Frontline®, expired in several countries, including Japan, Australia and Brazil. Fipronil still enjoys patent protection in the United States and in the major European markets (France, Italy, Germany and the United Kingdom). In those markets where the fipronil patent has expired Frontline® is still protected through formulation and combination patents.

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 5,800 employees worldwide.

In 2008, Merial enjoyed continued growth thanks to the integration of ANCARE, a New Zealand-based company acquired in October 2007. The expansion of innovative avian and swine vaccines launched in 2007 (Vaxxitek®, Circovac®), the production of vaccines against Blue Tongue Virus aimed at containing the spreading epizooty in Europe, and the launch of Zactran a new antibiotic for the treatment of respiratory tract infections in ruminants in France also contributed to Merial s growth.

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;

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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, this period of effective protection may be extended by procedures established to compensate significant regulatory delay in Europe (a supplementary protection certificate, SPC), the United States (a Patent Term Extension, PTE) and Japan (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 January 2008, an EPO patent application may cover the 34 EP 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.

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

The expiration or loss of a product patent may result in significant competition from generic products and can result in a dramatic reduction in sales of the original branded product. 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, product, structure, formulations, methods of treatment, indications or delivery systems. Certain categories of products, such as traditional vaccines and insulins, 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. 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 of the innovation represented by a newly approved drug product for a limited time. This exclusivity operates independently of patent protection and may protect the product from generic competition even if there is no patent covering the product.

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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. It will accept the filing of an Abbreviated New Drug Application (ANDA) containing a patent challenge a year before the end of this regulatory exclusivity period (see the descriptions of ANDAs, below). In addition to this exclusivity granted to new drug products, significant line extensions of existing NCEs may qualify for an additional 3-year regulatory exclusivity. Also, under certain limited conditions, it is possible to extend any unexpired U.S. regulatory and patent-related exclusivities by a pediatric extension. See Pediatric Extension , below).

In the European Union, generic drug applications will not be accepted for review until eight years after the first marketing authorization (data exclusivity) or approved for marketing until ten years after the first marketing authorization of the reference product (marketing exclusivity). These exclusivities may be extended in some cases. While this exclusivity is intended to be applicable throughout the European Union, in a decentralized system, national authorities may act in ways that are inconsistent with EU data 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 and 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.

No data protection is available in Canada for products for which the first marketing authorization (NOC) was issued before June 2006. A generic drug application for marketing in Canada will not be accepted for six years after the first NOC or approved for marketing for eight years after the first marketing authorization but only for products where the first NOC is issued after June 2006. The eight year period can be supplemented by a six month pediatric extension.

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

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, this also extends any FDA exclusivities related to the product s patents.

In the United States, the FDA may ask 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 top 15 products. Under the Hatch-Waxman Act, timely provision of data meeting the FDA s requirements may result in the FDA treating the product as if its regulatory exclusivity and patent life had been extended by six months, to the extent these protections have not already expired (the so-called pediatric exclusivity). The Top 15 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 new regulation on pediatric medicines entered into force on January 26, 2007. This regulation provides for the progressive implementation through 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.

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Product Overview

We summarize below the intellectual property coverage in our major markets of the products described above at Principal Pharmaceutical Products . In the discussion of patents below, we focus on compound patents and any secondary 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 secondary 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. See Patents, Intellectual Property and other Rights above.

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.

Lovenox® (enoxaparin sodium)

U.S.	**E.U.**	**Japan**
Compound: Declared unenforceable by a February 2007 U.S. District Court decision	Compound: June 2011 in most of EU; exceptions: June 2010 in France, no compound patent in force in Spain, Portugal, Finland, Norway, Greece and much of Eastern Europe	Compound: expired
		Regulatory exclusivity until 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.	Compound: 2013
Secondary: two patents covering the crystalline form 2 each expiring in 2019		Secondary: crystalline form 2 (2020)
	Secondary: crystalline form 2 (2019)	
		Regulatory exclusivity until 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
Secondary: Formulation (2015)		Secondary: Formulation (2021)

Secondary: coverage ranging through 2016 (Formulation patent)	Regulatory exclusivity until 2016

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Lantus® (insulin glargine)

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

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
Secondary: formulation (2012 to 2013)		Secondary: formulation (2012 to 2013)
	Secondary: additional patent coverage ranging through 2013	

Eloxatine® (oxaliplatin)[1]

U.S.	**E.U.**	**Japan**
Compound: expired	Compound: expired	N/A
Secondary: coverage ranging through 2016	Genericized	
Regulatory exclusivity: expired February 2008		

Copaxone® (glatiramer acetate)[2]

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

Actonel® (risedronate sodium)[3]

U.S.	**E.U.**	**Japan**
Compound: December 2013	December 2010 in Austria, Belgium, France, Germany, the Netherlands, the United Kingdom, Sweden, Switzerland and Italy; 2013 in Spain; expired elsewhere	N/A
Secondary: coverage ranging through 2018		
	Secondary: coverage ranging through 2018	

Stilnox® (zolpidem tartrate)

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

Secondary: Ambien® CR formulation (2019)	Genericized	Secondary: Ambien® CR formulation (2019)
Regulatory exclusivity until March 2009 for Ambien® CR (regulatory exclusivity on active ingredient has expired)		Regulatory exclusivity until 2010 on all formulations

1 We do not own most Eloxatine® patents but license them from Debiopharm for marketing.
2 Sanofi-aventis has licensed Copaxone® from Teva, with which we co-promote the product; the co-promotion in the United States expired in March 2008 (see Markets Alliances Teva Pharmaceutical Industries below).
3 We commercialize Actonel® with Procter & Gamble Pharmaceuticals, which holds the NDA and the patents for this product in the United States.

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Allegra® (fexofenadine hydrochloride)

U.S.	**E.U.**	**Japan**
Compound: expired	Compound: expired	Compound: expired
Secondary: coverage ranging through 2017	Genericized	Secondary: coverage ranging through 2016
Single entity form genericized, licensed generic D®-12 Hour form in November 2009[1]		

Depakine® (sodium valproate)

U.S.	**E.U.**	**Japan**
N/A	Compound: expired	Compound: expired
	Secondary: Depakine® Chronosphere® formulation (2017)	Secondary: Depakine® Chronosphere® formulation (2017)

Nasacort® (triamcinolone acetonide)

U.S.	**E.U.**	**Japan**
Compound: expired	Compound: expired	Compound: expired
Secondary: formulation and method of use 2016	Secondary: formulation 2017	Secondary: formulation 2017 (application pending)
Generic licensed as early as 2011[1]		

Xatral® (alfuzosin hydrochloride)

U.S.	**E.U.**	**Japan**
Compound: expired	Compound: expired	Compound: expired
Secondary: formulation 2017	Secondary: formulation 2017	Secondary: formulation 2017
Regulatory exclusivity: expired June 2008		

Tritace® (ramipril)

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

Amaryl® (glimepiride)

U.S.	**E.U.**	**Japan**
Compound: expired	Compound: expired	Compound: expired
Genericized	Genericized	Regulatory exclusivity until March 2009

[1] License granted to Barr in settlement of patent litigation.

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, Allegra® in the United States and Plavix® in Germany.

In 2008, we agreed to settle certain U.S. patent litigation pertaining to Allegra®, Allegra® D-12 Hour and Nasacort®. As disclosed in Note D.22.b) to our consolidated financial statements included at Item 18 of this annual report, we are involved in significant litigation concerning the patent protection of a number of products.

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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.

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. This period is reduced to four years if the ANDA includes a challenge to a patent listed in the FDA s list of Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the 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 a 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 Canada, an Abbreviated New Drug Submission may be filed with respect to a generic version of an existing drug only after data exclusivity has expired, and a stay on regulatory approval of a generic for up to 24 months may be obtained if a listed patent is asserted.

In the European Union, a generic drug manufacturer may 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 bar the competent authorities from granting the marketing approval by bringing patent infringement litigation prior to approval. As a result, generic products may be approved for marketing following the expiration of marketing exclusivity without regard to the patent holder s rights.

Nevertheless, in most of these jurisdictions once the product is launched and in some jurisdictions already before (once launch is imminent), the patent holder can seek an injunction against this marketing if its patents are infringed. See Item 8. Financial Information A. Consolidated Financial Statements and Other Information Information on Legal or Arbitral Proceedings and 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 because of such factors 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.

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Trademarks

Our products are sold around the world under brand-name trademarks that we consider to be of material importance in the aggregate. It is our policy to register our trademarks worldwide, and to monitor the trademarks in our portfolio and defend them worldwide.

The degree of trademark protection varies country by country, as each state implements its own laws applicable 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. Thus we outsource a part of the production of the active ingredients used in Stilnox® or 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.

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, 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. In 2008, we recalled a limited number of batches of Lovenox® and depreciated substantial unused stocks following the discovery of impurities in raw materials purchased from a Chinese supplier.

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 and Argentina.

All 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 and Kansas City 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.

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More details about our manufacturing sites are set forth below under 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 for compliance with them. This investment, which aims to respect health, safety and the environment, varies from year to year and totaled approximately 120 million in 2008.

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 company, 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 company 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 company 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 2008, sanofi-aventis spent more than 48 million on rehabilitating sites previously contaminated by ground pollution. As of December 2008, the most comprehensive review possible had been carried out of the legacy of environmental pollution. In light of data collected during this review, the Group adjusted the provisions to approximately 589 million as at December 31, 2008.

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.

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

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and that all the environmental permits required to operate our facilities have been obtained. Regular HSE audits (45 in 2008) are carried out by the Group in order to detect possible instances of non-compliance with regulations and to initiate corrective measures. Moreover, 88 loss prevention technical visits were carried out in 2008.

Sanofi-aventis has implemented a worldwide 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 policy to be an integral part of our commitment to social responsibility. In order to implement this policy, 77 rules 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 COVALIS committee classifies all chemical and pharmaceutical products handled within the Group and establishes workplace exposure limits for each of them. The 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.

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 a rigorous policy to identify and evaluate risks and to develop preventive 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 thresholds). In accordance with the 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

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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 the 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. 34 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. As of January 1, 2008, six of the Group s European sites were included in the scope of the European CO_2 Emissions Credit Trading Scheme aimed at helping to reach the targets set by the Kyoto protocol.

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 11% and our direct and indirect carbon dioxide emissions in relation to our activity levels per unit produced by 10%.

In order to assess the environmental impact of the pharmaceutical agents found in products marketed by sanofi-aventis, a committee of experts called ECOVAL has been set up. 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 2006, 2007 and 2008 can be found at Note D.35. to our consolidated financial statements included at Item 18 of this annual report.

The following market shares and ranking information is based on sales data from IMS Health MIDAS, retail and hospital, for calendar year 2008, in constant euros (unless otherwise indicated). For more information, see Presentation of Financial and Other Information at the beginning of this document.

Marketing and Distribution

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

the United States, also the world s largest pharmaceutical market

We rank 12th in the United States with a 3.45% market share. Key events in 2008 include:

- strong performance of Lovenox®, Taxotere® and Lantus® driven by SoloSTAR®;
- the transfer of the Copaxone® business to Teva effective April;
- the full-year effect of the launch in October 2007 of our prescription allergy treatment Xyzal®.

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Europe

We are France s leading pharmaceutical company, but were affected during 2008 by growing competition from generics for several of our products and public authorities cost containment measures. Our market share is 13.14%. Plavix®, Lovenox®, Taxotere® and Lantus® are the top-selling products in their respective fields. In 2008, Lovenox® shipments were affected by the impact on inventories of low levels of an impurity in some batches.

We rank second in Germany, with a 5.7% market share. Our major products are Plavix®, Lovenox®, Lantus® and Taxotere®. In 2008, we had to face the launch of two clopidogrel besylates competing with Plavix® in the monotherapy segment, and public authorities cost containment measures.

Japan

We rank 10th in Japan with a 2.8% market share, representing a sharp rise versus 2007, with a strong contribution from Plavix®. Our main products are Allegra®, Amaryl®, Taxotere® and zolpidem tartrate, sold under the brand name Myslee®. Key events in 2008 include:

- strong ramp-up of Plavix® and Myslee® sales;
- launch of Lantus® SoloSTAR®;
- approval of Taxotere® in the treatment of prostate cancer.

We are also enhancing our presence in certain developing markets with significant growth prospects, especially Brazil, Russia, India, China, and Mexico. 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, 2008 Compared with Year Ended December 31, 2007.

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

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

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. Throughout 2008 we carried on our worldwide project initiated in 2007 aimed at increasing our sales forces competitiveness and productivity. It resulted in the deployment of new management tools and the building of a more customer-focused selling model, that more comprehensively takes into consideration all

stakeholders in access to medicine decisions.

We have a global sales force of some 33,500 representatives, including approximately 10,400 in Europe, 7,600 in the United States, 1,800 in Japan and 2,300 in China.

We also use modern communication tools in our relations with healthcare professionals and patients, such as websites, to reinforce communication about our mature products and accelerate the penetration of our more recent products.

As most pharmaceutical companies do, 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 are used to improve patients coverage on 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 below under Alliances .

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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.

Alliances

We have two principal alliances through which three of our main products are marketed. The first, with Bristol-Myers Squibb, governs the development and marketing of Plavix® and Aprovel®/CoAprovel®. The second, with Procter & Gamble Pharmaceuticals, governs the development and commercialization of Actonel®. We also have a marketing agreement with Teva Pharmaceutical Industries regarding Copaxone®.

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.

Bristol-Myers Squibb (BMS)

We market Plavix® and Aprovel® 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 through license and sub-license agreements signed with BMS. The BMS alliance does not cover rights to Plavix® in Japan.

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

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

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

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). Since September 2006, we have had the exclusive right to market Aprovel® in 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.

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Procter & Gamble Pharmaceuticals (P&G)

We in-license Actonel® from P&G. An alliance with P&G was concluded 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 with P&G 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.

Under the alliance arrangements with P&G, there are five principal territories with different marketing arrangements:

*co-promotion territor*y: the product is jointly marketed through the alliance arrangements under the brand name Actonel® with sales booked by P&G. 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. The United Kingdom was also included until December 31, 2008. P&G 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 Italy. In Italy the product is sold under the brand name Actonel® by P&G 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 P&G and under the brand name Actonel® by sanofi-aventis;

P&G only territory: the product has been marketed by P&G independently under the brand name Actonel® 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;

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.

Teva Pharmaceutical Industries (Teva)

We in-license Copaxone® from Teva and market it through an agreement with Teva, which was originally concluded in 1995, and has been amended several times, most recently in 2005.

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

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

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 shares certain marketing expenses with respect to the United States and Canada and, for a period of two years, will receive from Teva a royalty of 25% of sales in these markets.

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Under the terms of our agreement, the Copaxone® business in countries other than the United States and Canada will be transferred to Teva over a period running from the fourth quarter of 2009 to the first quarter of 2012 at the latest, depending on the country.

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 position relative to the competition.

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.

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; Eli Lilly in osteoporosis, diabetes and oncology; GlaxoSmithKline in oncology, allergies, diabetes and thrombosis; Merck & Co. in hypertension, osteoporosis, diabetes and benign prostatic hyperplasia; Novartis in hypertension and oncology; Novo Nordisk in diabetes; Pfizer in antibiotics, oncology, thrombosis and allergies; and Roche in oncology and osteoporosis.

In our vaccines business, we compete primarily with Merck & Co, GlaxoSmithKline, Wyeth and Novartis.

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 going off patent.

Generics manufacturers who have received all necessary regulatory approvals for a product may decide to launch a generic version before the patent expiry date. This 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 of the risk it will be required to pay damages to the owner of the original product; however, they may also significantly impair the profitability of the pharmaceutical company whose product is challenged.

Another competitive issue drug manufacturers are facing is the increasing incidence of parallel trade, also known as reimportation. This takes place when drugs sold abroad under the same brand name as in a domestic market, are then 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 for a product arising from factors including sales costs, market conditions (such as intermediate trading stages), tax rates, or national regulation of prices.

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Finally, pharmaceutical companies face illegal competition from counterfeit drugs. The WHO estimates that counterfeit products account for 10% of the market worldwide, rising to as much as 30% in some countries. However, in markets where powerful regulatory controls are in place, counterfeit drugs are estimated to represent less than 1% of market value. The WHO also estimates that 50% of sales over the Internet are of counterfeit drugs.

Regulation

The global production and distribution of pharmaceuticals is highly regulated. National and supranational regulatory authorities administer a vast array of laws, directives and regulations that dictate the pre-approval testing, and the quality standards, in order to ensure safety and efficacy of a new drug. 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 product approval, or 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 data before and also after granting an approval, even though the relevant product has already been approved in one or several other countries. Regulatory authorities also have the authority to request product recalls, seizure of products and other penalties for violations of regulations based on data that are made available to them.

Europe, the United States, Japan and other Health Authorities 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 among the United States, the European Union, Japan and also other regions 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.

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 (EMEA), 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 compulsory for medicinal products derived from biotechnology and for drugs intended to treat certain conditions and is also available at the request of companies for any other innovative products. In the Centralized Procedure the license application is submitted directly to the EMEA. The Committee for Medicinal Products (CHMP) evaluates the application for human use. The European Commission makes the final binding decision. Once granted, an approval via the Centralized Procedure is valid

throughout the European Union without further action and the drug may be marketed within all European Union member states;

the Mutual Recognition Procedure (MRP) operates by having one country (*i.e.*, the Reference Member State, RMS) carry out the primary evaluation of a new compound. Once the first license is granted by the RMS, other European Union member states (Concerned Member States, CMS) must then decide whether they will accept, request clarifications or reject the approval granted by the RMS; and

the Decentralized Procedure applies to products that have not yet obtained a marketing authorization in a European member state. The key procedural difference compared to the Mutual Recognition Procedure is that an initial evaluation is done by the RMS with all the CMS being involved earlier in the process by contributing to the draft assessment report.

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The EMEA has introduced a series of initiatives aiming at improving the openness and the transparency of its activities, such as procedures dealing with the publication of the European Public Assessment Report (for approved, withdrawn or rejected projects), which will now be more detailed. New initiatives are being proposed with regard to the publication of question and answer documents and of safety bulletins on medicines for human use.

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.

A new regulation in pediatric development came into force in January 2007 with implementation ongoing until 2009. 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).

Generic drugs are subject to harmonized European procedures in all countries of the European Union. A generic drug contains the same active medicinal substance as an originator pharmaceutical 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 drugs can be filed and approved by the European Union Health Authorities only after the eight year data exclusivity period has expired. Further, generic manufacturers can only market their generic products after a 10- or 11-year period from the date of approval of the reference product has elapsed.

In the United States, applications for drug approval are submitted for review by the U.S. Food and Drug Administration (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).

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).

Once marketing authorization is granted, the new drug may be prescribed by physicians. Thereafter, the drug owner must submit periodic reports to the regulatory authorities including assessment of adverse reactions. For some medications, regulatory authorities may require additional studies to evaluate long-term effects or to gather information on the use of the product under special conditions. In addition, manufacturing facilities must be approved by regulatory authorities, and are subject to periodic inspections. Non-U.S. manufacturing facilities that export products for sale in the United States must be approved by the FDA in addition to local regulatory approvals, and are also subject to periodic FDA inspections.

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 to demonstrate that their product is bioequivalent, *i.e.*, that it performs in humans in the same manner as the

innovator s product. Consequently, the length of time and cost required for development of such product can be considerably less than for the innovator s drug. See Patents, Intellectual Property and Other Rights , above, for additional information. The ANDA procedures in the United States can be used exclusively 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 also require data to determine

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the appropriateness of the dosages for Japanese patients. In the past, these additional procedures have created differences of several years in the registration dates of some of our products in Japan compared to our other major countries.

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., antibodies, insulins, vaccines). Most biologics are complex molecules or mixture of molecules which are difficult if not impossible to fully characterize. For the characterisation and determination of these products quality a combination of physico-chemical-biological testing, together with their production process and its control, is needed.

Consequently the concept of generic cannot apply to most of these products; it is the concept of biosimilar products that must be considered. Because the cost of developing and maintaining the industrial expertise and capacity required to manufacture biologicals and, follow-on versions of a biologic (so-called biosimilar versions) frequently face cost structures and development times similar to that of the reference product, as well as the time and expense of clinical trials. Indeed the simple bioequivalence study used for traditional generics is normally insufficient where biologicals are concerned. For these reasons, applications with respect to proposed biosimilar versions of biologics have in practice been substantially less frequent than generic applications with respect to traditional synthetic chemical drugs.

In the European Union, a specific regulatory scheme has been in place since 2003 which establishes an abbreviated procedure for registration of biosimilar versions of existing biological drugs. The CHMP has issued several guidelines on specific classes of biosimilar products. Biosimilar applications frequently require preclinical and clinical trials to be conducted in healthy subjects and patients in order to demonstrate safety and efficacy. With respect to vaccines in particular, 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. With respect to Low Molecular Weight Heparins (LMWH) such as Lovenox®, the draft Guideline on Similar Biological Medicinal Products Containing LMWHs issued by the CHMP in April 2008 addresses in its clinical section the efficacy and safety studies to be conducted for demonstrating two LMWHs being similar biological medicinal products. We therefore expect that in final CHMP guidance clinical trials will be required prior to registration of a biosimilar version of LMWH.

In Japan a draft guideline on biosimilar products has been released in September 2008 for public comments.

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. Inclusion of an abbreviated pathway for these products 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 be used notably 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, notably 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.

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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 utilizing 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.

In the United States, the 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 approximately 16.9% of the U.S. population. 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 but does not manage. While they cannot directly control prices, 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. However, the new Democratic leadership in both the presidency and Congress has announced an intention to seek reform that could increase direct government involvement throughout the healthcare system in issues involving cost, equality and coverage.

Outside the United States, governments frequently directly control pricing and reimbursement of drugs. Some of these countries, especially in the European Union, either currently have or are considering reimbursement limitations based on comparative effectiveness data, in addition to traditional clinical efficacy and safety criteria. Other issues include decentralization of healthcare authority in some countries, as well as parallel importation in many markets. All of these factors, which are specific to each country, represent additional financial and logistical challenges to pharmaceutical organizations.

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, drawing 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.

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

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Our captive, which participates in the first three of these programs, is run as an insurance company under the supervision of the Irish regulatory authorities, 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 two 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 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 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.

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. Our cover has been designed to reflect our risk profile and the capacity available in the insurance market. By centralizing our major programs, not only do we reduce costs, but we also provide world-class coverage for the entire Group.

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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, 2008. 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%
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 US LLC	United States	100%
Sanofi-aventis US Inc.	United States	100%
Sanofi Pasteur Inc.	United States	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 business segments: pharmaceutical products and human vaccines.

The patents and trademarks of the pharmaceuticals 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 Alliances, 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 worldwide headquarters and principal executive offices are located in Paris, France. Our U.S. headquarters are located in Bridgewater, New Jersey.

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.

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Breakdown of sites by nature

Industrial	55%
Research	14%
Offices	24%
Logistics	7%

Research and Development Sites for the Pharmaceutical Activity

Research and Development activities are housed at 29 sites:

- 13 sites in France, the largest in terms of surface area being in Vitry/Alfortville (approximately 96,000 sq.m), Montpellier (78,000 sq.m), Chilly/Longjumeau (77,000 sq.m) and Toulouse (38,000 sq.m);
- 7 sites in other European countries (Germany, United Kingdom, Hungary and Italy), the largest being in Frankfurt, Germany (84,000 sq.m). In Italy, a Research center located in Milan was inaugurated in May 2008;
- 5 sites in the United States, the largest being in Bridgewater, New Jersey (111,000 sq.m);
- 2 sites in Japan, in Tokyo and Kawagoe;
- 2 sites 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 Directorate, which is also in charge of most of our logistics facilities (distribution and storage centers).

We have 64 industrial sites worldwide. The sites where the major sanofi-aventis drugs, active ingredients and medical devices are manufactured are:

- France: Ambarès (Aprovel®, Depakine®), 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);

Italy: Scoppito (Tritace®, Amaryl®);

United Kingdom: Dagenham (Taxotere®), Fawdon (Plavix®, Aprovel®);

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

United States: Kansas City (Allegra®, Amaryl®).

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) and Pilar (Argentina).

Breakdown of sites between owned and leased

Leased	72%
Owned	28%

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.

* Sites acquired in 2008 with Acambis.

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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. 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.

Capital Expenditures and Divestitures

The book value of our property, plant and equipment at December 31, 2008 was 6,961 million. During 2008, we invested 1,359 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 divestitures for the years 2008, 2007 and 2006 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. Significant Acquisitions , Note D.2. Significant Divestments and Note D.4. Intangible assets and Goodwill).

Our principal investments in progress are related to:

- the Pharmaceutical activity with the construction or expansion of several Research and Development facilities in France (Chilly/Longjumeau, Montpellier, Toulouse, Massy and Vitry/Alfortville) and the United States (Tucson, Az.) and the construction of a filling and conditioning lines in Le Trait (France);

- the Vaccines activity with the construction of a state-of-the-art research facility in Toronto (Canada), the creation of a new vaccine campus in Neuville (France), the construction of formulation and filling facilities in Val de Reuil, of a bacteriological bulk facility in Marcy l Etoile (France), of a flu bulk facility in Shenzhen (China) and the finalization of bulk and filling facilities in Swiftwater (United States), mainly dedicated to influenza and meningitis.

We believe that our existing cash resources and unused credit facilities will be sufficient to finance these investments.

Item 4A. Unresolved Staff Comments

N/A

Item 5. Operating and Financial Review and Prospects

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

Our consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and with IFRS adopted by the European Union as of December 31, 2008.

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.

2008 Overview

During 2008, sanofi-aventis once again demonstrated its ability to meet the challenge of delivering solid performances in a global market undergoing profound upheavals.

We generated net sales for the year of 27,568 million, an increase of 3.7% on a comparable basis (excluding the effects of exchange rates and changes in Group structure, See Presentation of Net Sales below) relative to 2007, driven by very good performances from flagship products such as Lantus®, Lovenox®,

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Taxotere®, Plavix® and Aprovel®, and by the buoyancy of our human vaccines business. Sales growth in Europe was again hampered by the impact of generics of Eloxatine®, and over the closing months of the year by competition from clopidogrel besylates in Germany affecting part of the market for Plavix®. On the positive side, we continued to record growth ahead of the market in the United States, despite the impact of generics of Ambien® IR from the second quarter of 2007. We also achieved double-digit growth in emerging markets during 2008. In the fourth quarter of 2008, the U.S. Court of Appeals for the Federal Circuit upheld an earlier favorable ruling in the Plavix® patent infringement suit brought against a generics manufacturer, thereby also upholding the injunction preventing that manufacturer from selling a generic of Plavix® until the patent protection expires.

We also continued with measures to adapt our resources in Europe and the United States during 2008, resulting in a further improvement in operating ratios. Our selling and general expenses fell by 5.1%, and represented just 26.0% of our net sales compared with 26.9% in 2007.

Operating income before restructuring, impairment of property, plant and equipment and intangibles, gains/losses on disposals, and litigation rose by 5.7% in absolute terms in 2008, to 6,457 million (+1.6 points of net sales), largely as a result of the reduction in selling and general expenses (-0.9 of a point of net sales).

Operating income fell by 25.7% to 4,394 million (-5.1 points of net sales), reflecting the recognition of impairment losses on intangible assets (1,554 million, versus 58 million in 2007) and restructuring costs (585 million, versus 137 million in 2007).

Net income attributable to equity holders of the Company for 2008 was 3,851 million against 5,263 million for 2007. Our adjusted net income amounted to 7,068 million in 2008, 0.6% lower than in 2007 (7,110 million), mainly due to restructuring costs (389 million, versus 95 million in 2007, net of taxes). Adjusted net income represented 25.6% of net sales in 2008, compared with 25.3% in 2007.

Adjusted net income is a non-GAAP financial measure which our management uses to monitor our operational performance, and which is defined at Sources of Revenues and Expenses Adjusted Net Income, below.

Earnings per share (EPS) for the year ended December 31, 2008 was 2.94, compared with 3.91 for the previous year (based on an average number of shares outstanding of 1,309.3 million in 2008 and 1,346.9 million in 2007). Adjusted earnings per share (adjusted EPS) was 5.40 for 2008, 2.3% higher than the 2007 figure (5.28), with the year-on-year trend boosted by the implementation of the 3 billion share repurchase program authorized by the Shareholders Annual General Meeting in May 2007.

Our operations generate significant cash flow. We recorded 8,523 million of net cash provided by operating activities in 2008 against 7,106 million in 2007. In 2004, we incurred significant debt to finance the acquisition of Aventis. As of year end 2008, we have reimbursed substantially all of this debt. In terms of financial position, we ended 2008 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) reduced to 1.8 billion (2007: 4.2 billion) despite share repurchases of 1.2 billion and a dividend payout of 2.7 billion in 2008. 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 improved from 9.5% at the end of 2007 to 3.9% at the end of 2008. See Liquidity and Capital Resources Consolidated Balance Sheet and Debt , below.

In response to the profound changes in our markets and the challenges facing the pharmaceutical industry over the coming years, our Board of Directors recommended the adoption of a new strategy, and announced its decision to appoint Christopher Viehbacher to oversee the implementation of this strategy as Chief Executive Officer with effect from December 1, 2008.

Our new strategic vision hinges on three priorities: establishing a new R&D model, adapting our structures to meet the challenges of the future, and exploring external growth opportunities. The broad outlines of this new vision were unveiled to coincide with the announcement of our 2008 full-year results.

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We stepped up our acquisitions and alliances policy during 2008. In June, we announced an offer for the entire share capital of Zentiva N.V., in which we already own a 24.88% stake. Zentiva offers a portfolio of branded equivalent drugs tailored to the needs of markets in Central and Eastern Europe. The offer period expired on February 20, 2009 and on February 25, 2009 sanofi-aventis announced that enough shares had been tendered to bring its holding to about 94%. The offer closes on March 11, 2009. In the field of vaccines, we acquired Acambis plc in September. Acambis plc has a portfolio that includes a smallpox vaccine, three programs in clinical development (previously conducted under collaboration agreements with sanofi pasteur) to develop and market vaccines against Japanese encephalitis, dengue fever and West Nile virus, and novel early stage programs in clostridium difficile, influenza and genital herpes. Also in September, we acquired Symbion CP Holdings Pty Ltd, an Australian company specializing in nutraceuticals (vitamins and mineral supplements) and over the counter medicines. In biotechnologies, we signed a number of alliance and license agreements (principally with Dyax Corp. in February and with Novozymes in December), giving us access to new technologies and expanding or enhancing our expertise in our existing research fields.

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

Our results of operations and financial condition for the years ended December 31, 2008, December 31, 2007 and December 31, 2006 have been significantly affected by our August 2004 acquisition of Aventis and certain subsequent transactions.

The acquisition gave rise to significant amortization (3,298 million in 2008, 3,511 million in 2007 and 3,866 million in 2006) and impairments of intangible assets (1,503 million in 2008, 58 million in 2007 and 946 million in 2006).

In order to isolate the impact of these items, we use as an evaluation tool a non-GAAP financial measure that we refer to as adjusted net income. For a further discussion and definition of adjusted net income , see Sources of Revenues and Expenses Adjusted Net Income, below. For consistency of application of this principle, adjusted net income is also adjusted for the impact of our subsequent acquisitions.

Adjusted net income breaks down as follows:

(*million, except per share data)*	2008	2007	2006
Net income attributable to equity holders of the Company	**3,851**	**5,263**	**4,006**
Material accounting adjustments related to business combinations	**3,217**	**1,847**	**2,969**
elimination of expense arising on the workdown of acquired inventories remeasured at fair value, net of tax	2(1)		21
elimination of expenses arising on amortization and impairment of intangible assets, net of tax (portion attributable to equity holders of the Company)	3,137(2)	1,684(3)	2,935
elimination of expenses arising from the impact of the acquisitions on equity investees (workdown of acquired inventory, amortization and impairment of intangible assets, and impairment of goodwill)	78(4)	163(4)	13(5)
elimination of impairment losses charged against goodwill			
Elimination of acquisition-related integration and restructuring charges, net of tax			**65**
Adjusted net income	**7,068**	**7,110**	**7,040**
Adjusted earnings per share (in euro) (6)	**5.40**	**5.28**	**5.23**

(1) Impact of the acquisition of Symbion Consumer (see Note D.1. to our consolidated financial statements included at Item 18 of this annual report).

(2) Includes 1,485 million of impairment losses (972 million net of tax) on Aventis intangible assets. (see Note D.5. to our consolidated financial statements included at Item 18 of this annual report).

(3) Includes a gain of 566 million due to the effect of cuts in tax rates (primarily in Germany) on deferred tax liabilities recognized in 2004 on the remeasurement of acquired intangible assets of Aventis.

(4) Includes the impact of the Zentiva acquisition: 3 million in 2008, and 108 million in 2007 (including 102 million of impairment losses on the investment in Zentiva).

(5) Includes the impact of the Zentiva acquisition (11 million); amortization and impairment (net of tax) associated with the acquisition of Aventis (97 million); and reversal of a deferred tax liability relating to the investment in Merial (95 million).

(6) Based on 1,309.3 million shares for 2008, 1,346.9 million shares for 2007 and 1,346.8 million shares for 2006, representing the weighted average number of shares outstanding.

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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 the consolidated financial statements included at Item 18 of this annual report. We sell pharmaceutical products and human vaccines directly, through alliances, and through licensees throughout the world. When we sell products directly, we record sales revenues as part of our consolidated net sales. When we sell products through alliances, the revenues reflected in our consolidated financial statements are based on the overall level of sales of the products and on the arrangements governing those alliances. For more information about our alliances, see Financial Presentation of Alliances, below. When we sell products through licensees, we receive royalty income that we record in Other revenues. See Note C. to the consolidated financial statements included at Item 18 of this annual report.

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

Adjusted Net Income. We believe that investors understanding of our operational performance following the combination of Sanofi-Synthélabo and Aventis is enhanced by disclosing our adjusted net income.

We define adjusted net income, an unaudited non-GAAP financial measure, as net income attributable to equity holders of the Company determined under IFRS, adjusted to exclude (i) the material impacts of the application of purchase accounting to acquisitions (primarily the Aventis acquisition) and (ii) certain acquisition-related integration and restructuring costs. We view adjusted net income as an operating performance measure and believe that the most directly comparable IFRS measure is net income attributable to equity holders of the Company.

Non-GAAP adjusted net income excludes the effects of purchase-accounting treatment under IFRS related to acquisitions (primarily our acquisition of Aventis). We believe that excluding these non-cash charges will enhance an investor s understanding of our underlying economic performance after the combination with Aventis because we do not consider that the excluded charges reflect the combined entity s ongoing operating performance. Rather, we consider that each of the excluded charges reflects the decision to acquire the businesses concerned.

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

- the charges to cost of sales resulting from the workdown of acquired inventory that was written up to fair value, net of tax;
- the charges related to the impairment of the goodwill; and
- the charges related to the amortization and impairment of intangible assets, net of tax and minority interests.

For the periods under review the principal non-Aventis adjustments relate to the impact of the acquisition of a minority stake in Zentiva (purchased in 2006). The purchase-accounting effects of this acquisition on 2008 net income primarily relate to the amortization of Zentiva intangible assets (3 million). The purchase-accounting effects on 2007 net income primarily relate to impairment losses on the investment in Zentiva (102 million). The purchase-accounting effects on 2006 net income primarily relate to the charges to cost of sales resulting from the workdown of acquired inventory that was written up to fair value, net of tax and to the charges related to the amortization and impairment of Zentiva definite-lived intangible assets. Zentiva is accounted for as an associate using the equity method.

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We believe (subject to the material limitations discussed below) that disclosing non-GAAP adjusted net income also enhances the comparability of our ongoing operating performance. The elimination of the non-recurring items, such as the increase in cost of sales arising from the workdown of inventories remeasured at fair value, improves comparability between one period and the next. Lastly, we believe that the elimination of charges related to the amortization of definite-lived intangible assets also 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.

As a result of the acquisition of Aventis, we have incurred significant integration and restructuring costs. We believe it is appropriate to exclude these costs from non-GAAP adjusted net income because they are directly and only incurred in connection with the acquisition of Aventis. As of year-end 2006, the Company had incurred all the announced integration and restructuring costs related to the acquisition of Aventis and the subsequent merger. No such cost was incurred in 2007 and 2008.

Our management uses and intends to use non-GAAP adjusted 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, to assist investors in analyzing the factors and trends affecting our business performance. We also report non-GAAP adjusted net income as a subtotal in reporting our segment information. See Note D.35. to our consolidated financial statements included in Item 18 of this annual report. Our management also uses the measure as a component in setting incentive compensation targets, because it better measures the underlying operational performance of the business and excludes charges over which managers have no control. Our management also uses adjusted net income as the basis for proposing dividend policy for the Group. Accordingly, management believes that an investor s understanding of trends in our dividend policy is enhanced by disclosing non-GAAP adjusted net income.

We have also decided to report adjusted earnings per share. Adjusted earnings per share is a specific financial indicator, which we define as adjusted net income divided by the weighted average number of shares outstanding. Our management also intends to give earnings guidance based on adjusted earnings per share.

We remind investors, however, that non-GAAP adjusted net income should not be considered in isolation from, or as a substitute for, net income 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 non-GAAP adjusted net income as compared to the use of IFRS net income in evaluating our performance, as described below:

The results presented by non-GAAP adjusted net income cannot be achieved without incurring the following costs that the measure excludes:

Amortization of identifiable intangible assets acquired, primarily from Aventis. Although this 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 the identifiable intangible assets of Aventis (principally patents and trademarks). We paid an aggregate of 31,279 million for these intangible assets (which, in general, will be amortized over their useful lives, which represents an average amortization period of eight years). A large part of our revenues after the combination could not be generated without owning these assets. Also, a significant portion of the purchase price paid for these assets has been financed by debt obligations, a portion of which will continue to be repaid in cash in the future. Further, if we do not continuously replace revenue-generating

intangible assets as they become unproductive (for example, through researching and developing new pharmaceutical products), we may not be able to maintain or grow our revenues.

Integration and restructuring costs. Non-GAAP adjusted net income does not reflect any integration and restructuring costs even though it reflects any synergies that arise from the merger of sanofi-aventis and Aventis.

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The difference in treatment of similar charges may complicate the use of non-GAAP adjusted net income as a comparative measure:

Amortization of identifiable intangible assets. Non-GAAP adjusted net income reflects amortization charges related to intangible assets that we owned at the time that we acquired Aventis and to intangible assets that we may acquire after that acquisition, even though non-GAAP adjusted net income will not reflect the amortization charges related to identifiable intangible assets acquired from Aventis and potential future other business combinations.

We compensate for the above-described material limitations by using non-GAAP adjusted 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 non-GAAP adjusted 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 non-GAAP adjusted 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 non-GAAP adjusted net income, our management intends to take into account the fact that the adjustments reflected in non-GAAP adjusted net income have no effect on the underlying amount of cash available to pay dividends, and that 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 discussion and analysis of adjusted net income on the basis of consolidated financial data. Because our non-GAAP adjusted net income is not a standardized measure, it may not be comparable with the non-GAAP financial measures of other companies having the same or a similar name.

Presentation of Net Sales

In the discussion below, we present our consolidated net sales for 2008, 2007 and 2006. 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 also present and discuss comparable sales, another unaudited non-GAAP indicator that we believe is a useful measurement tool to explain changes in our reported net sales.

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 percentage for consolidated entities). For any two periods, we exclude the impact of exchange rates by recalculating net sales for the earlier period on the basis of exchange rates used in the later period. We exclude the impact of acquisitions by including sales for a portion of the prior period equal to the portion of the current period during which we owned the entity or product rights based on sales information we receive from the party from whom we make the acquisition. Similarly, we exclude sales in the relevant portion of the prior period when we have sold an entity or rights to a product. If there is a change in the consolidation percentage of a consolidated entity, the prior period is recalculated on the basis of the consolidation method used for the current period.

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 and Results of Operations Year Ended December 31, 2007 compared with Year Ended December 31, 2006 Net Sales below.

Financial Presentation of Alliances

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

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Bristol-Myers Squibb (BMS) Alliance

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), 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 a discovery royalty on all sales of Aprovel® and Plavix® 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®. Each legal entity that markets products pays a development royalty. We record development royalties paid to BMS in our consolidated income statement as an increase to our cost of sales in countries where we consolidate sales of the products. We record development royalties that we receive as other revenues in countries where BMS consolidates sales of the products.

Under the alliance arrangements, there are two territories, one under our operational management and the other under the operational management of BMS. The territory under our operational management consists of Europe and most of Africa and Asia, while the territory under the operational management of BMS consists of the rest of the world (excluding Japan). In Japan, Aprovel® has been marketed jointly by Shionogi Pharmaceuticals and Dainippon Sumitomo Pharma Co.Ltd since June 2008 through license and sub-license agreements entered into with BMS. 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 of 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). Since September 2006, we have had the exclusive right to market Aprovel® in Scandinavia and in Ireland.

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

- we use the co-promotion system in the United States 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.

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 .

Procter & Gamble Pharmaceuticals (P&G) Alliance

The agreement with P&G covers the worldwide development and marketing arrangements of Actonel®, except Japan for which we hold no rights. The local marketing arrangements may take various forms.

- *Co-promotion,* whereby sales resources are pooled but only one of the two partners invoices product sales. Co-promotion is carried out under contractual agreements and is not based on any specific legal entity. P&G sells the product and incurs all the related costs for the following countries: United States, Canada and France. This co-promotion scheme also included Germany, Belgium and Luxembourg until December 31, 2007 and the Netherlands until March 31, 2008. We recognize our share of income under the agreement in the income statement as a component of operating income on the line 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 in our consolidated income statement;

- *Co-marketing*, which applies in Italy and Spain, whereby each partner sells the product in the country under its own brand name and recognizes all revenues and expenses from its own operations in its income statement;

- *P&G only territories*: the product has been marketed by P&G independently under the brand name Actonel® 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; 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 P&G 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 2008, we earned 31.2% 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

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of our alliance with BMS in the United States, which is under the operational management of BMS, as described in Financial Presentation of Alliances BMS Alliance 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.

Divestments

There were no significant divestments during 2008 and 2007.

Our main divestment during 2006 was the transfer of our rights to Exubera® and our interest in the Diabel joint venture to Pfizer. In return for the transfer of these assets and rights, sanofi-aventis received a payment of $1.3 billion (net of German taxes). The impact of this transaction in 2006 was a pre-tax gain of 460 million, recognized in ***Gains and losses on disposals, and litigation***, and an after-tax gain of 384 million.

Acquisitions

The principal acquisitions during 2008 were as follows:

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 S.A. 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.4. to our consolidated financial statements included at item 18 of this annual report.

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 around AUD190 million. Symbion Consumer is the market leader in Australia, with an estimated 21% market share. See Note D.4. to our consolidated financial statements included at item 18 of this annual report.

The principal acquisition during 2007 was as follows:

In June 2007, sanofi-aventis bought out preferred shares representing a financial interest of 36.7% in Carderm Capital LP for $250 million. (See Note D.18.4. to our consolidated financial statements included at Item 18).

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).

The principal acquisition during 2006 was as follows:

On March 27, 2006, sanofi-aventis paid 433 million (including acquisition costs) to acquire the entire interest in Zentiva N.V. (7,487,742 shares) held by Warburg Pincus, and a further 1,998,921 shares held by certain managers and employees of Zentiva. On completion of this transaction and as of December 31, 2008, sanofi-aventis held a 24.9% interest in the capital of Zentiva. Sanofi-aventis has appointed two members of Zentiva s Board of Directors. In 2008, sanofi-aventis made an offer to acquire all the shares of Zentiva (see Note D.21. to our consolidated financial statements included at Item 18).

As of December 31, 2008, sanofi-aventis does not control Zentiva, although as a result of its significant interest in Zentiva, this investment is accounted for using the equity method (see Note D.6. to our consolidated financial statements included at Item 18).

Zentiva is an international pharmaceutical company that develops, manufactures and markets low-cost branded pharmaceutical products. The company has very strong positions in the Czech Republic, Slovakia and Romania, and is expanding rapidly in Poland, Turkey, Russia and the Baltic countries.

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Results of Operations

Year Ended December 31, 2008 Compared with Year Ended December 31, 2007

The consolidated income statements for the years ended December 31, 2008 and December 31, 2007 break down as follows:

(under IFRS)	2008		2007	
(million)		as % of net sales		as % of net sales
Net sales	**27,568**	**100.0%**	**28,052**	**100.0%**
Other revenues	1,249	4.5%	1,155	4.1%
Cost of sales	(7,337)	(26.6%)	(7,571)	(27.0%)
Gross profit	**21,480**	**77.9%**	**21,636**	**77.1%**
Research & development expenses	(4,575)	(16.6%)	(4,537)	(16.2%)
Selling & general expenses	(7,168)	(26.0%)	(7,554)	(26.9%)
Other operating income	556	2.0%	522	1.9%
Other operating expenses	(353)	(1.3%)	(307)	(1.1%)
Amortization of intangibles	(3,483)	(12.6%)	(3,654)	(13.0%)
Operating income before restructuring, impairment of property, plant & equipment and intangibles, gains & losses on disposals, and litigation	**6,457**	**23.4%**	**6,106**	**21.8%**
Restructuring costs	(585)	(2.1%)	(137)	(0.5%)
Impairment of property, plant & equipment and intangibles	(1,554)	(5.6%)	(58)	(0.2%)
Gains and losses on disposals, and litigation	76	0.3%		
Operating income	**4,394**	**16.0%**	**5,911**	**21.1%**
Financial expenses	(335)	(1.2%)	(329)	(1.2%)
Financial income	103	0.4%	190	0.7%
Income before tax and associates	**4,162**	**15.2%**	**5,772**	**20.6%**
Income tax expense	(682)	(2.5%)	(687)	(2.5%)
Share of profit/loss of associates	812	2.9%	597	2.1%
Net income	**4,292**	**15.6%**	**5,682**	**20.2%**
- attributable to minority interests	441	1.6%	419	1.5%
- attributable to equity holders of the Company	**3,851**	**14.0%**	**5,263**	**18.7%**
Average number of shares outstanding (million)	1,309.3		1,346.9	
Basic earnings per share (in euros)	2.94		3.91	

Net Sales

Net sales for the year ended December 31, 2008 were 27,568 million, down by 3.7% on a comparable basis relative to 2007. Exchange rate movements had a negative effect of 3.9 points, nearly 75% of which was related to the U.S. dollar. Changes in Group structure had a negative effect of 1.5 points. After taking these effects into account, net sales fell by 1.7% on a reported basis.

The following table sets forth a reconciliation of our reported net sales for the year ended December 31, 2007 to our comparable net sales for that year based on 2008 exchange rates and Group structure:

(million)	2007
2007 Net Sales	**28,052**
Impact of changes in Group structure	(393)
Impact of exchange rates	(1,083)
2007 Comparable Net Sales	**26,576**

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Our net sales are generated by our two business segments: Pharmaceuticals and Human Vaccines (Vaccines). The following table breaks down our 2008 and 2007 net sales by business segment:

(million)	2008	2007 Reported	2007 Comparable	Reported basis growth (%)	Comparable basis growth (%)
Pharmaceuticals	24,707	25,274	23,965	-2.2%	+3.1%
Vaccines	2,861	2,778	2,611	+3.0%	+9.6%
Total	**27,568**	**28,052**	**26,576**	**-1.7%**	**+3.7%**

Net Sales by Product Pharmaceuticals

Our pharmaceutical business generated net sales of 24,707 million in 2008, up by 3.1% on a comparable basis and down by 2.2% on a reported basis.

Net sales of our top 15 products advanced by 5.2% on a comparable basis to 16,657 million in 2008, representing 67.4% of pharmaceutical net sales against 67.5% in 2007 (on a comparable basis). The introduction of generics of Ambien® IR in the United States and of Eloxatine® in Europe (i.e. excluding net sales of Ambien® IR in the United States in the first quarter of 2007 and in the first quarter of 2008, and of Eloxatine® in Europe in 2007 and 2008) pared around 2.2 points off growth (on a comparable basis).

Net sales of other pharmaceutical products fell by 1.1% on a comparable basis to 8,050 million in 2008. Sales of these products were down by 4.8% on a comparable basis in Europe (at 4,831 million) and up by 7.7% on a comparable basis in the United States (at 602 million) in 2008. In the Other Countries region, these products reported sales growth of 4.4% to 2,617 million.

For a description of our other pharmaceutical products, see Item 4. Information on the Company B. Business Overview Other Pharmaceutical Products.

The following table breaks down our net sales for the pharmaceutical business by product:

(million)					Reported basis growth	Comparable basis growth
Product	**Indication**	**2008**	**2007 Reported**	**2007 Comparable**	**(%)**	**(%)**
Lovenox®	Thrombosis	2,738	2,612	2,475	+4.8%	+10.6%
Plavix®	Atherothrombosis	2,616	2,424	2,368	+7.9%	+10.5%
Lantus®	Diabetes	2,450	2,031	1,918	+20.6%	+27.7%
Taxotere®	Breast, Non small cell lung, Prostate, Gastric, Head and neck cancers	2,033	1,874	1,796	+8.5%	+13.2%
Eloxatine®	Colorectal cancer	1,348	1,521	1,430	-11.4%	-5.7%

Aprovel®/CoAprovel®	Hypertension	1,202	1,080	1,053	+11.3%	+14.2%
Stilnox®/Ambien®/Myslee®	Sleep disorders	829	1,250	1,258	-33.7%	-34.1%
Allegra®	Allergic rhinitis, Urticaria	688	706	674	-2.5%	+2.1%
Copaxone®	Multiple sclerosis	622	1,177	520	-47.2%	+19.6%
Tritace®	Hypertension, Congestive heart failure after myocardinal infarction	513	741	734	-30.8%	-30.1%
Amaryl®	Diabetes	387	392	392	-1.3%	-1.3%
Xatral®	Benign prostatic hyperplasia	331	333	320	-0.6%	+3.4%
Actonel®	Osteoporosis	330	320	309	+3.1%	+6.8%
Depakine®	Epilepsy	329	316	306	+4.1%	+7.5%
Nasacort®	Allergic rhinitis	241	294	274	-18.0%	-12.0%
Sub-total Top 15 products		**16,657**	**17,071**	**15,827**	**-2.4%**	**+5.2%**
Other products		8,050	8,203	8,138	-1.9%	-1.1%
Total Pharmaceuticals		**24,707**	**25,274**	**23,965**	**-2.2%**	**+3.1%**

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The table below breaks down sales of our top 15 products by geographic region in 2008:

(million)						
Product	**Europe**	**Comparable basis growth (%)**	**United States**	**Comparable basis growth (%)**	**Other countries**	**Comparable basis growth (%)**
Lovenox®	815	+8.1%	1,625	+11.7%	298	+12.0%
Plavix®	1,732	+3.5%	172	+3.0%	712	+34.8%
Lantus®	713	+16.3%	1,452	+30.8%	285	+46.2%
Taxotere®	900	+10.8%	737	+15.9%	396	+13.8%
Eloxatine®	214	-42.6%	948	+6.2%	186	+13.4%
Aprovel®/CoAprovel®	910	+9.9%			292	+29.8%
Stilnox®/Ambien®/Myslee®	82	-4.7%	547	-44.9%	200	+11.1%
Allegra®	39	-25.0%	333	-0.9%	316	+10.5%
Copaxone®	381	+18.3%	210	+19.3%	31	+40.9%
Tritace®	358	-29.4%			155	-31.4%
Amaryl®	100	-15.3%	6	-25.0%	281	+5.6%
Xatral®	148	-10.3%	119	+20.2%	64	+14.3%
Actonel®	220	+8.9%			110	+2.8%
Depakine®	219	+3.3%			110	+17.0%
Nasacort®	39	-9.3%	175	-13.8%	27	-3.6%

Top 15 Products [(1)]

Over 2008 as a whole, net sales of **Lovenox®,** the leading low molecular weight heparin on the market, were up 10.6% on a comparable basis at 2,738 million. In the United States, the product reported growth of 11.7% on a comparable basis at 1,625 million. In Europe, after two quarters adversely affected by limited product availability (following the withdrawal of certain batches in which small quantities of an impurity were present), Lovenox® achieved growth of 8.1% on a comparable basis, to 815 million (double digit growth in the fourth quarter of 11.1% on a comparable basis).

Lantus®, the world s leading insulin brand, was the biggest contributor to the Group s top-line growth in 2008. The product achieved strong growth in all three regions: 30.8% in the United States, 16.3% in Europe and 46.2% in the Other Countries region, on a comparable basis. The new-generation Lantus® SoloSTAR® pen was a significant driver of sales growth in the United States. Our goal is to establish Lantus® as the leading anti-diabetic in the world by value.

Full-year sales of **Taxotere®** exceeded 2 billion for the first time in 2008 (2,033 million), with double-digit growth (on a comparable basis) in all three regions: 15.9% in the United States (where net sales were driven by the product s use in adjuvant breast cancer treatment and in prostate cancer), 10.8% in Europe, and 13.8% in the Other Countries region.

Full-year sales of the hypnotics **Ambien® CR** and **Ambien® IR** in the United States were $681 million and $125 million respectively. In Japan, **Myslee®**, the leading hypnotic on the market, again performed well: net sales (consolidated by sanofi-aventis since January 1, 2008) increased by 14.9% on a comparable basis to 142 million over the full year.

In the United States, net sales of **Eloxatine®**, the leading cytotoxic agent in the colorectal cancer market as an adjuvant and in the metastatic phase, rose by 6.2% (on a comparable basis) to 948 million over 2008 as a whole, driven by the adjuvant indication. In the Other Countries region, the product reported robust growth of 13.4% on a comparable basis to 186 million.

Sales of **Tritace®** were 513 million in 2008, down by 30.1% on a comparable basis. Sales were hampered by competition from generics in Canada in 2007. A generic version of ramipril became available in Italy in 2008, negatively affecting our sales there.

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

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In addition to the blockbuster products described above, each of which registered annual net sales of over 1 billion in 2008, our remaining top 15 pharmaceutical products contributed net sales in the aggregate of approximately 4,270 million in 2008, or about 17.3% of our total pharmaceutical sales for the year.

Net sales of **Acomplia®**, which was withdrawn from the market in the fourth quarter, totaled 72 million in 2008.

Net Sales Human Vaccines (Vaccines)

Our Vaccines business generated net sales of 2,861 million in 2008, an increase of 9.6% on a comparable basis (3.0% on a reported basis), including 1,683 million in 2008 in the United States (an increase of 9.7% on a comparable basis).

Net sales of **influenza vaccines** rose by 1.5% (on a comparable basis) in 2008 to 736 million, a figure that includes the shipment during the second quarter of H5N1 vaccine for the U.S. Department of Health and Human Services worth $192.5 million (compared with $113 million in 2007).

Pentacel® (the first 5-in-1 pediatric combination vaccine to protect against diphtheria, tetanus, pertussis, polio and *haemophilus influenzae* type b), which was launched in the United States in July 2008, confirmed its success with net sales of 82 million in 2008.

Net sales of **Menactra®** (quadrivalent meningococcal meningitis vaccine) were up 7.9% on a comparable basis at 404 million in 2008.

Adacel® (adult and adolescent tetanus-diphtheria-pertussis booster) continued to perform very well in the United States, driving net sales up by 20.0% (on a comparable basis) over 2008 as a whole to 255 million.

Sales of **Act-Hib®** increased by 19.9% (on a comparable basis) to 120 million in 2008, driven by a significant commercial and industrial effort to provide additional doses to the U.S. market during a competitor s supply shortage combined with the launch of Act-Hib® in Japan in December 2008.

2008 sales growth was also driven by the uptake of **Pentaxim®** (another 5-in-1 pediatric combo vaccine, which protects against diphtheria, tetanus, pertussis, polio and *haemophilus influenzae* type b) in the Other Countries region.

The following table presents the 2008 sales of our Vaccines activity by range of products:

(million)	**2008**

		2007 Reported	2007 Comparable	Reported basis growth (%)	Comparable basis growth (%)
Pediatric Combination and Polio. Vaccines	768	660	630	+16.4%	+21.9%
Influenza Vaccines*	736	766	725	-3.9%	+1.5%
Meningitis/Pneumonia Vaccines	472	482	441	-2.1%	+7.0%
Adult and Adolescent Booster Vaccines	399	402	369	-0.7%	+8.1%
Travel and Endemic Vaccines	309	327	314	-5.5%	-1.6%
Other Vaccines	177	141	132	+25.5%	+34.1%
Total Human Vaccines	**2,861**	**2,778**	**2,611**	**+3.0%**	**+9.6%**

* Seasonal and pandemic influenza vaccines.

The following table presents the 2008 sales of our Vaccines activity by range of products and by region:

(*million)*	Europe	Comparable basis growth (%)	United States	Comparable basis growth (%)	Other countries	Comparable basis growth (%)
Pediatric Combination and Polio. Vaccines	160	+20.3%	317	+36.6%	291	+9.8%
Influenza Vaccines*	94	-8.7%	459	+3.1%	183	+3.4%
Meningitis/Pneumonia Vaccines	11	-8.3%	400	+7.0%	61	+10.9%
Adult and Adolescent Booster Vaccines	54	+22.7%	317	+5.7%	28	+12.0%
Travel and Endemic Vaccines	31	-3.1%	76	-8.4%	202	+1.5%
Other Vaccines	45	+181.3%	114	+14.0%	18	+12.5%

* Seasonal and pandemic influenza vaccines.

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In addition to the Vaccines activity reflected in our consolidated net sales, sales of Sanofi Pasteur MSD, the joint venture with Merck & Co. in Western Europe, reached 1,272 million in 2008, an increase of 21.8% on a reported basis. Full-year net sales of **Gardasil®**, the first vaccine licensed in Europe against papillomavirus infection, a major cause of cervical cancer, were 584 million, compared with 341 million in 2007.

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 2008 and 2007 net sales by region:

(million)	2008	2007 Reported	2007 Comparable	Reported basis growth (%)	Comparable basis growth (%)
Europe	12,096	12,184	12,173	-0.7%	-0.6%
United States	8,609	9,474	8,169	-9.1%	+5.4%
Other countries	6,863	6,394	6,234	+7.3%	+10.1%
Total	**27,568**	**28,052**	**26,576**	**-1.7%**	**+3.7%**

During 2008, sales in France and Germany hampered net sales in Europe, which fell slightly (by 0.6% on a comparable basis). Generics of Eloxatine® (i.e. excluding net sales of Eloxatine® in Europe in 2007 and 2008) (especially in France) pared around 1.3 points of growth in Europe. Since August 2008, sales of Plavix® in Germany have been affected by competition from several clopidogrel besylates in certain indications.

In the United States, sales growth resumed at a healthier pace in the last two quarters of 2008 after having been hampered by competition from generics of Ambien® IR, due to particularly excellent performances from Lantus® and Taxotere®. Generics of Ambien® IR (i.e. excluding net sales of Ambien® IR in the United States in the first quarter of 2007 and the first quarter of 2008) cost 4.6 points of sales growth over 2008 as a whole (on a comparable basis).

Net sales in the Other Countries region during 2008 were lifted by a particularly strong performance in Japan (up 18.5% on a comparable basis at 1,408 million), driven by the success of Plavix® (net sales reached 182 million in 2008 vs. 66 million in 2007) and Myslee® (net sales reached 142 million in 2008, up 14.9% on a comparable basis).

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 BMS Alliance 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 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 lines of our income statement, in particular the lines Other revenues where royalties received on those sales are booked (see Other Revenues); Share of profit/loss of associates (see Share of Profit/Loss of Associates) where our share of profit/loss of entities included in the BMS Alliance and under BMS operational management is recorded; and Net income attributable to minority interests (see Net Income Attributable to Minority Interests) where the BMS share of profit/loss of entities included in the BMS Alliance and under our operational management is recorded.

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The table below sets forth the worldwide sales of Plavix® and Aprovel® in 2008 and 2007, by geographic region:

(million)	2008			2007			Change (%)
	sanofi-aventis (2)	BMS (3)	Total	sanofi-aventis (2)	BMS (3)	Total	
Plavix®/Iscover® (1)							
Europe	1,622	211	1,833	1,583	225	1,808	+1.4%
United States		3,351	3,351		2,988	2,988	+12.1%
Other countries	711	248	959	553	273	826	+16.1%
Total	**2,333**	**3,810**	**6,143**	**2,136**	**3,486**	**5,622**	**+9.3%**

(million)	2008			2007			Change (%)
	sanofi-aventis (5)	BMS (3)	Total	sanofi-aventis (5)	BMS (3)	Total	
Aprovel®/Avapro®/Karvea® (4)							
Europe	816	176	992	750	172	922	+7.6%
United States		499	499		507	507	-1.6%
Other countries	291	184	475	243	179	422	+12.6%
Total	**1,107**	**859**	**1,966**	**993**	**858**	**1,851**	**+6.2%**

(1) Plavix® is marketed under the trademarks Plavix® and Iscover®.
(2) Net sales of Plavix® consolidated by sanofi-aventis, excluding sales to BMS (282 million in 2008 and 288 million in 2007).
(3) Translated into euros by sanofi-aventis using the method described in Note B.2 to our consolidated financial statements (Foreign currency translation) 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 (94 million in 2008 and 87 million in 2007).

Comparable-basis trends in worldwide sales of Plavix® and Aprovel® in 2008 and 2007 by geographic region are as follows:

(million)	2008	2007 Reported	2007 Comparable	Comparable basis growth (%)
Plavix®/Iscover®				
Europe	1,833	1,808	1,776	+3.2%
United States	3,351	2,988	2,768	+21.1%
Other countries	959	826	786	+22.0%
Total	**6,143**	**5,622**	**5,330**	**+15.3%**
Aprovel®/Avapro®/Karvea®				
Europe	992	922	912	+8.8%
United States	499	507	469	+6.4%
Other countries	475	422	394	+20.6%
Total	**1,966**	**1,851**	**1,775**	**+10.8%**

Full-year 2008 sales of **Plavix®** (clopidogrel bisulfate) in the United States (consolidated by BMS) were sharply higher than in 2007 (growth of 21.1% on a comparable basis), when sales were affected by competition from a generic version in the early part of the year.

In Europe, net sales were 1,833 million in 2008. The product s 3.2% growth rate reflected competition from several clopidogrel besylates in the monotherapy segment since August in Germany, where the market share of Plavix®/Iscover® by volume was still around 75% in December (IMS Pharmatrend, week commencing December 22, 2008).

In the Other Countries region, growth for Plavix® benefited from its success in Japan, where net sales reached 182 million over 2008 as a whole (vs. 66 million in 2007).

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Despite a very competitive environment, worldwide sales of Aprovel® achieved double-digit growth in 2008 (10.8% on a comparable basis), to 1,966 million.

In September 2008, the Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion on the authorization of a generic of irbesartan (the active ingredient for Aprovel®) as a monotherapy in Europe. However, the active ingredient of irbesartan is protected by a patent in the principal European countries until August 2012. In some countries (Spain, Portugal, Finland, Norway, and some Eastern European countries), irbesartan is not protected by this active ingredient patent, though other patents may be in force locally. Net sales of Aprovel® as a monotherapy in European countries not covered by the active ingredient patent were approximately 50 million in 2008.

Other Revenues

Other revenues, which mainly comprise royalty income under licensing agreements contracted in connection with ongoing operations, amounted to 1,249 million in 2008 compared with 1,155 million in 2007.

License revenues under the worldwide alliance with Bristol-Myers Squibb (BMS) on Plavix® and Aprovel® amounted to 985 million in 2008, compared with 897 million in 2007. These revenues were boosted by the strong rise in U.S. sales of Plavix® (up 21.1% on a comparable basis in 2008), but were adversely affected by the unfavorable trend in the U.S. dollar/euro exchange rate.

Gross Profit

Gross profit for 2008 was 21,480 million, against 21,636 in 2007. The gross margin ratio was 77.9% in 2008, compared with 77.1% in 2007.

The 0.8-point increase in the gross margin ratio reflected a 0.4-point increase in royalty income and a 0.4-point improvement in the ratio of cost of sales to net sales.

The main reasons for the improvement in the ratio of cost of sales to net sales were a favorable product mix plus, from April 1, 2008, the discontinuation by sanofi-aventis of commercialization of Copaxone® in North America, a product that generated a lower level of contractual gross margin than the average for the portfolio. These effects were partly offset by the introduction of generics of Ambien® IR in the United States as from April 1, 2007 and the weakening of the U.S. dollar against the euro.

Research and Development Expenses

Research and development expenses rose by 0.8% in 2008 to 4,575 million (2007: 4,537 million), and represented 16.6% of net sales (as compared to 16.2% in 2007). Excluding the effect of exchange rates (i.e. at 2007 actual exchange rates), research and development expenses rose by 3.2%. Phase III programs were launched in 2008 in thrombosis, metabolic disorders and oncology. We also incurred costs under clinical

programs for further development of existing products (Plavix®, Allegra®), through alliances such as those recently concluded with Regeneron Pharmaceuticals Inc, and from the discontinuation of programs (primarily Acomplia®).

Selling and General Expenses

Selling and general expenses totaled 7,168 million in 2008 (26.0% of net sales), compared with 7,554 million in 2007 (26.9% of net sales). This represents a reduction of 5.1% (or 2.0% after excluding the effect of exchange rates, i.e. at 2007 actual exchange rates), reflecting the impact of our ongoing selective cost adaptation policy. This policy is a response to the local erosion of some product sales in Europe and in the United States, in an environment marked by competition from generic drugs and pressure on selling prices. We have, however, increased spending on resources in emerging markets.

In addition, in accordance with the terms of its agreement with sanofi-aventis, Teva Pharmaceuticals Industries (Teva) took over the selling of Copaxone® on April 1, 2008, in the United States and Canada. As from this date, sanofi-aventis stopped sharing some commercialization costs in these countries.

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Other Operating Income and Expenses

In 2008, we recorded other operating income of 556 million (2007: 522 million) and other operating expenses of 353 million (as compared to 307 million in 2007). This represents a net other operating income figure of 203 million, compared with 215 million in 2007. Net other operating income generated with pharmaceutical partners (294 million in 2008 compared with 212 million in 2007) includes from April 1, 2008 onwards the share of profit on Copaxone® following the takeover by Teva of commercialization of this product in the United States and Canada. We also recorded gains on disposals on current operations (24 million in 2008 against 60 million in 2007) and a net operating foreign exchange loss (94 million against 33 million in 2007).

The 2007 figures included an expense of 61 million arising from the signature of agreements on welfare and healthcare obligations in France for retirees and their beneficiaries.

Amortization of Intangibles

Amortization charged against intangible assets totaled 3,483 million in the year ended December 31, 2008, compared with 3,654 million in the year ended December 31, 2007. The reduction was mainly due to the weakening of the U.S. dollar against the euro.

These charges mainly relate to the amortization of intangible assets remeasured at fair value at the time of the Aventis acquisition (3,298 million in 2008 as compared with 3,511 million in 2007).

Operating Income before Restructuring, Impairment of Property, Plant & Equipment and Intangibles, Gains and Losses on Disposals, and Litigation

This indicator came to 6,457 million in 2008, compared with 6,106 million in 2007.

The table below shows trends in Operating income before restructuring, impairment of property, plant & equipment and intangibles, gains and losses on disposals, and litigation by business segment in 2008 and 2007:

(million)	**2008**	**2007**
Pharmaceuticals	5,864	5,509
Vaccines	593	597
Total	**6,457**	**6,106**

The table below shows Operating income before restructuring, impairment of property, plant & equipment and intangibles, gains and losses on disposals, and litigation by geographic region in 2008 and 2007:

(*million)*	**2008**	**2007**
Europe	5,001	4,742
United States	4,718	4,952
Other countries	2,454	2,173
Unallocated costs [1]	(5,716)	(5,761)
Total [2]	**6,457**	**6,106**

[1] Unallocated costs consist mainly of fundamental research and worldwide development of pharmaceutical molecules, and part of the cost of support functions.
[2] After charges for amortization of intangible assets of 3,483 million in 2008 and 3,654 million in 2007.

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Restructuring Costs

Restructuring costs amounted to 585 million in 2008, compared with 137 million in 2007. The 2008 figure relates to costs incurred on the adaptation of industrial facilities in France and measures taken to adjust our sales force in response to the changing pharmaceutical markets in Europe (primarily France, Italy, Spain, Portugal) and in the United States. In 2007, restructuring costs related to the ongoing adaptation plan in France and in Germany.

Impairment of Property, Plant & Equipment and Intangibles

Net impairment losses charged against property, plant and equipment and intangible assets were 1,554 million in 2008. This charge reflected the results of impairment tests conducted further to the discontinuation of research projects and to the introduction of generics of existing products commercialized by the Group, originating mainly from Aventis.

The discontinuation of research projects relates to larotaxel and cabazitaxel (new taxane derivatives) in breast cancer (1,175 million) and the antihypertensive ilepatril (57 million) (all of which were recognized as assets on the acquisition of Aventis in 2004), plus the oral anti-cancer agent S-1 following the termination of the agreement with Taiho Pharmaceutical for the development and commercialization of the product (51 million). In addition, Nasacort® (recognized as an asset on the acquisition of Aventis) has been impaired further to the settlement agreed with Barr in the United States (114 million).

In 2007, net impairment losses charged against property, plant and equipment and intangible assets were 58 million. This charge reflected the results of impairment tests, which identified impairment losses in respect of intangible assets recognized as part of the allocation of the purchase price of Aventis.

Gains and Losses on Disposals, and Litigation

In 2008, this line comprised 76 million of releases of provisions for litigation.

The Group did not make any major disposals during 2008 and 2007.

Operating Income

Operating income for 2008 came to 4,394 million, compared with 5,911 million for 2007.

Financial Income and Expenses

Net financial expense amounted to 232 million in 2008, compared with 139 million in 2007, an increase of 93 million.

Interest expense directly related to our debt, net of cash and cash equivalents (short-term debt plus long-term debt, minus cash and cash equivalents) totaled 183 million in 2008, against 209 million in 2007. This situation reflects two contrasting trends: a reduction in the amount of our debt during the period and the unfavorable interest rate trends.

Sanofi-aventis tendered its shares in Millennium Pharmaceuticals, Inc. (Millennium) to the public tender offer for Millennium by Takeda Pharmaceuticals Company Ltd. This transaction generated a gain of 38 million, recognized in the first half of 2008.

We recorded a net foreign exchange loss for 2008 of 74 million, compared to a net gain of 87 million in 2007. This was mainly due to the impact of the differential in interest rates between the U.S. dollar and the euro on hedges of cash invested by our American subsidiaries. This impact was favorable in 2007.

Income before Tax and Associates

Income before tax and associates for 2008 was 4,162 million, compared with 5,772 million for 2007.

Income Tax Expense

The reported tax rate for 2008 was 16.3%, compared with 11.9% for 2007.

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In 2008, this reduced tax rate was a result of a gain of 221 million on reversals of tax provisions, related to the settlement of tax audits.

In 2007, this item comprised a net gain of 336 million on net reversals of tax provisions, related to the settlement of tax audits, and a net gain of 515 million on the change in deferred tax liabilities arising from cuts in tax rates, primarily in Germany, including a gain of 566 million relating to deferred tax liabilities recognized in 2004 on the remeasurement of acquired intangible assets of Aventis.

Share of Profit/Loss of Associates

Our share of the net profits of associates was 812 million in 2008, compared with 597 million in 2007. This item mainly comprises our share of after-tax profits from the territories managed by BMS under the Plavix® and Avapro® alliance (624 million in 2008, compared to 525 million in 2007). The increase in our profit share was a direct result of the increase in Plavix® sales during the period, despite the unfavorable trends in the euro/U.S. dollar exchange rate.

In addition, Sanofi Pasteur MSD made a positive contribution in 2008. The contribution from our interest in Merial showed a further decrease, penalized by the unfavorable trends in the euro/U.S. dollar exchange rate.

In 2007, this line also included an impairment loss of 102 million on the equity-accounted investment in Zentiva.

Net Income

Net income (before minority interests) totaled 4,292 million in 2008, compared with 5,682 million in 2007.

Net Income Attributable to Minority Interests

Net income attributable to minority interests totaled 441 million in 2008, compared to 419 million in 2007. This item includes the share of pre-tax income paid over to BMS from territories managed by sanofi-aventis (422 million in 2008, compared to 403 million in 2007).

Net Income Attributable to Equity Holders of the Company

Net income attributable to equity holders of the Company for 2008 was 3,851 million, against 5,263 million for 2007.

The table below shows trends in net income attributable to equity holders of the Company by business segment for 2008 and 2007:

(*million)*	**2008**	**2007**
Pharmaceuticals	3,429	4,851
Vaccines	422	412
Total net income attributable to equity holders of the Company	**3,851**	**5,263**

Earnings per share (EPS) was 2.94, compared with 3.91 for 2007, based on an average number of shares outstanding of 1,309.3 million in 2008 (2007: 1,346.9 million).

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Adjusted Net Income

Adjusted net income breaks down as follows:

(million, except per share data)	2008	2007
Net income attributable to equity holders of the Company	**3,851**	**5,263**
Material accounting adjustments related to business combinations	**3,217**	**1,847**
elimination of expense arising on the workdown of acquired inventories remeasured at fair value, net of tax	2(1)	
elimination of expenses arising on amortization and impairment of intangible assets, net of tax (portion attributable to equity holders of the Company)	3,137(2)	1,684(3)
elimination of expenses arising from the impact of the acquisitions on equity investees (workdown of acquired inventory, amortization and impairment of intangible assets, and impairment of goodwill)	78(4)	163(4)
elimination of impairment losses charged against goodwill		
Elimination of acquisition-related integration and restructuring charges, net of tax		
Adjusted net income	**7,068**	**7,110**
Adjusted earnings per share (in euro) (5)	**5.40**	**5.28**

(1) Impact of the acquisition of Symbion Consumer (see Note D.1. to our consolidated financial statements included at Item 18 of this annual report).
(2) Includes 1,485 million of impairment losses (972 million net of tax) on Aventis intangible assets (see Note D.5. to our consolidated financial statements included at Item 18 of this annual report).
(3) Includes a gain of 566 million due to the effect of cuts in tax rates (primarily in Germany) on deferred tax liabilities recognized in 2004 on the remeasurement of acquired intangible assets of Aventis.
(4) Includes the impact of the Zentiva acquisition: 3 million in 2008, and 108 million in 2007 (including 102 million of impairment losses on the investment in Zentiva).
(5) Based on 1,309.3 million shares for 2008 and 1,346.9 million shares for 2007, representing the weighted average number of shares outstanding.

Adjusted net income for 2008 was 7,068 million, a decrease of 0.6% on the 2007 figure of 7,110 million, and represented 25.6% of net sales compared with 25.3% in 2007. The decrease was mainly due to restructuring costs recognized in 2008 (389 million net of tax) as compared with 2007 (95 million net of tax).

The table below shows trends in adjusted net income by business segment for 2008 and 2007:

(million)	2008	2007
Pharmaceuticals	6,455	6,501
Vaccines	613	609
Total adjusted net income	**7,068**	**7,110**

Adjusted Earnings Per Share

We also report adjusted earnings per share, a specific financial indicator, which we define as adjusted net income divided by the weighted average number of shares outstanding. Our adjusted earnings per share for 2008 was 5.40 (up 2.3% on the 2007 adjusted earnings per share figure of 5.28), boosted by the 3 billion share repurchase program authorized by the Shareholders Annual General Meeting of May 2007. The weighted average number of shares outstanding was 1,309.3 million in 2008 and 1,346.9 million in 2007.

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Year Ended December 31, 2007 Compared with Year Ended December 31, 2006

The consolidated income statements for the years ended December 31, 2007 and December 31, 2006 break down as follows:

(under IFRS)	2007		2006	
(million)		as % of net sales		as % of net sales
Net sales	**28,052**	**100.0%**	**28,373**	**100.0%**
Other revenues	1,155	4.1%	1,116	3.9%
Cost of sales	(7,571)	(27.0%)	(7,587)	(26.7%)
Gross profit	**21,636**	**77.1%**	**21,902**	**77.2%**
Research & development expenses	(4,537)	(16.2%)	(4,430)	(15.6%)
Selling & general expenses	(7,554)	(26.9%)	(8,020)	(28.3%)
Other operating income	522	1.9%	391	1.4%
Other operating expenses	(307)	(1.1%)	(116)	(0.4%)
Amortization of intangibles	(3,654)	(13.0%)	(3,998)	(14.1%)
Operating income before restructuring, impairment of property, plant & equipment and intangibles, gains & losses on disposals, and litigation	**6,106**	**21.8%**	**5,729**	**20.2%**
Restructuring costs	(137)	(0.5%)	(274)	(1.0%)
Impairment of property, plant & equipment and intangibles	(58)	(0.2%)	(1,163)	(4.1%)
Gains and losses on disposals, and litigation			536	1.9%
Operating income	**5,911**	**21.1%**	**4,828**	**17.0%**
Financial expenses	(329)	(1.2%)	(455)	(1.6%)
Financial income	190	0.7%	375	1.3%
Income before tax and associates	**5,772**	**20.6%**	**4,748**	**16.7%**
Income tax expense	(687)	(2.5%)	(800)	(2.8%)
Share of profit/loss of associates	597	2.1%	451	1.6%
Net income	**5,682**	**20.2%**	**4,399**	**15.5%**
- attributable to minority interests	419	1.5%	393	1.4%
- attributable to equity holders of the Company	**5,263**	**18.7%**	**4,006**	**14.1%**
Average number of shares outstanding (million)	1,346.9		1,346.8	
Basic earnings per share (in euros)	3.91		2.97	

Net Sales

Net sales for the year ended December 31, 2007 were 28,052 million, a rise of 2.8% on a comparable basis relative to 2006. Exchange rate movements had a negative effect of 3.8 points, nearly 80% of which was related to the U.S. dollar. Changes in Group structure had a negative effect of 0.1 of a point. After taking these effects into account, net sales fell by 1.1% on a reported basis.

The following table sets forth a reconciliation of our reported net sales for the year ended December 31, 2006 to our comparable net sales for that year based on 2007 exchange rates and Group structure:

(million)	**2006**
2006 Net Sales	**28,373**
Impact of changes in Group structure	(15)
Impact of exchange rates	(1,069)
2006 Comparable Net Sales	**27,289**

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Our net sales are generated by our two business segments: Pharmaceuticals and Human Vaccines (Vaccines). The following table breaks down our 2007 and 2006 net sales by business segment:

(*million)*	2007	2006 Reported	2006 Comparable	Reported basis growth (%)	Comparable basis growth (%)
Pharmaceuticals	25,274	25,840	24,863	-2.2%	+1.7%
Vaccines	2,778	2,533	2,426	+9.7%	+14.5%
Total	**28,052**	**28,373**	**27,289**	**-1.1%**	**+2.8%**

Net Sales by Product Pharmaceuticals

Our pharmaceutical business generated net sales of 25,274 million in 2007, up by 1.7% on a comparable basis and down by 2.2% on a reported basis. During the year, net sales for the pharmaceutical business were adversely affected by the introduction of generic competition for the immediate release formulation of Ambien® in the United States starting in April and for Eloxatine® in Europe over the full year, and by the effect of healthcare system reforms in France and Germany.

Net sales of our top 15 products advanced by 3.2% on a comparable basis to 17,071 million in 2007, representing 67.5% of pharmaceutical net sales against 66.5% in 2006 (on a comparable basis).

Excluding the impact of generics of Ambien® IR in the United States and of Eloxatine® in Europe (i.e. excluding net sales of Ambien® IR in the United States starting in April, and net sales of Eloxatine® in Europe over the full year), our top 15 products would have recorded growth of 10.7% on a comparable basis in 2007.

Net sales of other pharmaceutical products fell by 1.5% on a comparable basis to 8,203 million in 2007. Sales of these products were down by 2.1% in Europe (at 5,061 million) and by 16.5% in the United States (at 578 million) in 2007. In the Other Countries region, these products reported sales growth of 4.1% to 2,564 million. In Latin America, growth was even stronger, reaching 10.2% (918 million in 2007). For a description of our other pharmaceutical products, see Item 4. Information on the Company B. Business Overview Other Pharmaceutical Products.

The following table breaks down our net sales for the pharmaceutical business by product:

(*million)* Product	Indication	2007	2006 Reported	2006 Comparable	Reported basis growth (%)	Comparable basis growth (%)
Lovenox®	Thrombosis	2,612	2,435	2,303	+7.3%	+13.4%
Plavix®	Atherothrombosis	2,424	2,229	2,214	+8.7%	+9.5%
Lantus®	Diabetes	2,031	1,666	1,575	+21.9%	+29.0%
Taxotere®		1,874	1,752	1,675	+7.0%	+11.9%

	Breast, lung, prostate, head and neck* cancers					
Eloxatine®	Colorectal cancer	1,521	1,693	1,606	-10.2%	-5.3%
Stilnox®/Ambien®/Myslee®	Insomnia	1,250	2,026	1,868	-38.3%	-33.1%
Copaxone®	Multiple sclerosis	1,177	1,069	1,005	+10.1%	+17.1%
Aprovel®/CoAprovel®	Hypertension	1,080	1,015	1,007	+6.4%	+7.2%
Tritace®	Hypertension	741	977	963	-24.2%	-23.1%
Allegra®	Allergic rhinitis	706	688	637	+2.6%	+10.8%
Amaryl®	Diabetes	392	451	433	-13.1%	-9.5%
Actonel®	Osteoporosis, Paget s disease	320	351	348	-8.8%	-8.0%
Xatral®	Benign prostatic hyperplasia	333	353	343	-5.7%	-2.9%
Nasacort®	Allergic rhinitis	294	283	263	+3.9%	+11.8%
Depakine®	Epilepsy	316	301	299	+5.0%	+5.7%
Sub-total top 15 products		**17,071**	**17,289**	**16,539**	**-1.3%**	**+3.2%**
Other products		8,203	8,551	8,324	-4.1%	-1.5%
Total pharmaceuticals		**25,274**	**25,840**	**24,863**	**-2.2%**	**+1.7%**

* From 2007.

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The table below breaks down sales of our top 15 products by geographic region in 2007:

(million) Product	Europe	Comparable basis growth (%)	United States	Comparable basis growth (%)	Other countries	Comparable basis growth (%)
Lovenox®	756	+9.4%	1,579	+14.8%	277	+16.9%
Plavix®	1,704	+5.3%	167	+7.7%	553	+25.7%
Lantus®	627	+20.6%	1,200	+30.3%	204	+52.2%
Taxotere®	819	+14.5%	691	+6.5%	364	+17.0%
Eloxatine®	374	-33.7%	971	+9.8%	176	+11.4%
Stilnox®/Ambien®/Myslee®	85	-11.5%	1,093	-35.0%	72	-20.0%
Copaxone®	324	+16.1%	801	+19.4%	52	-5.5%
Aprovel®/CoAprovel®	838	+3.8%			242	+21.0%
Tritace®	466	-8.8%	1	-92.9%	274	-37.4%
Allegra®	54	+3.8%	369	+4.8%	283	+21.5%
Amaryl®	116	-33.7%	9	-35.7%	267	+9.4%
Actonel®	204	-16.0%			116	+10.5%
Xatral®	167	-20.5%	107	+25.9%	59	+22.9%
Nasacort®	44	+10.0%	222	+13.3%	28	+3.7%
Depakine®	216	2.4%			100	+13.6%

Top 15 Products [1]

Net sales of Lovenox® totaled 2,612 million in 2007, a rise of 7.3% on a reported basis and of 13.4% on a comparable basis. The product reported strong growth across all three regions: 14.8% in the United States, 9.4% in Europe, and 16.9% in the Other Countries region. In the United States, increased use in medical prophylaxis remained the main growth driver.

Lantus® became the first insulin brand in the world to exceed 2 billion of sales (2,031 million in 2007). During 2007, the product enjoyed strong growth across all three regions. The new SoloSTAR® disposable pen used to administer Lantus® helped to drive this product s growth.

Taxotere® enjoyed strong growth during 2007 in both Europe and the Other Countries region, where sales increased by 14.5% and 17.0% respectively on a comparable basis. In the United States, net sales rose by 6.5% on a comparable basis.

Ambien® CR reported net sales of $751 million in the United States in 2007. Net sales of Ambien® IR, which went off patent in the United States on April 20, 2007, totaled $30 million in the fourth quarter of 2007, against $352 million in the comparable period of 2006. Full-year net sales of Ambien® IR were $538 million in the United States.

In Japan, sales of Myslee® (not included in our consolidated net sales for the periods under review) reached 118 million in 2007, an increase of 9.8% on a comparable basis.

In the United States, Eloxatine® posted net sales growth of 9.8% in 2007 (on a comparable basis), to 971 million. In Europe, where the introduction of generic versions of the product was ongoing in 2007, full-year net sales fell by 33.7% on a comparable basis to 374 million. In the Other Countries region, net sales of Eloxatine® rose by 11.4% on a comparable basis to 176 million.

In addition to the blockbuster products described above, each of which registered annual net sales of over 1 billion in 2007, our remaining top 15 pharmaceutical products contributed net sales in the aggregate of approximately 3,102 million in 2007, or about 12.3% of our total pharmaceutical sales for the year.

Net sales of Tritace®, hampered by competition from generics in Canada in 2007, fell by 23.1% (on a comparable basis) to 741 million in 2007.

Net sales of Acomplia® totaled 79 million in 2007.

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

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Xyzal®, a new prescription oral antihistamine, was launched by sanofi-aventis and UCB in the United States at the start of October 2007. Fourth-quarter net sales were 8 million.

Net Sales Human Vaccines (Vaccines)

Our Vaccines business generated net sales of 2,778 million in 2007, an increase of 14.5% on a comparable basis and of 9.7% on a reported basis.

Net sales of Menactra® for 2007 totaled 415 million, up 86.1% on a comparable basis. An extension to the product s indications, covering children aged 2 to 10, was obtained in the United States in October 2007.

Adacel reported 2007 net sales of 234 million, an increase of 64.5% on a comparable basis.

Sanofi Pasteur produced over 180 million doses of seasonal influenza vaccine in 2007: the number of doses shipped represented an estimated 40%[(1)] of the world market. Excluding sales of H5N1 vaccines, sales of seasonal influenza vaccines rose by 2.6% on a comparable basis.

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

(*million)*	2007	2006 Reported	2006 Comparable	Reported basis growth (%)	Comparable basis growth (%)
Influenza Vaccines*	766	835	790	-8.3%	-3.0%
Pediatric Combination and Polio. Vaccines	660	633	628	+4.3%	+5.1%
Meningitis/Pneumonia Vaccines	482	310	292	+55.5%	+65.1%
Adult and Adolescent Booster Vaccines	402	337	317	+19.3%	+26.8%
Travel and Endemic Vaccines	327	284**	285	+15.1%	+14.7%
Other Vaccines	141	134**	114	+5.2%	+23.7%
Total Human Vaccines	**2,778**	**2,533**	**2,426**	**+9.7%**	**+14.5%**

* Seasonal and pandemic influenza vaccines.

** After reclassification of 45 million of net sales generated by MMR (Measles / Mumps / Rubella) vaccines from the Other Vaccines category to the Travel and Other Endemics Vaccines category.

The following table presents the 2007 sales of our Vaccines activity by range of products and by region:

(*million)*	Europe

		Comparable basis growth (%)	United States	Comparable basis growth (%)	Other countries	Comparable basis growth (%)
Influenza Vaccines*	100	-5.7%	485	-6.9%	181	+11.0%
Pediatric Combination and Polio. Vaccines	129	+6.6%	255	-4.9%	276	+15.5%
Meningitis/Pneumonia Vaccines	12	+9.1%	414	+74.7%	56	+27.3%
Adult and Adolescent Booster Vaccines	42	-6.7%	332	+36.1%	28	0.0%
Travel and Endemic Vaccines	31	-6.1%	91	+15.2%	205	+18.5%
Other Vaccines	15	+50.0%	110	+25.0%	16	0.0%

* Seasonal and pandemic influenza vaccines.

In addition to the Vaccines activity reflected in our consolidated net sales, sales of Sanofi Pasteur MSD, the joint venture with Merck & Co. in Europe, reached 1,040 million in 2007, up 43.6% on a reported basis. Sales were buoyed by the success of Gardasil®, which posted full-year net sales of 341 million and which Sanofi Pasteur MSD began marketing in Europe at the end of 2006.

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

(1) Internal estimate

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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 2007 and 2006 net sales by region:

(million)	2007	2006 Reported	2006 Comparable	Reported basis growth (%)	Comparable basis growth (%)
Europe	12,184	12,219	12,228	-0.3%	-0.4%
United States	9,474	9,966	9,128	-0.5%	+3.8%
Other countries	6,394	6,188	5,933	+3.3%	+7.8%
Total	**28,052**	**28,373**	**27,289**	**-1.1%**	**+2.8%**

Net sales in Europe, affected by healthcare cost containment measures, especially in France and Germany, fell by 0.4% in 2007 on a comparable basis. The introduction of generics of Eloxatine® pared approximately 1.6% off the full-year growth rate.

In the United States, net sales rose by 3.8% in 2007 on a comparable basis. This performance was achieved despite the second-quarter introduction of generics of Ambien® IR (which went off patent on April 20, 2007). Excluding the impact of generics of Ambien® IR from April, comparable-basis net sales growth in the United States would have been 15.1%.

Net sales in the Other Countries region rose by 7.8% on a comparable basis in 2007. Excluding the effect of the repurchase of inventories from Astellas and Chugai following the signature of agreements with these two companies on the buyout of several products and the effect of timing differences in shipments of influenza vaccines, the region s net sales would have risen by 8.4% on a comparable basis in 2007.

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 BMS Alliance .

The worldwide sales of these two products are an important indicator of the global market presence of sanofi-aventis products, and we believe this information facilitates a financial statement user s understanding and analysis of our consolidated income statement, in particular 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 lines of our income statement, in particular the lines Other revenues where royalties received on those sales are booked (see Other Revenues); Share of profit/loss of associates (see Share of Profit/Loss of Associates) where our share of profit/loss of entities included in the BMS Alliance and under BMS operational management is recorded; and Net income attributable to minority interests (see Minority Interests) where the BMS share of profit/loss of entities included in the BMS Alliance and under our operational management is recorded.

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The table below sets forth the worldwide sales of Plavix® and Aprovel® in 2007 and 2006, by geographic region:

(million)	2007			2006			Change (%)
	sanofi-aventis (2)	BMS (3)	Total	sanofi-aventis (2)	BMS (3)	Total	
Plavix®/Iscover® (1)							
Europe	1,583	225	1,808	1,485	230	1,715	+5.4%
United States		2,988	2,988	10	2,157	2,167	+37.9%
Other countries	553	273	826	456	246	702	+17.7%
Total	**2,136**	**3,486**	**5,622**	**1,951**	**2,633**	**4,584**	**+22.6%**

(million)	2007			2006			Change (%)
	sanofi-aventis (5)	BMS (3)	Total	sanofi-aventis (5)	BMS (3)	Total	
Aprovel®/Avapro®/Karvea® (4)							
Europe	750	172	922	704	174	878	+5.0%
United States		507	507		516	516	-1.7%
Other countries	243	179	422	207	163	370	+14.1%
Total	**993**	**858**	**1,851**	**911**	**853**	**1,764**	**+4.9%**

(1) Plavix® is marketed under the trademarks Plavix® and Iscover®.
(2) Net sales of Plavix® consolidated by sanofi-aventis, excluding sales to BMS (288 million in 2007 and 279 million in 2006).
(3) Translated into euros by sanofi-aventis using the method described in Note B.2 to our consolidated financial statements (Foreign currency translation) 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 (87 million in 2007 and 104 million in 2006).

Comparable-basis trends in worldwide sales of Plavix® and Aprovel® in 2007 and 2006 by geographic region were as follows:

(million)	2007	2006 Reported	2006 Comparable	Comparable basis growth (%)
Plavix®/Iscover®				
Europe	1,808	1,715	1,717	+5.3%
United States	2,988	2,167	1,987	+50.4%
Other countries	826	702	672	+22.9%
Total	**5,622**	**4,584**	**4,376**	**+28.5%**
Aprovel®/Avapro®/Karvea®				
Europe	922	878	877	+5.1%
United States	507	516	473	+7.2%
Other countries	422	370	352	+19.9%
Total	**1,851**	**1,764**	**1,702**	**+8.8%**

In the United States, sales of Plavix® (consolidated by BMS) totaled 2,988 million in 2007, up 50.4% on a comparable basis relative to 2006, when the product was affected by the availability of a generic version.

In Europe, 2007 full-year net sales of Plavix® reached 1,808 million, up 5.3% on a comparable basis, though sales were still affected by parallel imports in Germany.

In the Other Countries region, Plavix® posted net sales of 826 million, representing comparable-basis growth of 22.9%, boosted by the product s success in Japan. The two-week limit on prescriptions imposed by the Japanese authorities was lifted in May 2007, triggering an acceleration in sales growth, especially in the fourth quarter. Over the full year, Plavix® recorded Japanese sales of 61 million, compared with 11 million in 2006.

Worldwide sales of Aprovel®/Avapro®/Karvea® in 2007 were 1,851 million, up 8.8% on a comparable basis.

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Other Revenues

Other revenues, which mainly comprise royalty income under licensing agreements contracted in connection with ongoing operations, amounted to 1,155 million in 2007 compared with 1,116 million in 2006.

This rise was mainly due to an increase in royalty income from Plavix® and Aprovel® in the United States (despite the unfavorable effect of movements in the euro/U.S. dollar exchange rate), which more than offset the discontinuation of royalties from sales of fipronil (99 million in 2006) previously paid by Merial (our joint venture with Merck & Co. Inc.) with effect from January 2007 under the terms of the agreement between the two companies.

License revenues under the worldwide alliance with Bristol-Myers Squibb (BMS) on Plavix® and Aprovel® amounted to 897 million in 2007, compared with 697 million in 2006.

Gross Profit

Gross profit for 2007 was 21,636 million. The gross margin ratio was 77.1% in 2007, compared with 77.2% in 2006.

The 0.1-point deterioration in the gross margin ratio reflected a 0.3-point increase in the ratio of cost of sales to net sales, offset by a 0.2-point improvement in royalty income. The main reason for the higher ratio of cost of sales to net sales was the effect of the introduction of generics of Ambien® IR in the United States from April 2007.

During 2007, we recognized royalty expense of 99 million (2006: 90 million) under the worldwide alliance with BMS on Plavix® and Aprovel®.

Research and Development Expenses

Research and development expenses rose by 2.4% in 2007 to 4,537 million (2006: 4,430 million), and represented 16.2% of net sales (2006: 15.6%).

We continued to focus efforts on our seven fields of expertise (thrombosis, cardiovascular, metabolic disorders, oncology, central nervous system, internal medicine, and vaccines). New clinical programs started in 2007 included Plavix®, Xatral® (Japan), Acomplia®, volinanserin, otamixaban (acute coronary syndrome), eplivanserin (sleep disorders), amibegron and saredutant (depression and anxiety), dianicline (smoking cessation), the CB-1 receptor antagonist and GLP1 receptor agonist, and teriflunomide (multiple sclerosis). We also incurred research and development expenses under our ongoing collaboration agreements, in particular in the field of oncology with Taiho (agreement to develop and commercialize S-1, an oral anticancer agent) and with Oxford BioMedica (exclusive global licensing agreement to develop and commercialize the therapeutic vaccine TroVax®).

Selling and General Expenses

Selling and general expenses totaled 7,554 million in 2007 (26.9% of net sales), compared with 8,020 million in 2006 (28.3% of net sales). Apart from the favorable impact of the weakness of the U.S. dollar against the euro during 2007, this line showed the benefits of the adaptation measures we initiated in 2006 and 2007, especially in France, Germany and the United States, along with our ongoing cost control policy. Conversely, we increased spending on resources in high-growth regions of the world.

Other Operating Income and Expenses

In 2007, we recorded other operating income of 522 million and other operating expenses of 307 million. This represents a net other operating income figure of 215 million, compared with 275 million in 2006. The main reason for the year-on-year change was the recognition of an expense of 61 million arising from the signature of agreements on welfare and healthcare obligations in France for retirees and their beneficiaries.

Amortization of Intangibles

Amortization charged against intangible assets totaled 3,654 million in the year ended December 31, 2007, compared with 3,998 million in the year ended December 31, 2006. The reduction was mainly due to the weakening of the U.S. dollar against the euro.

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These charges mainly relate to the amortization of intangible assets remeasured at fair value at the time of the Aventis acquisition (3,511 million in 2007, compared to 3,866 million in 2006).

Operating Income before Restructuring, Impairment of Property, Plant & Equipment and Intangibles, Gains and Losses on Disposals, and Litigation

This indicator came to 6,106 million in 2007, compared with 5,729 million in 2006.

The table below shows trends in Operating income before restructuring, impairment of property, plant & equipment and intangibles, gains and losses on disposals, and litigation by business segment in 2007 and 2006:

(million)	**2007**	**2006**
Pharmaceuticals	5,509	5,217
Vaccines	597	512
Total	**6,106**	**5,729**

The table below shows Operating income before restructuring, impairment of property, plant & equipment and intangibles, gains and losses on disposals, and litigation by geographic region in 2006 and 2007:

(million)	**2007**	**2006**
Europe	4,742	4,603
United States	4,952	4,560
Other countries	2,173	2,082
Unallocated costs [(1)]	(5,761)	(5,516)
Total [(2)]	**6,106**	**5,729**

(1) Unallocated costs consist mainly of fundamental research and worldwide development of pharmaceutical molecules, and part of the cost of support functions.
(2) After charges for amortization of intangible assets of 3,654 million in 2007and 3,998 million in 2006.

Restructuring Costs

Restructuring costs amounted to 137 million in 2007, compared with 274 million in 2006, and comprise costs incurred on measures taken in response to the changing economic environment in Europe, primarily in France and Germany (137 million, versus 176 million in 2006). The 2006 figure also included the residual costs associated with the acquisition of Aventis (98 million).

Impairment of Property, Plant & Equipment and Intangibles

Net impairment losses charged against property, plant and equipment and intangible assets during 2007 were 58 million. This charge reflects the results of impairment tests, which identified impairment losses in respect of intangible assets recognized as part of the allocation of the purchase price of Aventis.

In 2006, net impairment losses charged against property, plant and equipment and intangible assets were 1,163 million. The bulk of this amount (953 million) related to the impairment of intangible assets, primarily the antibiotic Ketek® (following a restriction on the product s indications in the United States) and Tritace®/Altace® (following the at-risk launch of a generic version in Canada by Apotex).

Gains and Losses on Disposals, and Litigation

We made no major asset disposals during 2007.

In 2006, this line showed a net gain of 536 million. This included 550 million of gains on disposals (including a pre-tax gain of 460 million on the sale of the Exubera® rights to Pfizer, and 45 million on the sale of the residual 30% interest in an animal nutrition business).

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Operating Income

Operating income for 2007 came to 5,911 million, compared with 4,828 million for 2006.

Financial Income and Expenses

Net financial expense amounted to 139 million in 2007, compared with 80 million in 2006, an increase of 59 million.

Interest expense directly related to our debt, net of cash and cash equivalents (short-term debt plus long-term debt, minus cash and cash equivalents) totaled 209 million in 2007, against 275 million in 2006. This decrease reflects two contrasting trends: a reduction in the amount of our debt, and the unfavorable impact of higher interest rates.

Gains on disposals of investments totaled 7 million, against 108 million in 2006 (including a gain of 101 million on the sale of shares in Rhodia).

Financial instruments generated a net gain of 4 million, compared with 68 million in 2006. The 2006 figure was mainly due to the remeasurement of the additional purchase consideration receivable from CSL on the sale of Aventis Behring. We received this additional consideration on February 5, 2007, in advance of the original contractual due date. See Note D.20.2. to our consolidated financial statements included at Item 18 of this annual report.

We recorded a net foreign exchange gain for the year of 87 million, compared with 68 million in 2006.

Income before Tax and Associates

Income before tax and associates for 2007 was 5,772 million, compared with 4,748 million for 2006.

Income Tax Expense

The reported tax rate for 2007 was 11.9%, compared with 16.8% for 2006. The main reasons for the lower rate in 2007 were:

- a net gain of 336 million on net reversals of provisions, related to the settlement of tax audits;

a net gain of 515 million on the change in deferred tax liabilities arising from cuts in tax rates, primarily in Germany, including a gain of 566 million relating to deferred tax liabilities recognized in 2004 on the remeasurement of acquired intangible assets of Aventis.

In 2006, this line included a specific tax charge of 77 million on the disposal of the Exubera® rights, which was calculated at a reduced tax rate.

Share of Profit/Loss of Associates

Our share of the net profits of associates was 597 million in 2007, compared with 451 million in 2006. This item mainly comprises our share of after-tax profits from the territories managed by BMS under the Plavix® and Avapro® alliance (525 million in 2007, compared to 320 million in 2006). The increase in our profit share was a direct result of the recovery in sales of Plavix® during 2007 in the United States, where sales had been adversely affected by the availability of a generic version until the second quarter of 2007. This favorable effect was offset by unfavorable trends in the euro/U.S. dollar exchange rate.

In 2007, this line also included an impairment loss of 102 million on the equity-accounted investment in Zentiva. The contribution from our interest in Merial showed a further increase.

Net Income

Net income (before minority interests) totaled 5,682 million in 2007, compared to 4,399 million in 2006.

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Net Income Attributable to Minority Interests

Net income attributable to minority interests totaled 419 million in 2007, compared to 393 million in 2006. This item includes the share of pre-tax income paid over to BMS from territories managed by sanofi-aventis (403 million in 2007, compared to 375 million in 2006).

Net Income Attributable to Equity Holders of the Company

Net income attributable to equity holders of the Company for 2007 was 5,263 million, against 4,006 million for 2006.

The table below shows trends in net income attributable to equity holders of the Company by business segment for 2007 and 2006:

(*million)*	2007	2006
Pharmaceuticals	4,851	3,649
Vaccines	412	357
Total net income attributable to equity holders of the Company	**5,263**	**4,006**

Earnings per share (EPS) was 3.91, compared with 2.97 for 2006, based on an average number of shares outstanding of 1,346.9 million in 2007 (2006: 1,346.8 million).

Adjusted Net Income

Adjusted net income breaks down as follows:

(*million, except per share data)*	2007	2006
Net income attributable to equity holders of the Company	**5,263**	**4,006**
Material accounting adjustments related to business combinations	**1,847**	**2,969**
- elimination of expense arising on the workdown of acquired inventories remeasured at fair value, net of tax		21
- elimination of expenses arising on amortization and impairment of intangible assets, net of tax (portion attributable to equity holders of the Company)	1,684(2)	2,935
- elimination of expenses arising from the impact of the acquisitions on equity investees (workdown of acquired inventory, amortization and impairment of intangible assets, and impairment of goodwill)	163(3)	13(4)
- elimination of impairment losses charged against goodwill		
Elimination of acquisition-related integration and restructuring charges, net of tax		**65**
Adjusted net income	**7,110**	**7,040**

Adjusted earnings per share (in euro) [1]	**5.28**	**5.23**

(1) Based on 1,346.8 million shares for 2006 and 1,346.9 million shares for 2007, representing the weighted average number of shares outstanding.
(2) After taking account of a gain of 566 million arising from the impact of cuts in tax rates (primarily in Germany) on deferred tax liabilities recognized in 2004 on the remeasurement of acquired intangible assets of Aventis.
(3) Includes the impact of the acquisition of Zentiva (108 million, including 102 million of impairment losses on the investment in Zentiva).
(4) Includes the impact of the acquisition of Zentiva (11 million), amortization and impairment (net of tax) relating to the acquisition of Aventis (97 million), and the reversal of a deferred tax liability on the investment in Merial (95 million).

Adjusted net income for 2007 was 7,110 million, an increase of 1.0% on the 2006 figure of 7,040 million, and represented 25.3% of net sales compared with 24.8% in 2006.

The table below shows trends in adjusted net income by business segment for 2007 and 2006:

(million)	**2007**	**2006**
Pharmaceuticals	6,501	6,479
Vaccines	609	561
Total adjusted net income	**7,110**	**7,040**

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Adjusted Earnings Per Share

We also report adjusted earnings per share, a specific financial indicator, which we define as adjusted net income divided by the weighted average number of shares outstanding. Our adjusted earnings per share for 2007 was 5.28 (up 1.0% on the 2006 adjusted earnings per share figure of 5.23), based on 1,346.9 million shares in 2007 and 1,346.8 million in 2006.

Liquidity and Capital Resources

Our operations generate significant positive cash flow. We fund our investments primarily with operating cash flow and pay regular dividends on our shares. In connection with our acquisition of Aventis in 2004, we incurred significant debt, of which we have repaid substantially all. As of December 31, 2008, our debt, net of cash and cash equivalents, stood at 1.8 billion compared to 4.2 billion a year earlier. See Note D.13. to our consolidated financial statements.

Consolidated Statement of Cash Flows

Generally, factors that affect our earnings for example, pricing, volume, costs and exchange rates flow through to cash from operations. The most significant source of cash from operations is sales of our branded pharmaceutical products and human vaccines. Collections of royalty payments also contribute to cash from operations.

Net cash provided by operating activities in 2008 totaled 8,523 million, compared with 7,106 million in 2007. Operating cash flow before changes in working capital was 8,524 million in 2008, against 7,917 million in 2007. Working capital requirements stabilized in 2008, compared with an increase in working capital requirements of 811 million in 2007.

Investing activities generated a net cash outflow of 2,154 million in 2008, compared with 1,716 million in 2007.

Acquisitions of property, plant and equipment and intangible assets totaled 1,606 million in 2008 (as compared to 1,610 million in 2007), and mainly comprised investments in industrial facilities and research sites, plus contractual payments for intangible rights. These intangible rights (217 million in 2008) mainly comprise the buyout of commercial rights to our own products (including Mysle® in Japan, agreed at the end of 2007 with payment made early in 2008) or to third-party products, plus payments made under collaboration and marketing agreements with partners including Dyax and Crucell N.V.

In 2008, financial investments (667 million net of acquired cash) were mainly due to the buyout of the entire share capital of the British company Acambis plc (332 million) and of the Australian company Symbion CP Holdings Pty Ltd (329 million). In 2007, financial investments (435 million) mainly comprised 186 million on the buyout of preferred shares issued by our subsidiary Carderm Capital LP (see Note D.18. to our consolidated financial statements included at Item 18 of this annual report), and $312 million on the purchase of 12 million shares in Regeneron, taking our interest in the company s capital to approximately 19%.

In 2008, after-tax proceeds from disposals totaled 123 million and related mainly to the sale of the investment in Millennium in May 2008 ($112 million). In 2007, after-tax proceeds from disposals (329 million) included receipt from CSL of the contingent purchase consideration of $250 million (see Note D.20.2 to our consolidated financial statements included at Item 18 of this annual report).

Net cash used in financing activities totaled 3,809 million, against 4,820 million in 2007. This figure includes the dividend payout of 2,702 million (as compared to 2,364 million in 2007); additional external financing (net increase in short-term and long-term debt) of 69 million, as opposed to a net reduction of 934 million in 2007) when we paid down part of our debt; and the repurchase of 23.9 million of our own shares (for 1,227 million) under the share repurchase programs authorized by the Annual General Meeting on May 31, 2007 and May 14, 2008. In 2007, we repurchased 29.4 million of our own shares for 1,806 million under the repurchase programs.

After the impact of exchange rates, the net change in cash and equivalents during 2008 was an increase of 2,515 million, compared to an increase of 558 million in 2007.

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Consolidated Balance Sheet and Debt

Total assets stood at 71,987 million at December 31, 2008, 73 million higher than the previous year-end figure of 71,914 million.

At December 31, 2008, our debt, net of cash and cash equivalents stood at 1.8 billion, compared with 4.2 billion at December 31, 2007. We define debt, net of cash and cash equivalents as short-term debt plus long-term debt, minus cash and cash equivalents. Debt, net of cash and cash equivalents is a non-GAAP financial indicator used by management and investors to measure the Company s overall net indebtedness.

The table below shows changes in the Group s financial position over the last three years:

(*million)*	**2008**	**2007**	**2006**
Debt	6,006	5,941	6,944
Cash and cash equivalents	(4,226)	(1,711)	(1,153)
Debt, net of cash and cash equivalents	**1,780**	**4,230**	**5,791**

The gearing ratio (debt, net of cash and cash equivalents, to total equity) improved from 9.5% at the end of 2007 to 3.9% in 2008.

For an analysis of our debt at December 31, 2008 by type, maturity, interest rate and currency, see Note D.17. to our consolidated financial statements included in Item 18 of this financial annual report.

The financing in place at December 31, 2008 is not subject to covenants regarding financial ratios, and contains no clause linking credit spreads or fees to our credit rating.

Other key movements in balance sheet items for the period under review are summarized below.

Shareholders equity totaled 45,071 million at December 31, 2008, against 44,719 million at December 31, 2007. This net increase reflected the following factors:

Increases: net income attributable to equity holders of the Company for 2008 (3,851 million); the net change in the cumulative translation difference following the appreciation of various currencies against the euro (948 million, mainly on the U.S. dollar); and capital movements linked to share-based payment plans (43 million, arising from the exercise of stock options plus proceeds from the sale of treasury shares on exercise of stock options).

Reductions: payment of the 2007 dividend to our shareholders (2,702 million); repurchases of our own shares (1,227 million); and actuarial losses on employee benefit obligations under the option offered by the amendment to IAS 19 (693 million net of taxes).

At December 31, 2008, we held 10 million of our own shares (recorded as a deduction from shareholders equity), representing 0.76% of our share capital. We canceled 51.4 million of our treasury shares during 2008.

Goodwill (28,163 million at December 31, 2008) showed a net increase of 964 million year-on-year, mainly due to the net change in the cumulative translation difference arising from the appreciation of various currencies against the euro (impact: 567 million, mainly on the U.S. dollar). The increase also takes account of goodwill arising on the acquisitions of Symbion CP Holdings Pty Ltd (Symbion Consumer 206 million) and of Acambis Plc (Acambis 197 million).

Intangible assets (15,260 million at December 31, 2008) fell by 3,922 million. Amortization expenses and impairment losses accounted for 5,088 million, including 1,554 million of impairment losses recognized on the basis of the results of impairment tests. Intangible assets recognized in the purchase price allocation on the acquisition of Symbion Consumer and Acambis totaled 116 million and 223 million respectively, including 198 million for research projects. Other acquisitions of intangible assets during the year totaled 103 million, mainly in connection with license agreements (including collaboration agreements signed with Dyax Corp. and Novozymes). The net effect of the appreciation of various currencies (mainly the U.S. dollar and the yen) against the euro amounted to 674 million.

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Provisions and other non-current liabilities (7,730 million at December 31, 2008) rose by 873 million year-on-year, due to rises in provisions for pensions and other long-term employee benefits (670 million, including an 824 million increase due to recognition of actuarial losses) and for restructuring (178 million). These increases were partly offset by reversals of provisions for product liability risks, litigation and other (262 million).

Net deferred tax liabilities (2,748 million at December 31, 2008) fell by 1,275 million, largely as a result of reversals of deferred tax liabilities related to the amortization and impairment of intangible assets (1,651 million) and to an increase in deferred tax assets arising from the change in employee benefit obligations (155 million).

Liquidity

We expect that our existing cash resources and cash from operations will be sufficient to finance our foreseeable working capital requirements. At year end 2008, we held cash and cash equivalents amounting to 4,226 million, substantially all of which was held in euros (see Note D.13. to our consolidated financial statements). As at December 31, 2008, 429 million of our cash and cash equivalents was held by our captive insurance and reinsurance companies in accordance with insurance regulations. As of year end 2008, we had no commitments for capital expenditures that we consider to be material to our consolidated financial position. Undrawn confirmed credit facilities (that were not allocated to outstanding commercial paper drawdowns) amounted to a total of 10.8 billion at December 31, 2008. For a discussion of our treasury policies, see Item 11. Quantitative and Qualitative Disclosures about Market Risk.

Off-Balance Sheet Arrangements / Contractual Obligations and Other Commercial Commitments

We have various contractual obligations and other commercial commitments arising from our operations. These obligations and commitments are more fully described at Item 4. Information on the Company Targeted Partnerships to support the Development of Innovative Products, above.

Our contractual obligations and our other commercial commitments at December 31, 2008 are shown in Note D.21. to our consolidated financial statements, included at Item 18 of this annual report, which discloses details of commitments under our principal R&D collaboration agreements and the financial commitment related to the offer for all of the shares of Zentiva. Note D.22.e) to our consolidated financial statements describes our principal contractual commitments in respect of divestments.

The Group s contractual obligations and other commitments are set forth in the table below:

December 31, 2008		**Payments due by period**			
(million)	**Total**	**Under 1 year**	**From 1 to 3 years**	**From 3 to 5 years**	**Over 5 years**
Debt[(1)]:					
principal	5,921	1,784	1,857	1,969	311
interest	547	173	235	92	47
net cash flows related to derivative instruments	16	17	84	(44)	(41)
Operating lease obligations	1,192	265	353	185	389

Irrevocable purchase commitments[(2)]:					
given	2,575	1,666	390	131	388
received	(278)	(126)	(64)	(27)	(61)
Other commercial commitments	2,624	128	424		