

SANOFI-AVENTIS
Form 20-F
March 07, 2008
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

(Mark One)

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

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2007

OR

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

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

For the transition period from to

Commission File Number: 001-31368

Sanofi-Aventis

(Exact name of registrant as specified in its charter)

N/A

(Translation of registrant's name into English)

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France

(Jurisdiction of incorporation or organization)

174, avenue de France, 75013 Paris, France

(Address of principal executive offices)

Karen Linehan, 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
American Depositary Shares, each representing one half of one ordinary share, par value 2 per share	on which registered: 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, 2007 was:

Ordinary shares: 1,365,916,644

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

of the Securities Act.

YES NO

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

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

YES NO

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.

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Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

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

U.S. GAAP

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

Other

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

Item 17

Item 18

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

YES NO

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PRESENTATION OF FINANCIAL AND OTHER INFORMATION

The consolidated financial statements contained in this annual report on Form 20-F have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and with IFRS as adopted by the European Union, as of December 31, 2007.

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. References to Aventis refer to Aventis and its consolidated subsidiaries for periods prior to August 20, 2004.

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

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

trademarks used or that may be or have been used under license by sanofi-aventis and /or its affiliates, such as Actonel[®], Optinate[®] and Acrel[®], trademarks of Procter & Gamble Pharmaceuticals, Alvesco[®], a trademark of ALTANA Pharma AG, Campto[®], a trademark of Kabushiki Kaisha Yakult Honsha, Copaxone[®], a trademark of Teva Pharmaceutical Industries, Exubera[®], a trademark of Pfizer Products Inc., Mutagrip[®], a trademark of Institut Pasteur, PER.C6[®], a trademark of Crucell Holland B.V., TroVax[®], a trademark of Oxford BioMedica, Autopen[®]24, a trademark of Owen Mumford, Ltd., Gardasil[®] and Rotateq[®], trademarks of Merck & Co., Inc., Herceptin[®], a trademark of Genetech, NanoCrystal[®], a trademark of Elan Pharmaceuticals, VelocImmune[®], a trademark of Regeneron Pharmaceuticals, Inc., 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[®] and Heartgard[®], 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 Competition is based on sales data from IMS Health MIDAS (IMS) and GERS (for France), retail and hospital, for calendar year 2007, in constant euros (unless otherwise indicated).

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While we believe that the IMS/GERS 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

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

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:

the success of our research and development programs;

our ability to protect our intellectual property rights;

our ability to continue to maintain and expand our presence profitably in the United States;

the risks associated with reimbursement of healthcare costs and pricing reforms, particularly in the United States and Europe; and

trends in the exchange rate and interest rate environments.

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. Sanofi-aventis financial statements for the years ended December 31, 2007, 2006 and 2005 are included in Item 18 of this annual report.

The consolidated financial statements of sanofi-aventis for the years ended December 31, 2007, 2006 and 2005 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 standards (IAS and IFRS) and to interpretations of the interpretations committee (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. IFRS accounts have not been published for the year ended December 31, 2003.

Sanofi-aventis reports its financial results in euro.

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<i>(million, except per share data)</i>	As of and for the year ended December 31,				
	2007	2006	2005	2004	2003 ^(e)
IFRS Income statement data					
Net sales	28,052	28,373	27,311	14,871	
Gross profit	21,636	21,902	20,947	11,294	
Operating income	5,911	4,828	2,888	2,426	
Net income attributable to equity holders of the Company	5,263	4,006	2,258	1,986	
Earnings per share: basic () ^(a)	3.91	2.97	1.69	2.18	
Earnings per share: diluted () ^(b)	3.89	2.95	1.68	2.17	
IFRS Balance sheet data					
Intangible assets and goodwill	46,381	52,210	60,463	61,567	
Total assets	71,914	77,763	86,945	85,557	
Outstanding share capital	2,657	2,701	2,686	2,668	
Equity attributable to equity holders of the Company	44,542	45,600	46,128	40,810	
Long term debt	3,734	4,499	4,750	8,654	
Cash dividend paid per share () ^(c)	2.07 ^(d)	1.75	1.52	1.20	1.02
Cash dividend paid per share (\$) ^(c)	3.02 ^(d)	2.31	1.80	1.62	1.28

(a) Based on the weighted average number of shares outstanding in each period used to compute basic earnings per share, equal to 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 1,353.9 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 2007 will be proposed for approval at the annual general meeting scheduled for May, 14, 2008.

(e) We did not publish financial data in accordance with IFRS in 2003, because at the time our financial statements were required to be presented in conformity with French Generally Accepted Accounting Principles. For this reason, we have not provided selected financial data for 2003.

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The following table sets forth, for the periods and dates indicated, certain information concerning the exchange rates for the euro from 2003 through February 2008 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⁾ (U.S. dollar per euro)	High	Low
2003	1.26	1.14	1.26	1.04
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
Last 6 months				
2007				
September	1.42	1.39	1.42	1.36
October	1.45	1.42	1.45	1.41
November	1.47	1.47	1.49	1.44
December	1.46	1.46	1.48	1.43
2008				
January	1.48	1.47	1.49	1.46
February	1.52	1.48	1.52	1.45

⁽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.

On March 5, 2008 the Noon Buying Rate was 1.53 per euro.

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 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 are not currently known to us or that we deem immaterial at this time.

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Risks Relating to Legal Matters

If we are unable to protect our proprietary rights, we may be unable to compete effectively or operate profitably.

It is important for our success that we be able to effectively obtain and enforce our patents and other proprietary rights. We hold a broad portfolio of patents, patent licenses and patent applications worldwide. To the extent effective patent protection of our products is not maintained, these products will become exposed to competition from generic products. The entry of a generic product into the market typically is followed by a substantial decline in the brand-name product's sales volume and revenues in most markets.

Obtaining Patent Rights. Patent law relating to the scope of claims in the pharmaceutical field in which we operate is continually evolving and can be the subject of some uncertainty. Accordingly, we cannot be sure that:

new, additional inventions will be patentable;

patents for which applications are now pending will be issued or reissued to us;

the scope of any patent protection will be sufficiently broad to exclude competing products; or

the laws providing patent protection will not change in a way that would limit protection.

Patent protection once obtained is limited in time (typically 20 years, with a possible extension of up to 5 years), after which competitors may use the covered technology without obtaining a license from us. Because of the time required to obtain regulatory marketing approval, the period of effective patent protection for a marketed product is frequently substantially shorter.

Enforcing Patent Rights. Our competitors may infringe our patents or successfully avoid them through design innovation. To prevent infringement, we may file infringement claims, which are expensive and time consuming and which may result in decisions unfavorable to us. Policing unauthorized use of our intellectual property is difficult, and we may not be able to prevent misappropriation of our proprietary rights.

We may also be accused of infringing the rights of others who then seek substantial damages and royalties from us. For example, we are currently facing claims from third parties claiming that our new SoloSTAR[®] family of devices infringes their patent rights. This risk is increased by the growth in the number of patent applications filed and patents granted in the pharmaceutical industry.

Even prior to the scheduled expiration of a patent, third parties may challenge the validity of the patents issued or licensed to us, which may result in the invalidation of these rights and the loss of sales derived from the related products. Such challenges have become increasingly common in recent years. Typical assertions in suits challenging a patent are (i) that the competing product does not fall within the scope of the patent, (ii) that the patent claims matters that are not in fact patentable or enforceable, for example because they are not a true innovation; or (iii) that there were procedural flaws that invalidate the patent office's decision to issue the patent. Patent litigation is subject to substantial

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uncertainty, and we cannot be sure how much protection, if any, will be provided by our patents if we attempt to enforce them and they are challenged in court or in other proceedings.

Our patent claiming the active ingredient of Lovenox® in the United States was ruled unenforceable by a U.S. federal district court on February 8, 2007. We are currently appealing this decision, but can provide no assurances as to the final outcome of this litigation. While the U.S. Food and Drug Administration (FDA) has not to date approved a competing enoxaparin sodium product, there can be no guarantee that it will not do so in the future. To the extent the ruling of the district court is not reversed on appeal, we will not be in a position to assert this patent against any such competing product in the United States.

Additionally, if a competitor chooses to take the risk of launching an infringing product prior to a court's determination that our patent rights are valid, enforceable and infringed, there can be no assurance that we will (i) be successful in obtaining a preliminary injunction to halt further sales and remove the infringing product from the market prior to obtaining a final injunction at trial, and even if we are successful, (ii) be able to obtain an award of sufficient damages from the competitor to repair all harm caused to us and (iii) effectively collect this award. By way of example, following the Group's failure to obtain a preliminary injunction halting the

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launch at risk of a generic version of Allegra® in October 2005, the Allegra® franchise in the United States has been substantially eroded and the asserted patent claims have still not gone to trial. In addition, while we were successful in obtaining a preliminary injunction halting further sales of a generic Plavix® in August 2006, the quantities of generic product distributed prior to the injunction had a significant negative effect on 2006 and 2007 earnings.

Court decisions upholding our patent rights may be appealed by the opposing party. For example, on June 19, 2007, the U.S. federal court hearing the Plavix® patent infringement suit decided in our favor and replaced the preliminary injunction with a permanent injunction. The generic company appealed this decision to the Court of Appeals for the Federal Circuit, and oral argument took place March 3, 2008. There can be no guarantee as to the result of this appeal.

Additionally, our successful 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. For example, while we have been successful to date, subject to the opposing parties' right of appeal, in asserting our Plavix® patent rights in the United States and Canada, a court in Korea has held the claims of the corresponding Korean patent to be invalid under Korean law.

Our patent rights are material to our business, and if we were unsuccessful in asserting them or they were deemed invalid, any resulting introduction of generic versions of our products in the United States, in Europe or in other markets 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. 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 results and assets.

Significant challenges to our proprietary rights concern such leading Group products as Plavix®, Lovenox®, Eloxatine®, Taxotere®, Xatral®, Ambien CR® and Allegra® as well as our SoloSTAR® devices. We are also involved in litigation challenging the validity or enforceability of patents related to a number of other products in the United States, the European Union and elsewhere, and challenges to other products may be expected in the future. We can give no assurance that as a result of these challenges we will not face generic competition for additional group products. 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.

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

Product liability is a significant business risk for us, and has become a more significant risk as we expand 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. Several pharmaceutical companies have recalled or withdrawn products from the market based on 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 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

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can be no assurance that the Group will not face additional claims in the future.

Although we maintain insurance to cover the risk of product liability, available insurance may not be sufficient to cover all potential liabilities. Further, we face a general trend in the insurance industry to reduce

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product liability coverage, by excluding products or by imposing limits for liabilities, causing companies to rely increasingly on self-insurance. In the future it is possible that self-insurance may become the sole means available for managing the product liability risk of our pharmaceutical and vaccines businesses.

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 in the United States. For example, in Europe in January 2008 the European Commission opened sector inquiry into competition in the pharmaceuticals sector; and in the United States the Group is defending a number of lawsuits, relating to antitrust and/or pricing and marketing practices, including, for example, class action lawsuits and whistle blower litigation. In 2007, we settled claims in the United States related to a predecessor company's marketing of Anzemet in a transaction involving a Corporate Integrity Agreement monitored by the U.S. Department of Health and Human Services. See Note D.22.c) to our consolidated financial statements included at Item 18 of this annual report.

Following judgments holding the U.S. patent protection of Loveno[®] and of DDAVP[®] tablets to be unenforceable, a number of civil antitrust and fair trade claims have been filed against sanofi-aventis as putative class actions alleging that we have prevented competition and generated excess profits. Similar claims have followed an attempt to settle our U.S. Plavix[®] patent litigation. The proposed settlement of the U.S. Plavix[®] patent litigation against Apotex by the parties thereto is also the subject of a criminal investigation by the Antitrust Division of the U.S. Department of Justice and civil investigative demands by various federal and state government entities in the United States, of which the outcome and impact on sanofi-aventis cannot reasonably be assessed at this time. 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.

Our collaborations with third parties expose us to risks that they will claim intellectual property rights on our inventions or fail to keep our unpatented technology confidential.

We occasionally provide information and materials to research collaborators in academic institutions or other public or private entities, or request them to conduct tests to investigate certain materials. In all cases we enter into appropriate confidentiality and intellectual property rights agreements with such entities. However, those entities might claim intellectual property rights with respect to the results of the tests conducted by their collaborators, and might not grant licenses to us regarding their intellectual property rights on acceptable terms.

We also rely upon unpatented proprietary technology, processes, know-how and data that we regard as trade secrets and protect them in part by entering into confidentiality agreements with our employees, consultants and certain contractors. We cannot be sure that these agreements or other trade secret protections will provide meaningful protection, or, if they are breached, that we will have adequate remedies. See Item 4. Information on the Company B. Business Overview Patents, Intellectual Property and Other Rights for more information about our patents and licenses.

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

The Group faces significant litigation and government investigations in all of its principal markets, including litigation concerning product pricing, allegations of securities law violations, product liability claims, employment matters, patent and intellectual property disputes, consumer law claims and antitrust matters. 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 other pending litigation matters, or in future litigation could preclude the commercialization of products, negatively affect the profitability of existing products and 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. Any such result could materially and adversely affect our results of operations, financial condition, or business. See Item 8. Financial Information A. Consolidated Financial Statements and other Financial Information Information on Legal or Arbitration Proceedings and Note D.22.c) to our consolidated financial statements included at Item 18 of this annual report.

Risks Relating to Our Business

We must invest substantial sums in research and development in order to remain competitive, and we may not fully recover these investments if our products are unsuccessful in clinical trials or fail to receive and maintain regulatory approval.

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. In 2007, we spent 4,537 million on research and development, amounting to approximately 16.2 % of our net sales. Our ongoing investments in new product launches and research and development for future products could result in higher costs without a proportionate increase in revenues.

The research and development process is lengthy and carries a substantial risk of product failure. If our research and development does not yield sufficient new products that achieve commercial success, our future operating results may be adversely affected.

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.

For example, in order to develop a commercially viable product, we must demonstrate, through extensive pre-clinical and human clinical trials, that the pharmacological compounds have an acceptable benefit/risk profile for human use in the proposed indications. There is also no assurance that favorable results obtained in pre-clinical trials will be confirmed by later clinical trials, or that the clinical trials will establish safety and efficacy data sufficient for regulatory approval. As of our annual results update on February 12, 2008, we had 113 compounds in pre-clinical and clinical development in our targeted therapeutic areas, of which 47 were in Phase IIb or Phase III clinical trials. For additional information regarding clinical trials and the definition of the phases of clinical trials, see Item 4. Information on the Company B. Business Overview Research & Development. There can be no assurance that any of these compounds will be proven safe or effective, or that they will produce commercially successful products.

After completing the research and development process, we must invest substantial additional resources with a view to obtaining government approval in multiple jurisdictions, with no assurance that approval will be obtained. We must obtain and maintain regulatory approval for our pharmaceutical products from the European Union, the United States and other regulatory authorities before a given product may be sold in these markets. The submission of an application to a regulatory authority provides no assurance that the regulatory authority will grant a license to market the product. Each authority may impose its own requirements, including requiring local clinical studies, and may delay or refuse to grant approval, even though a product has already been approved in another country.

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In our principal markets, the approval process for one or more indications of a new product is complex and lengthy, and typically takes from six months to two years from the date of application depending on the country. Moreover, if regulatory approval of a product is granted, the approval may place limitations on the indicated uses for which it may be marketed. A marketed product is also subject to continual review even after regulatory approval. Later discovery of previously unknown problems may result in marketing restrictions or withdrawal of the product, as well as an increased risk of litigation. See also [Risks Relating to Legal Matters](#) Product liability claims could adversely affect our business, results of operations and financial condition, [above](#). In addition, we are subject to strict government controls on the manufacture, labeling, distribution and marketing of our products. Each of these factors may increase our costs of developing new products and the risk that we may not succeed in selling them successfully.

Obtaining regulatory marketing approval is not a guarantee that the product will achieve commercial success. Commercial success is dependent on a number of factors beyond our control, notably the level and type of reimbursement which is accorded to the product by public health entities and third-party payers in each country, the acceptance of the product by the medical establishment and patients, and the existence and price of competing products and alternative therapies.

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.

Price pressure is considerable in our two largest markets, Europe and the United States, which represented approximately 43.4% and 33.8%, respectively, of our net sales in 2007. 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. Pricing in the German market has posed significant challenges for the Group in recent years, including a decision to classify Acomplia® as a non-reimbursed life-style drug and the announcement that the government was evaluating restrictions on additional products. Changes in the pricing environments in the United States or European markets could have a significant impact on our sales and results of operations. 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.

Changes in the marketing status or competitive environment of our major products could adversely affect our results of operations.

In some cases, pharmaceutical products face the risk of being involuntarily switched from prescription drug status to over-the-counter (OTC) drug status by national regulatory authorities. OTC drugs may not benefit from the same reimbursement schemes and in some cases are priced significantly lower than brand-name prescription drugs. The competitive environment for our products could also be adversely affected if generic or OTC versions of competitors' products were to become available.

We depend on the United States market for a significant part of our current and future operating results. A failure to continue our strategy of profitable operations in that market could adversely affect our business, results of operations, financial condition or prospects.

We may not achieve our growth strategy if we do not maintain and continue to expand profitably our presence in the United States, the world's largest pharmaceuticals market. We have identified the United States,

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which accounted for approximately 33.8% of our net sales in 2007, as a potential major source of continued future growth and plan to capitalize on our direct presence in the United States in the coming years to build a strong position in this market. We face a number of challenges in maintaining profitable growth in the United States, including:

the targeting of new products and customer markets;

the fact that the United States market is dominated by major U.S. pharmaceutical companies;

slower growth of the U.S. pharmaceutical market than in recent years;

the fact that U.S. law does not require the FDA to determine first whether our patents are being infringed prior to approval of a generic for marketing;

aggressive generic competition (including launches at risk) reinforced by legislative initiatives to further facilitate the introduction of generic drug or comparable biologic products through accelerated approval procedures;

potential changes in health care reimbursement policies and possible cost control regulations in the United States, including possible unfavorable developments in coverage of prescription drugs by Medicare;

increased FDA demands, leading to a potentially longer, more costly and more restrictive approval process for innovative products;

heightened scrutiny of the pharmaceutical industry and the FDA by the public, the media and Congress; and

exposure to the euro-dollar exchange rate.

We rely on third parties for the marketing of some of our products. These third parties may act in ways that could harm our business.

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 Marketing and Distribution. 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

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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, specialized components, active ingredients and medical devices.

Availability of Raw Materials and Specialized Components. Third parties supply us with a substantial portion of our raw materials and specialized components. Some raw materials and specialized components essential to the manufacture of our products are not widely available from sources we consider reliable for example, there is a limited number of approved suppliers of heparins, which are used 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.

Third-Party Manufacturing of Active Ingredients. Although our general policy is to manufacture the active ingredients for our products ourselves, we subcontract the manufacture of some of our active ingredients to third parties, 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. The manufacture of the active ingredients for Eloxatine® and Xatral® and part of the manufacture of the active ingredient for Stilnox® are currently carried out by third parties, as are some of the manufacturing steps in the production of Lovenox®. Additionally, under our collaborative arrangement with BMS, pharmaceutical production of Plavix® and Aprovel® is conducted partly in sanofi-aventis plants and partly in BMS plants.

Third-Party Supply of Medical Devices. Medical devices related to some of our products, such as certain pens used to dispense insulin, are manufactured by third parties. Reliance on third parties exposes us to the risk of supply interruptions, including as a result of third-party manufacturing problems or intellectual property conflicts, as well as the risk of product liability for materials not produced by the Group. See Risks Relating to Legal Matters Product liability claims could adversely affect our business, results of operations and financial condition, above).

If disruptions or quality concerns were to arise in the third-party supply of raw materials, specialized components, active ingredients or medical devices, this could affect our ability to sell our products in the quantities demanded by the market and could damage our reputation and relationships with our customers. See also The manufacture of our products is technically complex, and supply interruptions, product recalls or inventory losses caused by unforeseen events may reduce sales, delay the launch of new products and adversely affect our operating results and financial condition, above. Even though we aim to have backup sources of supply whenever possible, including by manufacturing backup supplies of our principal active ingredients at a second or third facility when practicable, we cannot be certain they will be sufficient if our principal sources become unavailable. Any of these factors could adversely affect our business, operating results or financial condition.

Counterfeit products could harm the business of sanofi-aventis.

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

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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.

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 flammable 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.

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](#) for additional information regarding our environmental policies.

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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 the United States, 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 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 a lesser extent to currencies in emerging countries. In 2007, approximately 33.8% of our net sales were realized in the United States. While we incur expenses in those currencies, the impact of currency exchange rates on these expenses does not fully offset the impact of currency exchange rates on our revenues. As a result, currency exchange rate movements can have a considerable impact on our earnings. When deemed appropriate, 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.

Liquidity risk.

As of December 31, 2007, the Group's net debt amounted to 4.2 billion. In addition to debt outstanding, the Group has contracted a number of credit lines and put into place commercial paper and medium term note programs with the aim of providing liquidity. See Item 11. Quantitative and Qualitative Disclosures about Market Risk. In the event of a market-wide liquidity crisis, the Group 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).

As a holder of ADSs, you may face exchange rate risk. Our ADSs trade in U.S. dollars and our shares trade in euro. 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 euro. Fluctuations in the exchange

- ⁽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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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 you would receive upon our liquidation or upon the sale of assets, merger, tender offer or similar transactions denominated in euro or any foreign currency other than U.S. dollars.

If you hold ADSs rather than shares it may be difficult for you to exercise some of your rights as a shareholder.

As a holder of ADSs, it may be more difficult for you to exercise your rights as a shareholder than it would be if you directly held shares. For example, if we offer new shares and you have the right to subscribe for a portion of them, the depositary is allowed, at its own discretion, to sell for your benefit that right to subscribe for new shares instead of making it available to you. Also, to exercise your voting rights, as a holder of ADSs, you must instruct the depositary how to vote your shares. Because of this extra procedural step involving the depositary, the process for exercising voting rights will take longer for you, as a holder 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, 2007, Total and L'Oréal, our two largest shareholders, held approximately 12.70% and 8.66% of our issued share capital, respectively, accounting for approximately 19.56% and approximately 14.68%, 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 are, 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 L'Oréal has recently liquidated part of its 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 2007, our net sales amounted to 28,052 million. Based on 2007 sales, we are the fourth largest pharmaceutical group in the world and the largest pharmaceutical group in Europe (source: IMS sales year end 2007; 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 E to the consolidated financial statements included under 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 25,274 million in 2007, 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 for metabolic disorders include Lantus[®], a long acting analog insulin which is a leading brand in the insulin market, and Amaryl[®], a once-daily sulfonylurea. In 2006, we also started marketing Acomplia[®], the first medicine of a new class of a selective CB1 receptor blocker indicated in Europe in the treatment of obese or overweight patients with associated type 2 diabetes or dyslipidemia risk factors;

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[®].

Our top fifteen products in terms of net sales generated in 2007 are Lovenox[®], Plavix[®], Lantus[®], Taxotere[®], Eloxatine[®], Stilnox[®]/Ambien CR[®], Copaxone[®], Aprovel[®], Tritace[®], Allegra[®], Amaryl[®], Xatral[®], Actonel[®], Depakine[®] and Nasacort[®] which together accounted for 67.5% of our 2007 net sales for the pharmaceutical activity, or 17,071 million.

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We are a major player in the vaccines industry, with net sales of 2,778 million in 2007 and with leading vaccines in five areas:

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

Influenza vaccines such as Fluzone[®] and Vaxigrip[®], used for seasonal campaigns in both hemispheres. 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, Endemic and Measles, Mumps and Rubella (MMR) vaccines, which include a wide range of products against hepatitis A, typhoid, rabies, yellow fever, Japanese encephalitis, cholera, MMR and anti-venoms. Key products include Imovax[®] Rabies, Verorab[®], Typhim Vi[®], Avaxim[®] and Vivaxim[®].

In 2007, our vaccines activity was favorably impacted by the continued growth of two products launched in 2005 in the United States (Menactra[®] and Adacel[®]) and by the launch of Pentaxim[®] in the International region. Sanofi Pasteur also strengthened its leadership position in both seasonal and pre-pandemic flu.

We have a strong commitment to research and development with 30 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 2007 sales figures from IMS Health MIDAS;

For our vaccines activity, market shares and rankings are based on our own estimates. We have assembled information based on various sources, including industry contacts, statistical information we have collected and information published by competitors or otherwise; 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

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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 around 100,000 employees worldwide at year end 2007. Sanofi-Synthélabo and Aventis, our legacy companies, 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) for diversification purposes. Sanofi launched its first major product on the market, Ticlid[®], in 1978. 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, followed by the launch of its first major products: Aprovel[®] in 1997 and Plavix[®] in 1998.

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

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French cosmetics group L'Oréal acquired the majority of its share capital, and in 1988 Synthélabo launched two major products on the French market: Stilnox[®] and Xatral[®]. By 1994, Stilnox[®] had become the leading insomnia prescription medication worldwide (Source: IMS Health).

Sanofi and Synthélabo merged in 1999.

The formation of Aventis on December 1999 was the result of the combination of Rhône-Poulenc and Hoechst bringing together a broad portfolio of activities including prescription drugs and vaccines, which became the core business of Aventis.

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 (notably penicillin), 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. Hoechst was especially strong in metabolic disorders with Amaryl[®] and several insulin products, and cardiovascular diseases with Tritace[®].

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 (acetylsalicylic acid and penicillin). 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. Rhône-Poulenc's main therapeutic fields were thrombosis with Lovenox[®], oncology with Taxotere[®] and respiratory diseases with Nasacort[®], and vaccines.

Subsequent to a bid to acquire all of the shares of Aventis announced in April 2004, 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.

For a description of our main acquisitions and divestitures since 2005, see Notes D.1 and D.2 to our consolidated financial statements included in Item 18 of this annual report.

B. Business Overview

Strategy

As a leading player in the pharmaceutical industry (no.1 in Europe and no.4 in the world based on 2007 IMS sales), sanofi-aventis has a mission to discover and develop innovative molecules and vaccines and make them available to patients throughout the world, while making a broad range of drugs accessible to as many people as possible thanks to a well-adapted mix of products in terms of price and therapeutic indications.

In a fast-changing industry environment, we remain highly adaptive and proactive in pursuing our development strategy:

Building on our key therapeutic fields

We have a global presence in a number of high-growth therapeutic fields: metabolic disorders (especially diabetes), thrombosis, cardiovascular diseases, oncology, central nervous system, internal medicine and vaccines.

Our aim is to continue to develop innovative products while preserving growth and profitability. We have eight blockbusters, each with annual sales of over one billion euros. These include Lantus[®], the world's leading insulin brand in the treatment of diabetes; Loveno[®], world leader in a growing market where prophylaxis is still undeveloped; Taxotere[®], which ranks first among branded cytotoxic agents thanks to its broad range of indications; and Plavix[®], which still has opportunities for growth due to the number of suitable patients who remain untreated.

Vaccines are another area of major development. Sanofi Pasteur is already very well established in high-potential markets like influenza, pediatric combination and poliomyelitis, booster vaccines, meningitis and also in cervical cancer with Gardasil[®], a vaccine sold through the Sanofi Pasteur MSD joint venture in Europe.

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Sanofi Pasteur is significantly expanding production capacity to meet market needs, while stepping up research and development and contracting alliances, such as the recent deals with Crucell and Acambis. The Group's vaccines division, Sanofi Pasteur is also working to secure its long-term growth prospects by establishing alliances with biotechnology companies and research centers.

Finally, we aim to consolidate and maintain our base business our mature product offering which generates sales of over eight billion euros. See Other Pharmaceutical Products, below.

Maintaining our position in our established markets and enhancing our presence on tomorrow's major markets through a regionalized approach

With tough economic conditions prevailing on our established markets, and especially in Europe, we intend to maintain our position by supporting our major products and by implementing targeted measures to bring our structures in alignment with downward price pressure from drug benefit providers.

In Japan, optimization of our marketing and distribution agreements is ongoing to bring back in-house sales previously made through alliances. We are also looking to new product launches and appropriate development of our existing products to fuel strong growth in Japan, thereby enhancing our position in the world's second largest pharmaceutical market.

We also intend to support our future growth by fully exploiting the sizeable potential of selected developing markets. We are already a leading player in these markets especially Brazil, Russia, India, China, and Mexico thanks to a balanced and diversified product mix, tailored to each country's specific needs. We are also adopting an ever more regionalized approach to our markets so as to take best advantage of local growth opportunities, with sales forces mirroring local healthcare systems to the largest extent possible, and production and development sites dedicated to serving local markets.

Selectively and continuously adapting our resources

We intend to continue selectively adapting our resources in each of the markets where we operate. On our mature markets, we are particularly conscious of the need to keep tight control over costs and staff numbers and are taking the cross-disciplinary initiatives needed to adapt our organizational structures and preserve the effectiveness of our leading-edge industrial facilities. In everything we do, we will be mindful of our responsibilities towards our employees, the broader community and environment and our ethical responsibilities. In developing markets, we will continue to invest in order to participate in local growth.

Optimizing our potential in Research and Development

We have one of the most innovative and promising research pipelines in the sector. Our intention is to target our R&D efforts on fields with major unsatisfied medical needs: metabolic disorders, thrombosis, cardiovascular diseases, sleep disorders, depression, oncology and vaccines. We are also keen to extend the geographical reach of our R&D through targeted new footholds and international knowledge sharing to strengthen our research capability. Finally, we will continue to boost our expertise in biotechnologies, in particular through alliances such as those recently concluded with Regeneron Pharmaceuticals and Dyax.

Continuing to promote access to medicines

Sanofi-aventis recognizes that the majority of the world population has little or no access to medicines, and works to develop programs adapted to their needs. Year on year, we reaffirm our commitment in six fields where major public health needs converge with our pharmaceutical expertise: malaria, tuberculosis, sleeping sickness, leishmaniosis, epilepsy and vaccination.

Principal Pharmaceutical Products

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

Table of Contents**Top 15 Products**

The following table sets forth the net sales of our top 15 pharmaceutical products for the year ended December 31, 2007.

The sections that follow provide additional information on the indications and market position of our top 15 products in their principal markets. The Group's intellectual property relating to our top 15 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 our top 15 products including Lovenox®, Plavix®, Taxotere®, Tritace®, Eloxatine®, Stilnox®/Ambien CR®, Allegra®, Nasacort®, Xatral® and Actonel®.

Top 15 products

Therapeutic Area / Product Name	2007 Net Sales (million)	Drug Category /Main Areas of Use
Thrombosis		
Lovenox® (enoxaparin sodium)	2,612	Low molecular weight heparin Deep vein thrombosis
Plavix® (clopidogrel bisulfate)	2,424	Unstable angina / non-Q-Wave myocardial infarction Platelet adenosine disphosphate receptor antagonist Atherothrombosis
Cardiovascular		
Aprovel® (irbesartan)	1,080	Angiotensin II receptor antagonist Hypertension
Tritace® (ramipril)	741	Angiotensin Converting Enzyme Inhibitor Hypertension Congestive heart failure after myocardial infarction
Metabolic disorders		
Lantus® (insulin glargine)	2,031	Long-acting analog insulin Type 1 and 2 diabetes mellitus
Amaryl® (glimepiride)	392	Sulfonylurea Type 2 diabetes mellitus
Oncology		
Taxotere® (docetaxel)	1,874	Cytotoxic agent Breast cancer Non small cell lung cancer Prostate cancer Gastric cancer
Eloxatine® (oxaliplatin)	1,521	Head and Neck cancer Cytotoxic agent

Colorectal cancer

Central Nervous System

Stilnox®/Ambien CR® (zolpidem tartrate)	1,250	Hypnotic Sleep disorders
Copaxone® (glatiramer acetate)	1,177	Non-interferon immunomodulating agent Multiple sclerosis
Depakine® (sodium valproate)	316	Anti-epileptic Epilepsy

Internal Medicine*Respiratory/Allergy*

Allegra® (fexofenadine hydrochloride)	706	Antihistamine Allergic rhinitis
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Nasacort® (triamcinolone acetonide)	294	Urticaria Local corticosteroid Allergic rhinitis
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Urology

Xatral® (alfuzosin hydrochloride)	333	Uroselective alpha1-blocker Benign prostatic hypertrophy
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Osteoporosis

Actonel® (risedronate sodium)	320	Biphosphonate Osteoporosis
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Thrombosis

Thrombosis occurs when a thrombus, or blood clot, forms inside a blood vessel. Left unchecked, 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 it was first introduced in 1987 and is approved for more clinical indications than any other LMWH. A comprehensive dossier of clinical studies has demonstrated the benefits and safety of Lovenox® in the prophylaxis and treatment of deep vein thrombosis (DVT) and in acute coronary syndromes (ACS). It has become the product of reference in clinical trials for the development of new anti-coagulants in both venous and arterial indications.

In the cardiovascular field, Lovenox® was approved in the United States in May 2007 for the treatment of patients with ST-segment Elevation Myocardial Infarction (STEMI) after a priority review. Lovenox® was also approved for this indication in 2007 in other countries including France and Germany. The registration process for this indication is ongoing in the rest of Europe and the world.

This success is based on EXTRACT-TIMI 25, a Phase III clinical trial published in the New England Journal of Medicine in 2006. This study included over 20,000 acute STEMI patients. Lovenox® was shown to be superior to unfractionated heparin (UFH). The sustained reduction of death and myocardial infarction at 1 year evidenced in ExTRACT in 2007 confirmed the sustained superiority of Lovenox® over the UFH strategy in reducing death and myocardial infarction. Each year, more than 1 million people worldwide suffer from STEMI.

In patients undergoing elective percutaneous coronary intervention (PCI) or coronary angioplasty, the STEEPLE study has shown that a single intravenous bolus of Lovenox® is associated with significantly less major bleeding, more predictable anticoagulation levels and similar efficacy compared with the current standard, UFH. These data were confirmed in 2007 with the STEEPLE 1-year data where Lovenox® was associated with significantly lower incidence of early major bleeding with a 1-year mortality comparable with UFH.

In the major field of medical as opposed to surgical prophylaxis of venous thromboembolism, Lovenox® continues to grow and gain patient share from UFH in the United States (Source: Solucient).

PREVAIL has assessed the efficacy of Lovenox® versus UFH in the prevention of thromboembolic events in post-ischemic stroke patients. The PREVAIL study showed that in acute ischemic stroke patients treated with Lovenox, the risk of having a venous thromboembolism (VTE) was significantly lowered when compared to UFH. PREVAIL was presented at the American Stroke Association Congress in February 2007 and published in the Lancet in April 2007.

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EXCLAIM assessed the benefit of extended thromboprophylaxis in acutely ill medical patients with reduced mobility. It has shown that extending prophylaxis with Lovenox[®] to five weeks is more effective than standard duration (10 days) for reducing the risk of venous thromboembolism (VTE). With EXCLAIM, Lovenox[®] is confirmed as a reference therapy for VTE prevention in patients with prolonged immobilization. The EXCLAIM study was presented at the International Society of Thrombosis and Hemostasis (ISTH) in July 2007 and has been submitted for publication.

In terms of medical practice registries, GRACE (the Global Registry of Acute Coronary Events) continues and as of today, has evaluated more than 95,000 patients worldwide with acute coronary syndrome and led to the publication of 63 manuscripts in a variety of peer review medical journals.

In the field of venous thrombosis prevention, ENDORSE has collected hospital medical practice data on a historically wide scale, with 68,000 patients in 358 hospitals, 32 countries and five continents. This registry has enrolled medical and surgical patients at risk and has showed the high prevalence (52%) of patients at risk of venous thrombo-embolism (VTE) and the need to improve effective prophylaxis: only 50% of patients have received a method of VTE prophylaxis recommended by international guidelines.

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In January 2008 Lovenox[®]/Clexane[®] was approved for marketing in Japan for the prevention of VTE in patients undergoing orthopaedic surgery of the lower limbs such as total hip replacement, total knee replacement and hip fracture surgery. Approval of other indications is expected to follow.

Lovenox[®]/Clexane[®] is the leader in anti-thrombotics in the United States, Germany, France, Italy, Spain, and United Kingdom (source: IMS/GERS for France, 2007 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.

Plavix[®] was launched in 1998, and is now marketed in over 80 countries, including the United States, through our alliance with Bristol-Myers Squibb (BMS). In Japan a New Drug Application (NDA) for marketing authorization was approved in January 2006 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. Sales of Plavix[®] in Japan are consolidated by sanofi-aventis and are outside the scope of our alliance with BMS.

Since 2002, Plavix[®] has also been indicated for the treatment of non ST segment elevation acute coronary syndrome (ACS; non-Q-wave myocardial infarction and unstable angina) in combination with ASA following the very significant results of the CURE trial. This indication was rapidly incorporated into the guidelines of the American Heart Association, the American College of Cardiology and the European Society of Cardiology. The CURE trial demonstrated that Plavix[®] provided significant early- and long-term benefits in patients with Non ST segment elevation Acute Coronary Syndrome (ACS). Plavix[®] reduced the relative risk of atherothrombotic events (myocardial infarction, stroke and death from a cardiovascular cause) by 20% when added to standard therapy including ASA, with a 1% increase in the rate of major bleeding. With more than 12,000 patients enrolled, CURE is the largest clinical trial ever conducted in patients presenting unstable angina or non-Q-wave myocardial infarction. Based on its broad clinical evidence base in this population, Plavix[®] has gained the highest grade of recommendation in recent guidelines issued by medical societies for the management of ACS and percutaneous coronary intervention (PCI).

Also in the cardiology field, the results of the CLARITY and COMMIT clinical trials have led to the approval of a new indication in ST-segment elevation ACS (Q-wave myocardial infarction). This approval was granted by the U.S. Food and Drug Administration (FDA) in August 2006 and by the European Medicines Agency (EMA) in September 2006.

The CLARITY trial, which enrolled nearly 3,500 patients, demonstrated that Plavix[®], added to standard therapy including fibrinolytics and ASA, significantly reduced the odds of acute myocardial infarction patients having another occluded artery, a second heart attack or dying after one week of hospitalization, as well as the odds of clinical events such as cardiovascular death, recurrent myocardial infarction and certain recurrent ischemias at 30 days.

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The COMMIT trial, which enrolled nearly 46,000 patients, demonstrated that Plavix[®], added to standard therapy including ASA, significantly reduced mortality in acute myocardial infarction patients at day 28 in an in-hospital setting.

The indications resulting from the results of the CURE, CLARITY and COMMIT trials make Plavix[®] a cornerstone therapy in management of ACS patients.

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Other studies have also further explored the role of clopidogrel bisulfate in various patients' profiles (mostly atherothrombotic patients):

The results of the CREDO clinical trial, published in November 2002, confirmed the therapeutic value of Plavix® in the early- and long-term prevention of atherothrombotic events in patients having undergone coronary angioplasty, either with or without stenting. The CREDO trial, conducted in over 2,000 patients, demonstrated the efficacy of Plavix®, which reduces the relative risk of atherothrombotic events by 27% after one year;

The MATCH trial results released in May 2004 showed that ASA did not provide additional clinical value (benefit/risk ratio) in specific patients who have recently experienced a stroke or transient ischemic attack when added to Plavix® and other standard therapies.

The results of the CHARISMA trial were released at the 55th Annual Scientific Session of the American College of Cardiology in March 2006. The CHARISMA trial enrolled over 15,600 patients and aimed to demonstrate the clinical value of Plavix® on top of standard therapy including ASA in patients at high risk of future cardiovascular events. The study findings did not demonstrate an improvement of the risk/benefit ratio but significant differences by sub-group:

on the one hand, in patients with established atherothrombotic diseases (also referred to as secondary prevention), clopidogrel bisulfate in addition to ASA reduced the relative risk of recurrent heart attack, stroke or cardiovascular death by a statistically significant 12.5%, compared to patients receiving placebo and ASA. These patients accounted for almost 80% of the total CHARISMA study population;

on the other hand, patients with multiple risk factors but no clearly established vascular disease did not benefit from the addition of clopidogrel bisulfate to ASA, with a 20% relative risk increase. These patients represented approximately 20% of the overall study population. In this patient subgroup, there was an excess in cardiovascular mortality as well as a non-statistically significant increase in bleeding observed in patients treated with clopidogrel bisulfate and ASA.

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

ACTIVE, which is intended to assess the value of Plavix® in patients with atrial fibrillation for the prophylaxis of cardio-embolic 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. Results are expected in the third quarter of 2008;

the CURRENT study aims to optimize the dosing regimen of clopidogrel bisulfate in 12,000 patients with non ST elevation ACS, and planned to receive a stent. A loading dose of 600 mg followed by 150 mg daily for two weeks then followed by 75 mg daily 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 the fourth quarter of 2008.

Since 2003, 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).

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In addition to randomized controlled trials, one of the largest observational studies was initiated in 2003 to evaluate the real-life risk of patients with atherothrombosis. This registry, called REACH (Reduction of Atherothrombosis for Continued Health) includes 63,000 patients in more than 44 countries. The one-year results published in the landmark journal JAMA show a considerable rate of events, although in a population receiving the contemporary standard of care. This illustrates the high burden of atherothrombotic disease and the need to evolve pharmacological management more aggressively.

In the United States, the FDA approved a new dosage in October 2007: the 300 mg tablet, indicated in the setting of the loading dose for patients with Acute Coronary Syndromes.

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The extensive clinical program for Plavix[®], including all completed, ongoing and planned studies, is one of the largest of its kind and will enroll more than 100,000 patients overall. In addition, over 70 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.

Plavix[®] sales in the United States were negatively impacted in 2006 and early 2007 following the launch of an at-risk generic of 75-mg clopidogrel bisulfate in August 2006. In June 2007, the U.S. District Court for the Southern District of New-York confirmed the validity of the Plavix[®] patent in the United States and forbade the generic company from marketing generic clopidogrel bisulfate in the United States until the patent expires in 2011. The generic company appealed this decision to the Court of Appeals for the Federal Circuit, and oral argument took place March 3, 2008. See Note D.22 to our consolidated financial statements at Item 18.

Plavix[®] remains the leading product in the European and the U.S. markets for anti-platelet agents (source: IMS/GERS for France, 2007 sales, all available channels).

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 kidney, 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 anti-hypertensives, angiotensin II receptor antagonists, and is indicated as a first-line treatment for hypertension. Angiotensin II receptor antagonists, which are highly effective, 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 market CoAprovel[®]/Avalide[®]/Karvezide[®], a fixed dose combination of irbesartan 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[®] was launched in 1997 and is now marketed in more than 80 countries, including the United States (under the brand name Avapro[®]), through an alliance with Bristol-Myers Squibb (BMS). In Japan the product is licensed/sub-licensed to Shionogi Company Limited and Dainippon Sumitomo Pharma Company Limited respectively. The application for marketing authorization for the treatment of hypertension was resubmitted at the end of 2006, after it was supplemented with additional studies at the request of the Japanese health authorities. The launch is planned mid-2008.

Aprovel[®] is also approved for the treatment of nephropathy in hypertensive patients with type 2 diabetes, in both Europe and the United States. These approvals were based on the results of the PRIME program, a clinical program that demonstrated that irbesartan protects type-2 diabetic hypertensive patients from the progression of renal impairment, at both early and more advanced stages of the disease. Following the announcement of the PRIME results in 2002, the American Diabetes Association (ADA) recommended the use of angiotensin receptor antagonists, such as Aprovel[®], as a first-line treatment for renal disease in hypertensive patients with type-2 diabetes.

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In August 2006, the European Medicines Agency (EMA) approved a new fixed dose combination of 300 mg Aprovel® with 25 mg of HCTZ under the brand name CoAprovel®. This new dosage was also approved by the FDA in November 2007 under the brand name Avalide®. Avalide® may be used in appropriate patients whose blood pressure is not adequately controlled on monotherapy, and can now be used as initial therapy in appropriate patients who are likely to need multiple drugs to achieve their blood pressure goals.

The results of two further efficacy trials were released in 2006, demonstrating the benefits of rapid blood pressure control with CoAprovel® as a first-line treatment in patients with severe and moderate hypertension. These data have been integrated in the legal notices in Europe and led to a new marketing authorization for

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Avalide® in the United States in November 2007 for the first line treatment of patients with a severe to moderate hypertension.

Several clinical trials are ongoing in an effort to demonstrate the effects of Aprovel® beyond blood pressure control:

i-PRESERVE evaluates the benefit of Aprovel® in the treatment of heart failure with preserved systolic function, a common but not well recognized form of heart failure. This 4,100-patient study was initiated in 2002. Results are expected by the end of 2008; and

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 the end of 2008.

In 2007, based on the total sales of Aprovel® /Avapro®/Karvea® and CoAprovel®/Avalide®/Karvezide®, we rank third in Europe and in the United States among the angiotensin II receptor antagonists in the hypertension market. (source: IMS, 2007 sales).

Tritace®/Triatec®/Delix®/Altace®

Tritace® (ramipril) is an angiotensin converting enzyme (ACE) inhibitor indicated for the treatment of hypertension, congestive heart failure following 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 people at high risk for cardiovascular events and has the broadest spectrum of indications for the treatment of cardiovascular disease.

The new European Society of Hypertension (ESH) / European Society of Cardiology (ESC) guidelines on the management of hypertension published in June 2007 have highlighted the importance of taking global cardiovascular risk into account and the need to control hypertension. Based on the protective effect shown in the HOPE study, the available combinations with diuretics (ramipril + hydrochlorothiazide) and calcium channel blockers (ramipril + felodipine) are listed as preferred combinations in the newest guidelines for physicians to help patients reach their blood pressure goals without worsening their metabolic profile.

The three leading countries for sales of Tritace® in 2007 were Italy, Canada and France (source: IMS, 2007 sales). Generic ramipril became available in Canada in 2007, negatively affecting our sales there.

Tritace® is marketed by King Pharmaceuticals in the United States under the brand name Altace®.

Metabolic Disorders

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The prevalence of diabetes is expected to increase significantly over the next 20 years, as a direct result of sedentary life style, excessive weight and obesity, unhealthy diet and population aging. Our principal products are Lantus[®], an insulin analog, and Amaryl[®], a sulfonylurea. Sanofi-aventis is planning to strengthen its presence in metabolic disorders in particular with the launch of Acomplia[®], a blocker of CB-1 receptors critically involved in the regulation of body mass and body weight, lipid metabolism and insulin resistance.

Lantus[®]

Lantus[®] (insulin glargine) is a long-acting basal insulin analog, offering improved pharmacokinetic and pharmacodynamic profiles compared to neutral protamine hagedorn (NPH) insulin. 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 of six years and above with type 1 diabetes mellitus (T1DM).

Lantus[®], the number-one prescribed insulin in the world (IMS 2007), is the only, once-daily, 24-hour duration of action, peakless basal insulin.

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The uniqueness of the Lantus[®] profile was recently confirmed again in a direct comparison to another basal insulin analog where much greater effect from 12h to 24h after administration was observed with Lantus[®]. Thus, Lantus[®] was shown to have activity levels more than 4 times greater than those of the other basal insulin analog during this time period. Importantly, the same study showed a marked and highly significant difference in terms of duration of action: Lantus[®] showed a 24-hour coverage whereas the other basal insulin analog had a duration of action of only 17.5 hours.

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. Thus, 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.

A number of controlled and randomized studies have investigated the efficacy and safety of Lantus[®] plus prandial (meal-time) insulins in Type 1 diabetes mellitus. For instance, the one-year Porcellati study showed that in patients treated with NPH four times per day plus lispro (a fast-acting insulin analog) and randomized to either continue NPH four times per day or to switch to once daily Lantus[®] at dinner, A1C did not change with NPH and decreased with Lantus[®] (from 7.1% to 6.7%).

A number of controlled and randomized studies have investigated the efficacy and safety of Lantus[®] plus oral anti-diabetic agents (OADs) in Type 2 diabetes mellitus:

The 24-week Treat-to-Target study showed that, compared with NPH, significantly more type 2 diabetic patients treated with Lantus[®] achieved a target goal of A1C under or equal to 7%, without having an episode of nocturnal hypoglycemia. The rates of hypoglycemia were statistically lower with Lantus[®] relative to NPH;

A recent metaanalysis of 11 studies comparing Lantus[®] to NPH, confirmed a lower rate of hypoglycemia with Lantus[®] as compared to NPH in patients with either type 1 or type 2 diabetes;

The APOLLO study 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 and less injections and blood glucose monitoring than with a prandial insulin strategy;

The INITIATE study showed that Lantus[®] is an easy and effective way for 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; and

The 5001 trial, 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 target A1C of 7.0% after a 9-month period. This glycemic control is sustained in the long term, 20 months after Lantus[®] initiation. The neutral effect on weight observed at 9 months was confirmed at 20 months.

Sanofi-aventis has set-up a comprehensive clinical program to evaluate the acute and long-term effect of Lantus[®] on cardiovascular outcomes.

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As part of this broad effort, the INTENSIVE trial will compare the effects of tight glycemic control using insulin glargine and insulin glulisine (Apidra®) to usual care on cardiac function (infarction size) in patients with STEMI. Results are anticipated in 2009;

The ORIGIN trial is a large ongoing worldwide morbidity/mortality trial and will determine if Lantus®-mediated normoglycemia reduces cardiovascular events in high-risk dysglycemic patients. The recruitment of ORIGIN has been completed with over 12,000 subjects from 40 countries, who are being followed for at least 4 years. Results are expected in 2010;

Encouraging results come from the ROLE registry of healthcare claims in more than 20,000 patients with type 2 diabetes from an U.S. national managed care database. It has been found that the initiation

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of insulin therapy with Lantus[®] was associated with a lower incidence rate of subsequent myocardial infarction as compared with NPH insulin. The unadjusted incidence rate of MI events was reduced by 42% when patients were treated with Lantus[®].

The new disposable insulin pen, Lantus[®] SoloSTAR[®], was approved by the EMEA in September 2006 and by the U.S. FDA in April 2007. In 2007 Lantus[®] SoloSTAR[®] was launched in numerous countries around the world including the United States, France, Germany, United Kingdom, Italy, Spain, and Australia. Additional launches in the rest of the world are planned for 2008.

The portfolio of injection devices available for the administration of Lantus[®] also includes Lantus[®] OptiSet[®] (a disposable pen) and OptiPen[®] / OptiClik[®] (reusable pens) as well as Autopen[®]24 from Owen Mumford Ltd.

Lantus[®] has been launched in over 70 countries worldwide.

Lantus[®] has been the leading insulin brand worldwide since 2005. It is also the leading insulin brand worldwide in units sold. The United States is the largest contributor to Lantus[®] sales, followed by Germany and France (source: IMS, 2007 sales, all available channels).

Amaryl[®]/Amarel[®]/Solosa[®]

Amaryl[®] (glimepiride) is a once-daily sulfonylurea for the oral treatment of type 2 diabetes, as an adjunct to diet and exercise. Sulfonylureas are part of the guidelines for the first step of treatment for type 2 diabetes patients. Studies also prove the effective combination of Amaryl[®] with Lantus[®], if oral treatment alone does not provide tight diabetes control. 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. Studies demonstrate that a patient using Amaryl[®] can achieve a very good level of control with a low risk of hypoglycemia.

Acomplia[®]

Acomplia[®] (rimonabant) is the first in a new class of therapeutics called selective CB-1 receptor blockers which regulates energy balance and body weight, and improves glucose and lipid metabolism. Rimonabant is indicated in the treatment of obese or overweight patients with associated cardiometabolic risk factors such as type 2 diabetes or dyslipidemia.

Throughout extensive Phase III clinical trials it has been shown that treatment with Acomplia[®] results in reduction in weight and waist circumference (a key marker of abdominal obesity), together with improvements on HDL-C, TG and glycemic control in a broad range of patients with multiple cardio-metabolic risk factors. Approximately half of the improvements seen with Acomplia[®] on HDL-C, TG and HbA1C (a marker of glycemic control) is believed to arise directly from blockade of peripheral CB-1 receptors in metabolically active tissues such as the liver, adipose tissues, pancreas and skeletal muscles.

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With the aim of establishing rimonabant's efficacy in the control of type 2 diabetes and ultimately demonstrating its role in the prevention of type 2 diabetes and cardiovascular diseases, an ambitious life cycle management plan has been set up with 11 Phase IIIb clinical studies involving nearly 25,000 patients, investigating the interest of Acomplia® in the treatment of pre-diabetic and diabetic patients versus an active comparator and in combination with insulin. The latest release of data of the SERENADE study demonstrated that patients treated with rimonabant, as a monotherapy, showed significantly improved HbA1c, robust weight loss, reduced waist circumference and improved lipid profile. The results of SERENADE were included in the European regulatory authorities' updated Summary of Products characteristics in November 2007.

In Japan, the results of a Phase IIb study were consistent in terms of benefits on weight and cardio-metabolic risk factor reduction as compared to the results of previous European and U.S. studies. Rimonabant demonstrated a good safety profile in this population. In addition, a significant reduction in visceral fat was observed in patients who underwent CT-scan. Phase III studies are currently in progress for two indications: diabetes and weight management. A submission in Japan is planned for 2009 in obesity.

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In the United States, the FDA Endocrinologic and Metabolic Drugs Advisory Committee, held in June 2007, voted against recommending approval of rimonabant (Zimulti® in the United States) for the treatment of obese and overweight patients with associated risk factors. Consequently, sanofi-aventis decided to withdraw the New Drug Application (NDA) in the United States. Sanofi-aventis is confident in the positive benefit to risk ratio of rimonabant 20mg when used in the appropriate population and is committed to making rimonabant available to patients in the U.S. market.

Rimonabant (Acomplia®) was approved in Europe in June 2006. It is now approved in 52 countries and has already been launched in 21, including Germany, the United Kingdom, France (since the first quarter of 2007) and some other countries of Europe and Latin America. More than 250,000 patients have been prescribed Acomplia®. Sanofi-aventis has implemented responsible promotion and extensive medical education for Acomplia® to be properly used in the appropriate population.

Acomplia® has been listed in major guidelines by academic societies in the cardiometabolic field: International Diabetes Federation (IDF), European Society of Hypertension (ESH/ESC), European Society of Cardiology (ESC cardiovascular disease prevention).

The Group is working towards a submission of a Type 2 diabetes indication in 2009 and in cardiovascular disease in 2011.

Oncology

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

Taxotere®

Taxotere® (docetaxel), a drug in the taxoid class of chemotherapeutic agents, 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® was first licensed in 1995 in Europe, for use in patients with locally advanced or metastatic breast cancer. The following year, it was granted approval in the United States, Canada and Japan. It is now available in more than 100 countries and, in the 11 years since its launch, Taxotere® has gained approval for use in eleven indications in five different tumor types – breast, prostate, gastric, lung and head and neck.

Taxotere® is indicated for early stage and metastatic breast cancer, first-line and second-line metastatic non-small cell lung cancer (NSCLC), androgen-independent (hormone-refractory) metastatic prostate cancer, advanced gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction and for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck.

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In breast cancer Taxotere® is now used in a variety of doses and schedules, as first-line and second-line treatment. It has demonstrated a survival benefit in five studies for four indications in this setting: as monotherapy, or in combination with doxorubicin, capecitabine or trastuzumab.

Taxotere® received Priority Review in June 2007 by the Ministry of Health, Labour and Welfare (MHLW) of Japan following a supplemental New Drug Application (sNDA) for a new indication as a treatment of metastatic hormone refractory prostate cancer submitted in February 2007. Only a limited number of drugs with health insurance coverage are used to treat mHRPC in Japan. For this reason, Japanese urologists requested that the Japan Society of Clinical Oncology, the Japanese Urological Association and the Japanese Society of Medical Oncology solicit MHLW to perform a fast review for Taxotere® in this indication.

A meta-analysis of Individual Patient Data (IPD) including 2,867 patients from seven clinical trials demonstrated a significant overall survival benefit of Taxotere® over vinca-alkaloid-based regimens in the treatment of first line advanced Non Small Cell Lung Cancer (NSCLC) patients. Efficacy results of this IPD

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meta-analysis, called DOCMA-LC (DOCetaxel Meta-Analysis in Lung Cancer), were presented at the 12th World Conference on Lung Cancer in Seoul in September 2007. The aim of DOCMA-LC was to assess the overall survival and tolerability as well as to validate surrogate endpoints from all randomized clinical trials comparing Taxotere[®]-based chemotherapy to vinorelbine- or vindesine-based chemotherapy regimens in first-line treatment of advanced NSCLC. The findings of DOCMA-LC confirm the significant superiority of Taxotere[®]-based regimens compared to vinca-alkaloid regimens in terms of overall survival.

Important new results of two major clinical studies on Taxotere[®] were published in the same edition of the New England Journal of Medicine in October 2007. The Tax 324 study is a Phase III trial of Taxotere[®], Cisplatin and 5-Fluorouracil versus Cisplatin and 5-Fluorouracil induction chemotherapy, followed by chemoradiotherapy in patients with locally advanced squamous cell carcinoma of the head and neck; the previous Tax 323 study was conducted in inoperable patients only. Both studies confirmed significantly improved overall survival in patients with Taxotere[®]-based regimen.

The top four countries contributing to the sales of Taxotere[®] in 2007 were respectively the United States, France, Germany and Japan (based on 2007 net sales).

Eloxatine[®]

Eloxatine[®] (oxaliplatin) is currently the only platinum agent indicated both for the treatment of metastatic colorectal cancer and for the adjuvant treatment of stage III colon cancer.

In the United States, France, Germany, Italy, Spain, the United Kingdom and Japan more than 500,000 people are diagnosed every year with colorectal cancer for the first time. Colorectal cancer is the second cause of death from cancer in the United States. Colorectal cancer with distant metastases (referred to as stage IV) makes up around 30% of all new colorectal cancer diagnoses per year. When diagnosed at an early stage, chances of cure with surgery increase dramatically. Chemotherapy is used as an adjuvant therapy to surgery in order to reduce the risk of recurrences.

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. Further, in patients with resectable liver only metastases from colorectal cancer, the results of the EPOC study presented on behalf of the European Organisation for Research and Treatment of Cancer (EORTC) at the 43rd American Society of Clinical Oncology (ASCO) meeting in June 2007 demonstrated that peri-operative chemotherapy with Eloxatine[®] given in combination with 5-fluorouracil/leucovorin (the FOLFOX regimen) significantly reduced the risk of relapse by 27% 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 MOSAIC study presented at ASCO 2007 shows that FOLFOX significantly improved the overall survival in Stage III colon cancer surgically resected. Eloxatine[®] was the first anticancer agent to result in a significant improvement of the adjuvant treatment of colon cancer in a decade. FOLFOX is now the standard

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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 nearly 70 countries worldwide.

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Central Nervous System

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

Stilnox®/Ambien®/Myslee®

Stilnox® (zolpidem tartrate) is the leading hypnotic worldwide and is indicated in the short-term treatment of insomnia. Stilnox® is both chemically and pharmacologically distinct from benzodiazepines, and is distinguished by its selective binding to receptors that are presumed to mediate hypnotic activity. Due to this characteristic, 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 believe that Stilnox® is also one of the most studied hypnotics in the world to date, as data on its efficacy and safety have been generated from 160 clinical trials involving 80,000 patients worldwide.

To improve further the efficacy of Stilnox® in sleep maintenance without inducing next-day residual effects, we have developed a controlled release formulation of zolpidem tartrate, zolpidem CR (controlled release). Two three-week placebo-controlled studies conducted in sleep laboratories, ZOLADULT and ZOLELDERLY, assessed the efficacy and safety of Ambien CR® (zolpidem CR) in the treatment of patients experiencing insomnia. The studies showed that Ambien CR® improved sleep maintenance, sleep duration and the ability to fall asleep compared to a placebo. We launched Ambien CR® in the United States in September 2005. Ambien CR® is indicated for the treatment of insomnia with sleep induction and/or sleep maintenance disorders. A clinical development program has also been initiated in Japan, with results expected in 2008.

Stilnox® was first launched in 1988 in France and is marketed today in over 100 countries. It was launched in Japan (where it is sold 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. As part of the restructuring of our joint activities with Astellas in Japan, we obtained certain rights over Myslee® at the end of 2007.

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

Myslee® is the leading hypnotic brand in Japan (source: IMS 2007 sales).

Copaxone®

Copaxone® (glatiramer acetate) is an immunomodulating agent indicated for reducing the frequency of relapses in patients with relapsing-remitting multiple sclerosis. 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 twelve years both in reducing relapses and progression of disability. A significant effect on lesions has also been confirmed by nuclear magnetic resonance imaging.

Copaxone® was first launched in 1997 in the United States and between 2000 and 2002 in Europe. It is in-licensed from Teva and marketed via our alliance with that company. From March 31, 2008 Teva will assume the Copaxone® business, including sales of the product, in the United States and Canada. Additional details on this alliance can be found in [Alliances](#) below.

In Europe in 2004, in cooperation with our alliance partner Teva, we launched a new formulation of the product a pre-filled syringe in order to improve product delivery and patient comfort. In June 2007, the

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application for up to one month room temperature storage of the pre-filled syringe was approved in the United States and Europe, bringing increased comfort to patients in transporting and storing Copaxone®.

The three leading countries are the United States, Germany, and France (source: IMS, 2007 sales).

Depakine®

Depakine® (sodium valproate) is a broad-spectrum anti-epileptic that has been prescribed for 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. The SANAD study published in 2007 in *The Lancet* demonstrates that Depakine® is still the treatment of choice in generalized or unclassified epilepsies given its benefit/risk ratio in women of childbearing potential.

Depakine® is also registered throughout Europe and in other countries in the world in the treatment of manic episodes associated with bipolar disorder and in some countries in the prevention of mood episodes. Sodium valproate is recommended as a first-line treatment in these indications by international guidelines such as the guidelines of the American Psychiatric Association, the United States Expert Consensus Guideline Series and the U.K. NICE Guidance.

We provide a wide range of formulations of Depakine® (syrup, oral solution, injection, enteric-coated tablets and Chrono, a sustained release formulation in tablets) permitting its adaptation to most types of patients. Depakine Chronosphere, a new innovative, tasteless, sustained release formulation of Depakine® packaged in stick packs, facilitating its use by children, the elderly and adults with difficulties swallowing, is available in some European countries.

Depakine® is marketed in over 100 countries, including the United States, where it is licensed to Abbott.

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®

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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.

In January 2007, Allegra[®] Oral Suspension 30mg/5ml (6 mg/ml) was commercially launched in the United States for the treatment of hay fever symptoms in children aged 2-11 years and the treatment of the uncomplicated skin manifestations of hives in children aged 6 months to 11 years. In July 2007, the FDA approved the supplemental NDA for Allegra[®] Orally Disintegrating Tablets (ODT), 30 mg for use in the treatment of hay fever symptoms and uncomplicated skin manifestations of hives in children aged 6-11 years. Allegra[®] ODT is scheduled to be launched in the United States prior to the 2008 spring allergy season.

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 2007 net sales).

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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. It is indicated for the treatment of the nasal symptoms of seasonal and perennial allergic rhinitis in adults and children six years of age and older. 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.

Data presented at the American College of Allergy, Asthma & Immunology (ACAAI) annual meeting in November 2007 suggests that the intranasal corticosteroid Nasacort®AQ (triamcinolone acetonide) Nasal Spray may be used safely and effectively to treat children aged 2-5 years old with year-round allergic rhinitis. The same study also showed that during the study, Nasacort®AQ did not show a significant effect on adrenal function among a subset of the same patients.

A Nasacort®AQ supplemental new drug application (sNDA) for the treatment of seasonal and perennial allergic rhinitis in pediatric patients 2 to 5 years of age was accepted for review by the U.S. FDA in early 2008.

Our leading markets for Nasacort®AQ Spray are the United States, France and Turkey (source: IMS, 2007 sales).

Urology

Xatral®

Xatral® (alfuzosin hydrochloride) belongs to the class of alpha1-blockers. It was the first product of the class to be indicated exclusively for the treatment of symptoms of benign prostatic hyperplasia (BPH), as it was the first marketed product capable of acting selectively on the urinary system. Xatral® (extended release formulation) does not require dose titration, and shows a good tolerability, especially from a cardiovascular standpoint. Active from the first dose, it provides rapid and lasting symptom relief and improves patient quality of life. Xatral® has demonstrated a good safety profile, with very marginal blood pressure changes even in elderly or hypertensive patients. Cardiovascular safety results from the combination of Xatral® with a phosphodiesterase inhibitor (PDE5) were released in 2005 and published in *Urology* in 2006, further demonstrating Xatral®'s good cardiovascular safety profile.

Besides this symptomatic action, a large clinical program has been launched to document the use of Xatral® in the treatment of acute urinary retention (AUR) and in the prevention of BPH disease progression.

The results of a double-blind placebo-controlled study (ALFAUR) conducted in men with AUR showed that Xatral® doubles the probability of a return to normal voiding after catheter removal. The benefits of Xatral® on AUR have been confirmed by the largest registry ever established with respect to the management of AUR, Reten-World. Results of an interim analysis that included 3,785 patients with AUR and concomitant BPH confirmed that most urologists carry out a trial without catheter after

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an average 3 day catheterization. The percentage of patients returning to normal voiding was significantly higher when the patient received an alpha1-blocker (Xatral® in 2 cases out of 3) at the time of the catheter removal;

Xatral® is the only alpha1-blocker having clearly demonstrated its benefit in the treatment of AUR. Since 2003, we have obtained authorizations of this extension of the indication in 56 countries worldwide including 16 European countries;

Moreover, results of a double-blind placebo-controlled study (ALTESS) show that Xatral® administered for 2 years in patients at high risk of developing AUR, significantly reduces the risk of overall BPH progression (defined by worsening of symptoms and/or occurrence of AUR and/or need for BPH-related surgery). A real life practice study enrolling more than 6,000 patients (ALF-ONE) also shows that patients experiencing BPH progression can be rapidly identified with Xatral® treatment as they are in fact non-responders to treatment;

BPH is also widely known to be linked with various degrees of sexual dysfunction. The results of another international trial (ALF-LIFE) that included 3,374 European patients have shown that Xatral® preserves sexual function, particularly ejaculatory function, in patients suffering from BPH;

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In Japan, recruitment of a large Phase III clinical trial comparing Xatral® 10mg once daily versus tamsulosin 0.2mg once daily is now completed (1155 included patients). Results are expected early 2008. The registration dossier of the once-daily formulation of Xatral® is expected to be submitted in September 2008.

Since Xatral® was launched in 1988 in France, we have constantly worked on optimizing its formulation. 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 4 billion treatment days of alfuzosin have been prescribed worldwide since launch and it is the fastest growing medical treatment for BPH symptoms among urologists in the United States.

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

Actonel® 75 mg was launched in the United States in July 2007 for the treatment of PMO. Actonel® 75 mg is dosed on two consecutive days during the month.

A retrospective cohort study (Silverman & al., Osteoporosis Int.) showed that during the first year of treatment, patients treated with Actonel® weekly decreased their risk of hip fracture by 46% at 6 months and by 43% at 12 months compared to patients treated with alendronate weekly. These data confirmed the early onset of action (as early as 6 months) of Actonel®.

Actonel® is in-licensed from Procter & Gamble Pharmaceuticals (P&G) and is marketed by sanofi-aventis and P&G through the Alliance for Better Bone Health . In Japan, Actonel® was previously marketed by sanofi-aventis under a license from Ajinomoto. As of October 2005, with the agreement of Ajinomoto, distribution of Actonel® in Japan was transferred to Eisai.

The top four markets for Actonel® are the United States, France, Canada and Spain (source : IMS, 2007 sales, all available channels).

Other Pharmaceutical Products

In addition to the top 15 pharmaceutical products, sanofi-aventis' global portfolio comprises a wide range of other pharmaceutical products, including prescription drugs and products sold over the counter (OTC), making up our base business . Due to their long presence on the market, but also to their effectiveness and safety, many of these products have strong brand recognition by healthcare professionals and patients.

Although they represent only one third of the Group's worldwide pharmaceutical net sales (32.5% in 2007), these products account for a significantly higher share in the sales of some new, fast growing, markets : for instance they represent more than 60% of pharmaceutical net sales in the five BRIC-M countries (Brazil, Russia, India, China and Mexico) and have grown there by some 10% in 2007.

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Sanofi-aventis is 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 almost 300 generic molecules originating from other laboratories.

Principal Vaccines Products

Sanofi Pasteur is a fully integrated vaccine business offering the broadest range of vaccines in the industry. In 2007 sanofi pasteur immunized over 500 million people against 20 serious diseases and generated net sales of 2,778 million. Sales were very favorably impacted by the strong growth in markets outside of North America and Europe and the continued growth of Adacel® and Menactra®, both launched in 2005 in the United States. Sales growth was also due to a strong uptake of Pentaxim® sales in the international region, and the successful seasonal influenza vaccine campaigns.

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

In Europe, our vaccine products are marketed by Sanofi Pasteur MSD, a 50-50 joint venture between sanofi pasteur and Merck & Co, which serves 19 countries. Sanofi Pasteur MSD is the market leader in Europe overall and in particular in France and the United Kingdom. In 2007, net sales of Sanofi Pasteur MSD, which are accounted for using the equity method, amounted to 1,040 million.

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

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. Act-HIB® for the prevention of *Haemophilus influenzae* type b infections is also an important growth driver within the pediatric product line. Pentacel®, which is a vaccine against five diseases (pertussis, diphtheria, tetanus, polio and *Haemophilus influenzae* type b), is approved in nine countries and has been the standard for preventive care in Canada since its launch in 1997; licensure is expected in the United States in 2008. 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 oral (OPV) and enhanced injectable (eIPV). We expect the use of eIPV to 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 use eIPV in their pediatric immunization schedule.

Influenza

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 was increased to more than 180 million doses in 2007 to better meet an 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 heightened awareness of a potential influenza

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pandemic amongst health authorities, medical professionals and the public at large, the demand for influenza vaccines has increased in general. In 2007, sanofi pasteur completed the construction of a \$150 million new influenza vaccine manufacturing facility in the United States, which will double our production capacity there and help meet the increased demand from both inside and outside the United States. This new facility is expected to come on-line in late 2008 or early 2009 following the facility's licensing by the FDA. A \$200 million investment is underway for a formulation and filling facility in Val de Reuil, France, to boost filling capabilities, mainly for influenza vaccines.

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 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 in 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.

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

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 2007, 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[®] in 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 Canada. Additional submissions are expected during the coming years in various parts of the world. Meningococcal meningitis vaccines are expected to contribute significantly to growth due to their anticipated future use in multiple segments of the population.

Sanofi Pasteur has supplied vaccines for meningitis outbreak control in Africa for over 30 years and is today the sole provider of meningitis A and C vaccines used to combat devastating annual epidemics occurring in sub-saharan countries (African meningitis belt).

Travel, Endemic and Measles, Mumps, Rubella (MMR) 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, Japanese encephalitis, cholera, MMR and anti-venoms. These vaccines are used in endemic settings to protect large populations in the developing world against severe infectious diseases 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

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most of these vaccines, sanofi pasteur's Travel/Endemic activity has realized stable growth. Additionally, sanofi pasteur has several lifecycle and new vaccines projects in development, including vaccines for dengue fever, Japanese encephalitis, malaria, West Nile and rabies (a Vero serum-free improvement of our current Verorab® rabies vaccine, as well as a Rabies MoAB Post Exposure prophylaxis). These diseases are major burdens of disease-endemic areas in Asia, South America and Africa, as well as representing health risks for travelers to endemic zones.

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.

Global and focused organizations: Discovery and Development

Discovery Research

In 2007, 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 13 new molecules entered into development.

SAR474832, a low absorption inhibitor of the sodium-dependent glucose Transporter 1, for the treatment of Type 2 diabetes mellitus;

SAR548304, a bile acid reabsorption inhibitor, for the treatment of hypercholesterolemia;

SAR104772, a TAFIa inhibitor, as a profibrinolytic agent for the prevention and treatment of thrombo-embolic diseases;

SAR131675, a potent selective VEGFR3-TK inhibitor with anti-lymphangiogenic, anti-tumoral and anti-metastatic activities;

SAR567530, a potent and selective HSP90 ATPase inhibitor, as a combinatorial cytostatic / cytotoxic approach for cancer treatment;

SAR137272, an A3 receptor antagonist, for the treatment of asthma;

SAR135966 (CER/002400), a selective orally-active NPY Y1 receptor antagonist, for the treatment of Type 2 diabetes;

SAR106881, an FGF receptor agonist, aimed at improving post-ischemic revascularization;

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SAR132885, a new class of anti-tumor agent targeting both the mitotic kinesin CENP-E and α -tubulin, for the treatment of solid tumors;

SAR113945, an IKK- β inhibitor, for the intra-articular treatment of osteoarthritic joint pain;

SAR102608, an inhibitor of haematopoietic prostaglandin D2 synthase, for the treatment of allergic asthma and allergic rhinitis;

SAR650984, a naked humanized monoclonal antibody targeting CD38 antigen, for the treatment of haematological malignancies;