SANOFI-AVENTIS
Form 20-F
March 31, 2006
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

(Mark One)

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

OR

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2005

OR

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

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

For the transition period from to

Commission File Number: 001-31368

Sanofi-Aventis

(Exact name of registrant as specified in its charter)

N/A

(Translation of registrant s name into English)

France

(Jurisdiction of incorporation or organization)

174, avenue de France, 75013 Paris, France

(Address of principal executive offices)

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

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

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

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

The number of outstanding shares of each of the issuer s classes of capital or common stock as of December 31, 2005 was:

ordinary shares: 1,401,306,569

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

YES x NO ¨.

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

YES ¨ NO x.

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

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

Yes x No ¨

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

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

Indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 ¨ Item 18 x

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

YES ¨ NO x.

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PRESENTATION OF FINANCIAL AND OTHER INFORMATION

The consolidated financial statements contained in this annual report on Form 20-F have been prepared in accordance with International Financial Reporting Standards (IFRS) adopted by the European Union as of December 31, 2005 and with IFRS issued by the International Accounting Standards Board (IASB) as of the same date. IFRS differ in certain significant respects from U.S. generally accepted accounting principles (U.S. GAAP). For a description of the principal differences between IFRS and U.S. GAAP, as they relate to us and to our consolidated subsidiaries, and for a reconciliation of our shareholders equity and net income to U.S. GAAP, see Note G to our consolidated financial statements included at Item 18, of this annual report.

Our results of operations and financial condition as of and for the year ended December 31, 2004 and have been significantly affected by our August 2004 acquisition of Aventis and certain subsequent transactions (including the merger of Aventis with and into our Company in December 2004). The results of operations of Aventis for the period between August 20, 2004 and December 31, 2004 have been included in our consolidated income statement and cash flow statement. This resulted in a significant increase in revenues and significant changes in other financial statement items in 2004 compared to 2003. The assets and liabilities of Aventis are also included in our consolidated balance sheet at December 31, 2004. See Item 5. Operating and Financial Review and Prospects.

We have prepared unaudited pro forma income statements for 2004 that present our results of operations as if the acquisition had taken place on January 1, 2004, described under Item 5. Operating and Financial Review and Prospects. Because of the significance of the Aventis acquisition, we present certain 2004 financial information in this annual report, such as sales of particular pharmaceutical products, as a percentage of our unaudited pro forma sales, rather than as a percentage of our consolidated sales.

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., Genasense®, a trademark of Genta Inc in the United States, Tavanic®, a trademark of Daiichi Pharmaceutical Co. Ltd., Mutagrip®, a trademark of Institut Pasteur, Gardasil®, a trademark of Merck & Co., Inc., Herceptin®, a trademark of Genentech, NanoCrystal®, a trademark of Elan Pharmaceuticals, Uvidem®, a trademark of Immuno Design Molecule (IDM), Inc.;

trademarks sold by sanofi-aventis and/or its affiliates, such as Altace®, a trademark of King Pharmaceuticals in the United States, Arixta® and Fraxiparine®, trademarks of GlaxoSmithKline, Cardizem®, a trademark of Biovail in the United States, StarLink®, a

trademark of Bayer AG, Sabril®, a trademark of Ovation Pharmaceuticals in the United States;

Cipro® in the U.S. and Aspirin®, trademarks of Bayer AG, Ivomec®, Eprinex®, Frontline® and Heartgard®, trademarks of Merial and Hexavac®, a trademark of Sanofi Pasteur MSD.

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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 Risk Factors below, include but are not limited to:

- the impact of our acquisition of Aventis;
- our ability to continue to maintain and expand our presence profitably in the United States;
- the success of our research and development programs;
- our ability to protect our intellectual property rights;
- 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, 2005 and 2004 are included in Item 18 of this annual report.

The consolidated financial statements of sanofi-aventis for the year ended December 31, 2005 have been prepared in compliance with IFRS adopted by the European Union as of December 31, 2005 and with the IFRS issued by the International Accounting Standards Board (IASB) as of the same date. The term IFRS refers collectively to International Accounting Standards (IAS), International Financial Reporting Standards (IFRS), Standing Interpretations Committee (SIC) interpretations and International Financial Reporting Interpretations Committee (IFRIC) issued by the IASB. The opening balance sheet as of the transition date (January 1, 2004) and the comparative financial statements for the year ended December 31, 2004 have been prepared in accordance with the same principles.

Sanofi-aventis reports its financial results in euro and in conformity with IFRS, with a reconciliation to U.S. GAAP. Sanofi-aventis also publishes condensed U.S. GAAP information. A description of the principal differences between IFRS and U.S. GAAP as they relate to the sanofi-aventis consolidated financial statements are set forth in Note G to the sanofi-aventis audited consolidated financial statements included in this annual report.

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SELECTED CONDENSED FINANCIAL INFORMATION

	As of and for the year ended December 31,				
(in millions of euro, except per share data)	2001	2002	2003	2004	2005
IFRS Income statement data:					
Net sales				14,871	27,311
Gross profit				11,294	20,947
Operating income				2,426	2,888
Net income				1,986	2,258
Earnings per share: basic (a)				2.18	1.69
Earnings per share: diluted (b)				2.17	1.68
IFRS Balance sheet data:					
Intangible assets				33,229	30,229
Total assets				85,407	86,658
Long-term debt				8,654	4,750
Equity attributable to equity holders of the company				41,061	46,637
U.S. GAAP Data: (e)					
Revenues from sale of products	6,069	7,448	8,048	14,871	27,311
Gross profit	4,843	6,163	6,718	11,293	20,946
Operating profit (loss)	1,715	2,301	2,797	(2,999)	2,816
Net income (loss)	1,098	1,640	1,865	(3,665)	2,202
Earnings (loss) per share: basic (c)	1.52	2.30	2.71	(4.03)	1.65
Earnings (loss) per share: diluted (d)	1.51	2.28	2.70	(4.03)	1.64
Intangible assets	5,178	5,140	4,553	32,858	28,699
Total assets	18,232	17,362	17,424	82,846	86,241
Long-term debt	119	65	53	8,638	4,734
Equity attributable to equity holders of the company	12,749	12,599	12,736	41,632	46,403
Cash dividend paid per share (f)	0,66	0,84	1,02	1,20	

(a) Based on the weighted average number of shares outstanding in each period used to compute basic earnings per share, equal to 910.3 million shares in 2004 and 1,336.5 million shares in 2005.

(b) Based on the weighted average number of shares outstanding in each period used to compute diluted earnings per share, equal to 914.8 million shares in 2004 and 1,346.5 million shares in 2005.

(c) Based on the weighted average number of shares outstanding in each period used to compute basic earnings (loss) per share, equal to 720.7 million shares in 2001, 714.3 million shares in 2002, 689.0 million shares in 2003, 910.3 million in 2004, and 1,336.5 million in 2005.

(d) Based on the weighted average number of shares outstanding in each period used to compute diluted earnings (loss) per share, equal to 725.7 million shares in 2001, 718.0 million shares in 2002, 691.1 million shares in 2003, 914.9 million in 2004, and 1,346.5 million in 2005.

(e) Sanofi-aventis applied Statement of Financial Accounting Standard 142, Goodwill and Other Intangible Assets, as of January 1, 2002 and voluntarily adopted the fair value recognition provisions of Financial Accounting Standard 123, Accounting for Stock-Based Compensation, as of January 1, 2003.

Certain data as of and for the year ended December 31, 2004 have been reclassified to conform to the presentation adopted under IFRS with respect to joint ventures that are no longer accounted for under the proportionate consolidation method.

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

EXCHANGE RATE INFORMATION

Exchange Rates

The following table sets forth, for the periods and dates indicated, certain information concerning the exchange rates for the euro from 2001 through March 28, 2006 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

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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.

Selected Exchange Rate Information

	Period-end Rate	Average Rate [1]	High	Low
	(U.S. dollar per euro)			
2001	0.89	0.89	0.95	0.84
2002	1.05	0.95	1.05	0.86
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
Last 6 months				
2005				
September	1.21	1.22	1.25	1.20
October	1.20	1.20	1.21	1.19
November	1.18	1.18	1.21	1.17
December	1.18	1.19	1.20	1.17
2006				
January	1.22	1.21	1.23	1.20
February	1.19	1.19	1.21	1.19
March 1st to 28th	1.21	1.20	1.22	1.19

(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 28, 2006 the Noon Buying Rate was $1.2078 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.

Risks Relating to Our Company

The integration of the new Group s activities presents significant challenges that may result in the combined business not operating as effectively as expected or in the failure to achieve some or all of the anticipated benefits of the business combination.

The benefits and synergies expected to result from the combination of sanofi-aventis and Aventis will depend in part on whether the operations of Aventis can be integrated in a timely and efficient manner with those of sanofi-aventis. Sanofi-aventis faces significant challenges in consolidating sanofi-aventis functions with those of Aventis, and integrating the organizations, procedures and operations of the two businesses. The integration of the two businesses is complex and time-consuming, and management must dedicate substantial time and resources to it. These efforts could divert management s focus and resources from other strategic opportunities and from day-to-day operational matters during the integration process. Failure to integrate successfully the

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operations of sanofi-aventis and Aventis could result in delay or the failure to achieve some or all of the anticipated benefits from the business combination, including synergies and other operating efficiencies, and could have an adverse effect on our business, operating results, financial condition or prospects.

We incurred substantial debt in connection with the acquisition of Aventis, which limits our business flexibility and requires us to devote cash resources to debt service payments.

In connection with our acquisition of Aventis, our consolidated debt increased substantially, because we incurred new debt to finance the cash portion of the acquisition consideration, and because our consolidated debt includes the debt incurred by Aventis prior to the acquisition. As of December 31, 2005, our net consolidated debt (financial debt less cash and cash equivalents and short term investments) was 9.9 billion, compared to a positive consolidated net cash position of 2.4 billion as of December 31, 2003, prior to the acquisition of Aventis. We make significant debt service payments to our lenders and our current debt level could restrict our ability to engage in additional transactions or incur additional indebtedness. For more information on our debt, please see Item 5. Operating and Financial Review and Prospectus Liquidity and Capital Resources in this annual report.

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, which accounted for approximately 35% of our net sales in 2005, 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 our leadership in this market. We face a number of challenges in maintaining profitable growth in the United States, including:

- The success of the management organization that we have established in the United States.
- 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.
- Aggressive generic competition.
- 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.

Heightened scrutiny of the pharmaceutical industry by the public and the media.

Exposure to the euro-dollar exchange rate.

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

We commercialize some of our products in collaboration with other pharmaceutical companies. For example, we currently have a major collaborative arrangement with Bristol-Myers Squibb for the marketing of Plavix® and Aprovel® in the United States and several other countries, and co-marketing agreements with Procter & Gamble Pharmaceuticals for the osteoporosis treatment Actonel® and Teva for Copaxone®, as well as an agreement with Merck & Co., Inc. for the distribution of vaccines in Europe. We also have alliances with several Japanese companies for the marketing of our products in Japan. See Item 4. Information on the Company Business Overview Markets Marketing and Distribution. When we commercialize 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

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example, our alliances with Bristol-Myers Squibb (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. The complexity of these processes as well as strict company and government standards for the manufacture of our products subject us to production risks. The occurrence or suspected occurrence of out-of-specification production can lead to lost inventories, and in some cases product recalls, with consequential reputational damage and the risk of product liability (See Product liability claims could adversely affect our business, results of operations and financial condition, below). The investigation and remediation of any identified problems can cause production delays, substantial expense, lost sales and the delay of new product launches.

We depend 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 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. The manufacture of the active ingredients for Eloxatine® and Xatral® and part of the manufacture of the active ingredient for Stilnox® is 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, as well as the risk of product liability for materials not produced by the Group. See Product liability claims could adversely affect our business, results of operations and financial condition, below.

If disruptions or quality concerns were to arise in the third-party supply of raw materials, specialized components, active ingredients or devices, this would 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.

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Our collaborations with third parties expose us to risks that they will assert 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 assert 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. You should read Item 4. Information on the Company Business Overview Patents, Intellectual Property and Other Rights for more information about our patents and licenses.

Claims relating to marketing practices could adversely affect our business, results of operations and financial condition.

The marketing of our products is heavily regulated, and failure to comply fully with applicable regulations could result in civil or criminal actions against us, and in some circumstances potential disqualification from participation in government health programs. Sanofi-aventis and certain of its subsidiaries are under investigation by various federal government entities in the United States, and are defendants in a number of lawsuits, relating to antitrust and/or pricing and marketing practices, including an investigation of suspected misrepresentations in product price data provided to U.S. federal health programs allegedly leading to inflated government reimbursements. See Note D.22(c) to our consolidated financial statements included at Item 18 of this annual report.

In addition, following judgments holding the U.S. patents covering DDAVP® tablets and Lovenox® to be unenforceable, a number of civil antitrust and fair trade claims have been filed against sanofi-aventis as putative class actions alleging that the Group has prevented competition and generated excess profits.

Because many of these cases allege substantial unquantified damages, including treble damages, and seek significant punitive damages and penalties, it is possible that any final determination of liability could have a material adverse effect on our business, results of operations or financial condition.

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 2005, approximately 35% 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.

Risks Relating to Our Industry

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 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 2005, we spent 4,044 million on

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research and development, amounting to approximately 14.8% 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 are safe and effective for use in humans. 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. In the first quarter of 2006, we had 127 compounds in pre-clinical and clinical development in our targeted therapeutic areas, of which 55 were in phase II 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 Business Overview Research and 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.

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 Product liability claims could adversely affect our business, results of operations and financial condition, below. 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 of reimbursement which is accorded to the product by public health entities and third-party payers, the acceptance of the product by the medical establishment and patients, and the existence and price of competing products and alternative therapies.

If we are unable to protect our proprietary rights, we may fail 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 currently have over 50,000 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.

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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; or
- the scope of any patent protection will be sufficiently broad to exclude competitors.

Patent protection once obtained is limited in time (typically 20 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 from us. 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 that (i) the competing product does not fall within the scope of the patent, (ii) that the patent claims matters that are not in fact patentable, 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 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.

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 (i) that we will be successful in obtaining a preliminary injunction to remove the infringing product from the market prior to obtaining a final injunction at trial, and (ii) that we will be able effectively to both obtain and collect sufficient damages from the competitor to repair all harm caused to us.

Significant challenges to our proprietary rights include:

Plavix®: In the first half of 2002, two pharmaceutical companies, Apotex and Dr. Reddy s Laboratories, each filed an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA), seeking to market a purportedly generic form of Plavix® in the United States and challenging certain U.S. patents relating to Plavix®. Subsequently, in August 2004, Teva filed an ANDA challenging one of the U.S. patents relating to Plavix®. On January 24, 2006, we learned that the FDA had approved Apotex s ANDA. For additional information regarding ANDAs, see Item 4. Information on the Company Business Overview Regulation. We have filed suit against Apotex, Dr. Reddy s Laboratories and Teva for infringement of our patent rights. See Item 8. Financial Information Consolidated Financial Statements and Other Financial

Information Information on Legal and Arbitration Proceedings and Note D.22(b) to our consolidated financial statements included in this annual report at Item 18. The Plavix® patent rights are material to our business, and if we were unsuccessful in asserting them or they were deemed invalid, any resulting introduction of a generic version of Plavix® in the United States would reduce the price that we receive for this product and 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.

As a reference, the developed sales of Plavix® in 2005 in the United States amounted to 2,585 million out of total worldwide developed sales of sanofi-aventis for all products of 30,778 million. Developed sales is a non-GAAP financial measure we use to demonstrate the overall trends for our products in the market, and which consists of sales of our products, excluding sales to our alliance partners, and of sales that are made through our alliances but which are not included in our consolidated sales. In 2005, sanofi-aventis share of the profits of the

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Plavix® and Aprovel® alliance entities managed by BMS in North America amounted to 404 million after taxes. See Item 5. Operating and Financial Review and Prospects Results of Operations Year Ended December 31, 2005 Compared with Year Ended December 31, 2004 herein for additional information as well as a derivation of developed sales.

Allegra®: We have been notified that seven generic pharmaceutical companies are seeking FDA approval to market generic versions of Allegra® products in the United States. We have filed patent infringement lawsuits against all of these companies. Two of these companies, Barr and Teva, announced in September 2005, that they were launching their generic version of Allegra® immediately without first waiting for the judgment in the pending patent litigation. Although we continue to assert our patent rights against these companies, this generic launch has already resulted in a substantial decline in the Group s sales of Allegra®, which dropped to 160 million in the last quarter of 2005 compared to 373 million in the last quarter of the preceding year.

Lovenox®: In June 2003, we were notified that both Amphastar Pharmaceuticals and Teva Pharmaceuticals were seeking approval from the FDA for purportedly generic versions of Lovenox® and are challenging the patent protection of this product. In June 2005, the U.S. District Court for the Central District of California granted Amphastar s request for a summary judgment ruling our patent unenforceable on the grounds of inequitable conduct. Although we are appealing this decision, if we do not succeed in having the lower court decision overturned, we will no longer be able to assert our patent rights in the United States against purportedly generic versions of enoxaparin, the active ingredient of Lovenox®.

We are also involved in litigation challenging the validity or enforceability of patents related to a number of other products in the United States and the European Union, 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 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 commercial risk for us, and may 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. Several pharmaceutical companies have recently recalled or withdrawn products from the market based on actual or suspected product risks, 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 Information on Legal or Arbitration Proceedings.), and there can be no assurance that the Group will not face additional claims in the future. Although we maintain insurance to cover the risk of product liability, we cannot be certain that our insurance will be sufficient to cover all potential liabilities. Further, we face a general trend in the insurance industry to exclude certain products from coverage and to reduce insured limits for liabilities, causing companies to rely increasingly on self-insurance. Substantial product liability claims, if successful, could adversely affect our business, results of operations and financial condition.

Use of biologically derived ingredients may face consumer resistance, which could adversely affect sales and cause us to incur substantial costs.

In line with industry practice, we manufacture our vaccines and many of our prescription pharmaceutical products with ingredients derived from animal or plant tissue. Most of these products cannot be made economically, if at all, with synthetic ingredients. We subject our products

incorporating these ingredients to extensive tests and believe them to be safe. There have been instances in the past where the use of biologically derived ingredients by sanofi-aventis or its competitors has been alleged to be an actual or theoretical source of harm, including infection or allergic reaction, or instances where production facilities have been subject to prolonged periods of closure because of possible contamination. Such allegations have on occasion led to damage claims and increased consumer resistance 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

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safety measures, manufacturing delays, investment in consumer education, and development of synthetic substitutes for ingredients of biological origin. Such claims could also generate consumer resistance, with a corresponding adverse effect on sales and results of operations.

We face uncertainties over the pricing of pharmaceutical products.

The commercial success of our products depends in part on the conditions under which our products are reimbursed. Price pressure is strong due to:

- price controls imposed by governments in many countries;
- removal of a number of drugs from government reimbursement schemes; 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 44% and 35%, respectively, of our net sales in 2005. Changes in the pricing environments in the United States or Europe (on an individual country basis) could have a significant impact on our sales and results of operations. See Item 4. Information on the Company Business Overview Pricing 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.

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 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 are generally 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.

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

Pharmaceutical manufacturing activities, such as the chemical manufacturing of the active ingredients in our products and the related storage and transportation of raw materials, products and wastes expose us to various risks, including:

fires and/or explosions from inflammable substances;

storage tank leaks and ruptures; and

discharges or releases of toxic or hazardous substances.

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

the shutdown of affected facilities and

the imposition of civil or criminal penalties.

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

Although we maintain property, business interruption and casualty insurance that we believe is in accordance with customary industry practices, we cannot assure you that this insurance will be adequate to cover fully all potential hazards incidental to our business. For more detailed information on environmental issues, see Item 4. Information on the Company Business Overview Health, Safety and Environment.

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

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

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

These environmental remediation obligations could significantly reduce our operating results. 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 Business Overview Health, Safety and Environment for additional information regarding our environmental policies.

Furthermore, we are or may become involved in claims, lawsuits and administrative proceedings relating to environmental matters. Some current and former sanofi-aventis subsidiaries have been named as potentially responsible parties or the equivalent under the U.S. Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended (also known as Superfund), and similar statutes in the United States, France, Germany, 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 are currently involved, for example, in litigation with Albemarle and Rhodia over environmental remediation at several sites no longer owned by the Group. An adverse outcome in any of these 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 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 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

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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, 2005, Total and L Oréal, our two largest shareholders, held approximately 12.7% and 10.2% of our issued share capital, respectively, accounting for approximately 19.5% and approximately 17.4%, respectively, of the voting rights of sanofi-aventis. See Item 7. Major Shareholders and Related Party Transactions Major Shareholders Shareholders Agreement.

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. Continued ownership of a large percentage of the share capital and voting rights of sanofi-aventis by these two principal shareholders, affiliates of whom may also continue to be members of the sanofi-aventis board of directors, may have the effect of delaying, deferring or preventing a future change in the control of sanofi-aventis and may discourage future bids for sanofi-aventis other than with the support of these shareholders.

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. 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 2005, our net sales amounted to 27,311 million. On the basis of 2005 net sales, we are the third largest pharmaceutical group in the world and the largest pharmaceutical group in Europe (IMS/GERS year end 2005; 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: pharmaceuticals (principally prescription drugs) and human vaccines.

In our pharmaceuticals activity, which generated net sales of 25,249 million in 2005, we specialize in six therapeutic areas:

Cardiovascular: Our cardiovascular products include two major hypertension treatments: Aprovel® and Tritace®.

Thrombosis: Our thrombosis products 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 deep vein thrombosis and for unstable angina and non-Q-wave myocardial infarction.

Metabolic Disorders: Our products for metabolic disorders include Lantus®, a long acting analog which is a leading brand in the insulin market, and Amaryl®, a once-daily sulfonylurea.

Oncology: Our lead 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 metastatic colorectal cancer.

Central Nervous System (CNS): Our 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.

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 are Lovenox®, Plavix®, Taxotere®, Eloxatine®, Stilnox®, Allegra®, Lantus®, Tritace®, Copaxone®, Aprovel®, Amaryl®, Actonel®, Depakine®, Xatral® and Nasacort®, which together accounted for 64.1% of our net sales for the pharmaceutical activity, or 16,188 million, in 2005.

In the human vaccines activity, we are a major player with leading vaccines in five areas:

Pediatric combination vaccines providing protection against such diseases as pertussis, diphtheria, tetanus, and *Haemophilus influenza* type b. Our main products are Daptacel®, Tripedia®, Act-HIB®, Pentacel, Pediacel® and Tetract-Hib®. We also produce polio vaccines, such as Ipol® and Imovax® Polio, as well as oral polio formulations, all of which contribute to polio eradication strategies in both developed and developing countries.

Influenza vaccines, which experienced strong growth in the Northern Hemisphere with Fluzone® and Vaxigrip®.

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

Meningitis vaccines, where our main products are the quadrivalent vaccines Menactra® and Menomune®. Menactra® (approved by the FDA in January 2005) is a conjugate vaccine that is expected to provide a longer-lasting immune response.

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Travel/Endemic vaccines, which include a wide range of vaccines against hepatitis A, typhoid, rabies, yellow fever, Japanese encephalitis, cholera, Enterotoxigenic *Escherichia coli* (ETEC) and anti-venoms. Key products include Imovax® Rabies, Verorab®, Typhim Vi®, Avaxim® and Vivaxim®.

In 2005, the human vaccines business recorded net sales of 2,062 million, significantly boosted by three successful launches in the United States (Decavac® in January, Menactra® in March and Adacel® in July) and a highly successful influenza vaccination season.

We have a strong commitment to research and development. We have 28 research centers and over 17,600 employees (including Vaccines, Industrial Development and Medical/Regulatory staff in subsidiaries) devoted to research and development.

A. History and Development of the Company

Sanofi-aventis was incorporated under the laws of France in 1994 as a *société anonyme*, a form of limited liability company, for a term of 99 years. We operate under the commercial name sanofi-aventis. Our registered office is located at 174, avenue de France, 75013 Paris, France, and our main telephone number is +33 1 53 77 40 00. Our principal U.S. subsidiary s office is located at 300 Somerset Corporate Boulevard, Bridgewater, NJ 08807-2854.

Following the acquisition of Aventis in August 2004, sanofi-aventis is present in more than 100 countries on five continents and employed over 97,100 people worldwide at year end 2005. The main purpose of the merger of Sanofi-Synthélabo and Aventis was to create a platform for strong, sustainable and profitable growth. Our legacy companies bring to the Group more than a century of experience in the pharmaceutical industry. Sanofi-Synthélabo itself was the result of the 1999 merger of Sanofi and Synthélabo, two major French pharmaceutical companies.

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. Sanofi made a significant venture into the United States market in 1994, when it acquired the prescription pharmaceuticals business of Sterling Winthrop, an affiliate of Eastman Kodak. Sanofi launched its first major product on the U.S. market, Aprovel®, in 1997, followed by 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 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 (IMS Health).

The formation of Aventis on December 15, 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 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, Institut Mérieux in the area of vaccines in 1994 and the U.K. pharmaceuticals company Fisons in 1995. Rhône-Poulenc s main therapeutic fields were thrombosis with Lovenox®, oncology with Taxotere® and Campto® (divested in 2004), respiratory diseases with Nasacort®, and vaccines.

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The Acquisition

On January 26, 2004, Sanofi-Synthélabo announced a bid to acquire all of the shares of Aventis through mixed exchange/cash tender offers on substantially identical terms in France, Germany and the United States. On April 26, 2004, the managements of Sanofi-Synthélabo and Aventis announced that the Supervisory Board of Aventis had voted to recommend an improved offer to Aventis shareholders. On August 20, 2004 Sanofi-Synthélabo acquired control of Aventis upon the settlement of these offers. At that time, Sanofi-Synthélabo changed its registered name to sanofi-aventis. A subsequent offering period followed. As a result of these offers, sanofi-aventis acquired an aggregate of 791,317,811 Aventis ordinary shares, which represented slightly over 98% of the share capital and 98% of the voting rights of Aventis on an undiluted basis (or over 92.44% of the share capital and the voting rights on a fully diluted basis). In December 2004, the respective extraordinary shareholder meetings of Aventis and sanofi-aventis adopted an agreement and plan of merger, and on December 31, 2004, Aventis merged with and into sanofi-aventis, with sanofi-aventis as the surviving company.

We divested certain assets in connection with the acquisition, including two products, Fraxiparine® and Arixtra®, that we sold in order to respond to potential demands from competition authorities in relation to the acquisition. Aventis also divested certain assets, including its product Campto®.

Mandatory Offers Subsequent to the Acquisition

Hoechst

From October 1 to December 10, 2004, pursuant to the German securities laws, sanofi-aventis conducted a mandatory offer for the outstanding shares of Hoechst AG not already indirectly acquired through the acquisition of Aventis, which held approximately 98.1% of Hoechst AG s share capital. 583,515 Hoechst shares, representing approximately 0.1% of the share capital and voting rights of Hoechst AG, were tendered into the mandatory offer.

Following the mandatory offer, Aventis proposed a squeeze-out resolution to the remaining minority shareholders of Hoechst according to which the shares of the remaining minority shareholders would be transferred to Aventis (now sanofi-aventis) for cash compensation of 56.50 per share. On December 20 and 21, 2004 at an Extraordinary Shareholders Meeting, the shareholders of Hoechst AG approved this squeeze-out resolution. The price initially set out in the resolution was raised to 63.80 per share in settlement of shareholder suits contesting the validity of the squeeze-out, and the squeeze-out of the minority shareholders took legal effect on July 12, 2005. At the same time, Hoechst became a wholly owned subsidiary of the sanofi-aventis Group. Those minority shareholders who waived their right to any future price increase resulting from litigation received an additional 1.20 per share. Following the squeeze-out, a number of former minority shareholders have commenced litigation contesting the adequacy of the price paid by sanofi-aventis. These suits, which do not contest sanofi-aventis ownership of the shares acquired through the squeeze-out, are ongoing. See Note D.2. to the consolidated financial statements included under Item 18 of this annual report.

Aventis Pharma Limited India

In accordance with the Securities and Exchange Board of India takeover regulations, on August 11, 2004, sanofi-aventis announced that it intended to acquire up to 4,606,125 fully paid up equity shares of Aventis Pharma Limited India (a company that is 50.1% owned by Hoechst through its wholly owned subsidiary, Aventis Pharma Holding GmbH), for a cash offer price of Rupee 792.20 (13.96) per fully paid up equity

share and aggregate consideration of Rupee 3,648 million (64.27 million).

The shares of Aventis Pharma Limited India are listed on the Stock Exchange, Mumbai and the National Stock Exchange of India Limited. The offer to the shareholders of Aventis Pharma Limited India is being made as a result of the offers pursuant to which sanofi-aventis acquired indirect control of Aventis Pharma Limited India. As of the date of this annual report, the offer documentation for the proposed acquisition is still under review by the competent Indian authorities.

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B. Business Overview

Strategy

Our mission at sanofi-aventis, as the third largest pharmaceutical group in the world and first in Europe, is to do more, perform better and move faster in the field of health.

This means that we are committed to finding new compounds that bring hope and are essential to medical progress. We are equally committed to providing millions of patients with new, innovative and effective drugs to combat disease, to participating actively to make medicines accessible to the greatest number of people possible, and to seek to ensure the development of our Group through a strategy of strong, sustainable and profitable growth.

In 2005, we achieved a successful integration and exceeded objectives with:

Strong growth in excess of pharmaceutical markets in all three of our geographical regions (United States, Europe and Rest of World), acceleration of our vaccines sales growth and a number of successful launches.

Sustainable growth, thanks to an accelerated progression of our research and development portfolio, the increase in our sales forces worldwide, especially in fast growing markets, and investments in production facilities, especially in vaccines.

Profitable growth, by realizing synergies more quickly than expected as well as delivering a significant increase in earnings per share and a reduction of debt.

The key elements of our strategy for the coming years are to:

Capitalize on the potential of our pharmaceutical markets. Despite a tougher environment, with our presence in key therapeutic areas, we plan to respond to unmet healthcare needs in fields such as cardiovascular, central nervous system, diabetes, cancers, metabolic disorders, and pandemic infectious diseases, as well as to address new healthcare needs that an aging population is facing and to contribute to providing wider access to healthcare in emerging countries.

Increase the momentum of our products and strengthen our leading positions in major therapeutic areas: cardiovascular, thrombosis, oncology, metabolic disorders, central nervous system, internal medicine and human vaccines. We plan to continue to develop our large portfolio of fast-growing drugs with seven products having individual annual sales in excess of 1 billion during 2005 (Lovenox®, Plavix®, Allegra®, Lantus®, Taxotere®, Stilnox® and Eloxatine®) as well as to maximize the performance of our high-potential products. We intend to make the necessary investments in marketing and other resources to fully promote our high-potential products which are in early stages of their life cycles and have significant remaining potential for sustained growth.

Continue to defend all our products worldwide, including our mature products, which are of excellent quality and which play a vital role in balancing health care system costs. Over time, we intend to maintain and consolidate the part of our portfolio beyond the top 15 products through selective investments, remaining faithful to one of our fundamental principles: that there is no such thing as a small market or a small product.

Reinforce our leading position in innovation, with a significant number of blockbusters and significant prospects for the future (major launches are expected in 2006 and the coming years). We believe we now have one of the best portfolios in the pharmaceutical industry with, in particular, compounds which are first in class, as described below in the section A rich, innovative and balanced R&D Portfolio. The diversity of our researchers, combined with their access to high technology tools, leads to impressive cross-fertilization that we expect will contribute to the strength and pertinence of our Group. We intend to support our research and development strategy with a strong and increased level of spending.

Capitalize on a well balanced geographical development. We believe sanofi-aventis is well positioned with a well-balanced presence across the United States, Europe and Rest of the world.

Strengthen our leadership position in tomorrow s key markets (including Brazil, Russia, India and China). We intend to develop strong positions in these fast-growing markets, aiming to match our

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worldwide market share by seizing significant opportunities and developing local and integrative strategies. We intend to reinforce our commercial presence with strong investment in sales forces and further develop our industrial facilities, clinical research units and development centers. Finally, we aim to optimize the complementarity between pharmaceuticals and vaccines to leverage our global market penetration.

Major Products

Sanofi-aventis is organized around two main business activities: our pharmaceuticals business and our human vaccines business, the latter which is conducted through our wholly owned subsidiary sanofi pasteur.

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®).

For our pharmaceutical business, except where otherwise stated, all market share percentages and rankings are based on full-year 2005 sales figures from IMS Health MIDAS for all countries, except for France, for which they are based on full-year 2005 sales data from GERS.

For our human vaccines business, 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.

In this annual report, we present both our consolidated net sales from our leading products sold through alliances, and developed sales. See Item 5. Operating and Financial Review and Prospects Presentation of Net Sales for the definition of developed sales.

Pharmaceutical Activity

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

Top 15 products

The following table sets forth the net sales and developed sales, where applicable, of our top 15 products for the year ended December 31, 2005.

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Top 15 Products

Therapeutic Area / Product Name	2005 Net Sales	2005 Developed Sales*	Drug Category / Main Areas of Use
	(millions of)		
Cardiovascular			
Aprovel® (irbesartan)	892	1,559	Angiotensin II receptor antagonist Hypertension
Tritace® (ramipril)	1,009		Angiotensin Converting Enzyme Inhibitor Hypertension Congestive heart failure after myocardial infarction
Thrombosis			
Lovenox® (enoxaparin sodium)	2,143		Low molecular weight heparin Deep vein thrombosis Unstable angina / non-Q-wave myocardial infarction
Plavix® (clopidogrel)	2,026	4,739	Platelet adenosine disphosphate receptor antagonist Atherothrombosis
Metabolic disorders			
Lantus® (insulin glargine)	1,214		Long-acting analogue insulin Type 1 and 2 diabetes mellitus
Amaryl® (glimepiride)	677		Sulfonylurea Type 2 diabetes mellitus
Oncology			
Taxotere® (docetaxel)	1,609		Cytotoxic agent Breast cancer Non small cell lung cancer Prostate cancer
Eloxatine® (oxaliplatin)	1,564		Cytotoxic agent Colorectal cancer
Central Nervous System			
Stilnox® (zolpidem)	1,519	1,606	Hypnotic Sleep disorders
Copaxone® (glatiramer acetate)	902		Non-interferon immunomodulating agent Multiple sclerosis
Depakine® (sodium valproate)	318		Anti-epileptic Epilepsy
Internal Medicine			
Respiratory/Allergy			
Allegra® (fexofenadine)	1,345		Antihistaminic Allergic rhinitis Urticaria
Nasacort® (triamcinolone acetonide)	278		Local corticosteroid Allergic rhinitis
Urology			

Xatral® (alfuzosin)	328	Uroselective alpha1-blocker Benign prostatic hypertrophy
Osteoporosis		
Actonel® (risedronate)	364	Biphosphonate Osteoporosis

* *Developed sales is a non-GAAP financial measure, refer to Item 5.*

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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, 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, where the product is licensed to BMS and Shionogi, an application for marketing authorization for the treatment of hypertension was submitted in October 2002, and the review is still ongoing.

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.

In June 2005, results of the INCLUSIVE trial, an important efficacy clinical trial for CoAprovel® in uncontrolled hypertensive patients on monotherapy, were released and published at the European Society of Hypertension meeting. The trial demonstrated that CoAprovel® can result in the achievement of blood pressure goals in eight out of 10 patients from diverse patient populations. As less than a third of the treated hypertensive patients are currently treated to the blood pressure goal recommended by international guidelines, these results could move hypertension management towards a new standard.

Two further efficacy trials were completed in 2005 to evaluate Aprovel® and CoAprovel® in patients with severe and moderate hypertension. Results are due to be announced in 2006.

To continue to demonstrate the protective effects of Aprovel® beyond the blood pressure lowering efficacy, several clinical trials were initiated or completed in 2005:

The IMPROVE clinical trial, intended to demonstrate the end-organ protective effects of Aprovel® in patients at high risk for cardiovascular events, was completed in 2005. Results of this 400-patient study are expected in 2006.

Another 400-patient trial in hypertensive patients with metabolic syndrome was initiated in 2005 to determine the metabolic effect of Aprovel® in this patient population. Results are expected in 2007.

We also launched a large international survey, i-SEARCH, to evaluate the prevalence of microalbuminuria, a recognized cardiovascular risk marker, in hypertensive patients with or without cardiovascular disease. The survey will be conducted in approximately 23,000 patients across 33 countries. Results of this survey are expected in 2006.

We are currently conducting two large-scale clinical programs as part of our life cycle management program for Aprovel® that will enroll a total of 14,100 patients and that we expect to complete in 2006/2007:

I-PRESERVE evaluates the benefit of Aprovel® in the treatment of diastolic heart failure, a specific but common form of heart failure. This 4,100-patient study was initiated in 2002. Results are expected late 2007.

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ACTIVE-I evaluates the efficacy of Aprovel® combined with clopidogrel (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 in 2007.

A new dosage formulation and its pharmaceutical form, CoAprovel® 300 mg irbesartan / 25 mg HCTZ, was approved by the FDA and launched in the United States in June 2005. The same formulation has been submitted for marketing authorization in Europe in 2006.

At the end of 2005, based on the total sales of Aprovel® and CoAprovel®, we rank third in the top five European markets (all channels except Italy & Spain retail only) and third in the United States among the angiotensin II receptor antagonists in the hypertension market. (IMS sales December 2005, GERS for France, parallel trade sales re-allocated in Germany)

Tritace®/Triatec®/Delix®/Altace®

Tritace® (ramipril) is an angiotensin converting enzyme (ACE) inhibitor for the treatment of hypertension, congestive heart failure after myocardial infarction and nephropathy. Its use has widely increased since the initial publication of the Heart Outcomes Prevention Evaluation (HOPE) study in 2000 showing it to be effective in reducing the incidence of stroke, heart attacks and cardiovascular 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.

The long-term follow up study of the HOPE trial, HOPE TOO, was published in *Circulation* in September 2005. The results of HOPE TOO confirm that sustained vascular and metabolic benefits attained with Tritace® 10 mg on top of standard therapy are maintained in the long term. This indicated that the reduction in cardiovascular outcomes demonstrated at the end of the HOPE study were most likely an underestimate of the full effects of long-term Tritace® therapy. Subgroup analysis demonstrated that the benefits observed with Tritace® 10 mg are additive to those of other life-saving therapies and extended to all patients with vascular disease, independent of their baseline risk.

As of December 31, 2005, Tritace® was the market leader in Canada, France, Spain and Italy. Tritace® continues to be the market leader in Germany, with demand volumes increasing, despite the end of market exclusivity in Germany in January 2004. (IMS sales December 2005 GERS for France, ACE inhibitors)

The U.S. rights to Tritace® were sold to King Pharmaceuticals in 1998.

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 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 170 million patients in 96 countries since it was first introduced in 1987 and is approved for more clinical indications than any other LMWH. Numerous clinical studies have demonstrated the product s benefits as an effective way to reduce significantly the incidence of deep vein thrombosis in a wide range of patient populations with a good safety profile, and also as an effective prophylaxis of ischemic complications of unstable angina and non-Q-wave myocardial infarction when administered concomitantly with acetylsalicylic acid (ASA, the active ingredient in Aspirin®).

The results of STEEPLE (Safety and Efficacy of Enoxaparin in Percutaneous Coronary Intervention (PCI) patients), an international, prospective, randomized, open-label, parallel group trial were presented at the European Society of Cardiology meeting in Stockholm in September 2005. STEEPLE showed that a

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single intravenous bolus of enoxaparin is associated with significantly less major bleeding, more predictable anticoagulation levels and similar efficacy compared with the current standard, unfractionated heparin (UFH), in patients undergoing elective PCI or coronary angioplasty. PCI is increasingly used in the treatment of obstructive coronary lesions. More than 1 million PCI procedures are now performed worldwide each year.

ExTRACT is a Phase III study comparing Lovenox® to Unfractioned Heparin (UFH) as an adjunctive therapy in 20,500 patients with myocardial infarction receiving thrombolytic therapy, the most common treatment for this acute coronary syndrome. The study was presented at the American College of Cardiology s Annual Scientific Session in March 2006. It has demonstrated a significant 17% reduction of death and myocardial reinfarction compared to UFH with the lower rate of bleeding not previously observed with Lovenox® in the previous trials performed in this indication. This resulted in 28 patients saved with four non-fatal haemorrhages for each 1,000 patients treated by Lovenox® instead of UFH. These results should lead to a new indication in the coming months. More than 1 million people suffer from an ST elevation myocardial infarction each year.

In the Medical Prophylaxis market, Lovenox® continues to gain patient share from UFH, in the United States (Source: Solucient). Two major trials evaluating Lovenox® for the prevention of thromboembolic events in the setting of medically ill patients are expected to complete enrolment by the second quarter of 2006. Further, the EXCLAIM trial is currently examining the benefits of an extended Lovenox® prophylaxis regimen of 28 days versus the currently approved regimen of six to 10 days. The PREVAIL trial will assess the efficacy of Lovenox® given once daily versus UFH given twice daily in the prevention of thromboembolic events in post-ischemic stroke patients.

Lovenox® is the leader in antithrombotics, in the United States, Germany, France, Italy, Spain and the United Kingdom. (IMS sales December 2005 GERS for France).

Plavix® / Iscover®

Plavix® (clopidogrel), 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 in 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), was submitted for marketing authorization in February 2004 and approval was granted in January 2006, with launch expected later this year. Sales of Plavix® in Japan are outside the scope of our alliance with BMS.

Since 2002, Plavix® has also been indicated for the treatment of Acute Coronary Syndrom (ACS; non-Q-wave myocardial infarction and unstable angina) in combination with ASA following the impressive 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 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).

Since 2003, following an FDA written request for pediatric data, development of a pediatric indication for Plavix® in the United States in the form of the PICOLO study has been ongoing. Phase II studies have been completed, and the finalization of Phase III design is currently underway.

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The benefits of Plavix® are supported by an extensive program of clinical studies:

The results of the CREDO clinical trial, announced 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 March 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 CLARITY trial, conducted in nearly 3,500 patients, demonstrated that Plavix®, added to standard therapy including fibrinolytics and ASA, 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.

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

In both trials, the rates of major bleeding and intracranial hemorrhage were similar in both the Plavix® and placebo groups, underlining the favorable risk/benefit profile of Plavix®. Based on the findings of these trials, the FDA granted priority review for the Plavix® Supplemental New Drug Application (SNDA) for treatment of patients with acute ST-segment elevation myocardial infarction (STEMI) on January 18, 2006.

On March 12, 2006 the results of the CHARISMA trial were released at the 55th Annual Scientific Session of the American College of Cardiology. The CHARISMA landmark trial completed its enrollment of over 15,600 patients in 2003 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 demonstrated that :

On the one hand, in patients with established atherothrombotic diseases (also referred to as secondary prevention), clopidogrel in addition to aspirin and another standard therapy reduced the relative risk of recurrent heart attack, stroke or cardiovascular death by a statistically significant 12.5%, compared to patients receiving placebo and aspirin. 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 to aspirin, 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 and aspirin.

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

CASPAR, the objective of which is to assess the clinical value of Plavix® in patients with peripheral arterial disease who have undergone peripheral bypass surgery, which is to include 1,400 patients.

ACTIVE, which is intended to assess the value of Plavix® in patients with atrial fibrillation for the prophylaxis of cardio-embolic events. This study is expected to include 14,000 patients with results expected in 2007 or 2008. While one arm of the study ACTIVE W was terminated early, the other two arms, ACTIVE A and ACTIVE I, are ongoing.

In 2003, one of the largest disease registries was initiated to evaluate patients at risk of atherothrombosis. This registry, called REACH (Reduction of Atherothrombosis for Continued Health) includes 63,000 patients in more than 43 countries. Preliminary data from this registry indicate that although

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there are substantial differences in the incidence of risk factors, a consistent pattern of underachievement of therapeutic goals is nonetheless evident across patient types and geographic regions. Further analysis of this population will be presented in the first half of 2006.

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 41 million patients worldwide are estimated to have been treated with Plavix® since its launch, providing significant safety and efficacy experience with this product.

With Plavix® sanofi-aventis is the leader in the European and the U.S. markets for anti-platelet agents. (IMS sales, December 2005)

Metabolic Disorders

Lantus®

Lantus® (insulin glargine) is a long-acting analog insulin, indicated for once-daily subcutaneous administration in the treatment of adult patients with type 2 diabetes mellitus who require basal insulin for the control of hyperglycemia, and for adult and pediatric patients of six years and above with type 1 diabetes mellitus.

Lantus® is the first and only basal insulin with a 24-hour peak-less duration of action, allowing a once-daily regimen that can be taken at any time but at the same time every day, titration under safer conditions, and with less hypoglycemia than with Neutral Protamine Hagedorn (NPH).

This product allows more effective treatment than products with different action mechanisms, with the result that patients are able to reach their HbA1c target with an improved quality of life.

The simplicity of the once-daily insulin injection regimen can facilitate a more timely and effective insulin use in routine medical practice, improving the achievement of recommended standards of diabetes care.

Since the launch, two studies in particular, Treat-to-Target and LANMET, have been key to demonstrating Lantus® as the basis for a simple, standardized way to initiate basal insulin in routine type 2 diabetic patients and have confirmed the effectiveness of two different titration algorithms to achieve target HbA1c for a majority of patients.

The Treat-to-Target was published in November 2003 in Diabetes Care evaluating 756 type 2 diabetic patients with inadequate glycemic control on oral anti-diabetic drugs (OADs). This 24-week trial showed that, compared with NPH, significantly more type 2 diabetic patients treated with Lantus® achieved a target goal of HbA1c under or equal to 7%, (a measure indicating a good control of long-term blood sugar level), without having an episode of nocturnal hypoglycemia. Mean HbA1c was 6.96% in the Lantus® group. The rates of hypoglycemia were statistically lower with Lantus® relative to NPH.

The LANMET nine-month study, presented in 2004, showed that, in 110 insulin-naïve type 2 diabetic patients, good glycemic control can be achieved using Lantus® plus metformin, an OAD, with infrequent visits to a physician. Using modem-assisted glucose monitoring, patients can successfully self-monitor and self-adjust basal insulin dosing. Use of Lantus® was associated with better pre- and post-dinner glycemic control, and resulted in significantly less hypoglycemia than NPH. Symptomatic hypoglycemia was 44% more frequent with NPH than with Lantus®.

In 2005, three major studies were published:

The LAPTOP 24-week study demonstrated that, when oral anti-diabetic drugs alone no longer control hyperglycemia in 371 insulin-naïve type 2 diabetes patients, adding once-daily Lantus® while continuing OADs restores glycemic control more effectively and with less risk of hypoglycemia and lower insulin requirements than the conventional practice of switching to twice-daily premixed insulin without OADs. The HbA1c decline from baseline was greater with Lantus® plus OADs than with the conventional therapy and more subjects reached the target of HbA1c under 7% without documented nocturnal hypoglycemia.

A meta-analysis of four Lantus® trials involving 1,142 diabetic patients, confirmed that Lantus® used once daily consistently and significantly reduces the risk of hypoglycemia in type 2 diabetes patients failing oral agents versus NPH, most notably symptomatic, nocturnal and severe nocturnal hypoglycemia.

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AT-LANTUS, was a prospective, multicenter, multinational, open-label, 24-week randomized trial in 4,961 sub-optimally controlled type 2 patients. This study compared two treatment algorithms (Algs) for insulin glargine initiation and titration: Alg1 (led by investigators) versus Alg2 (performed by study subjects). At the end of the trial, there was no significant difference in the incidence of severe hypoglycemia between Alg1 and Alg2. There was a significant reduction in HbA1c with a greater decrease with Alg2 versus Alg1. A simple subject-administered titration Algs conferred significantly improved glycemic control with a low incidence of severe hypoglycemia compared with physician-managed titration in a large, diverse population with longstanding type 2 diabetes.

In 2005, two major studies were presented and/or published at the American Diabetes Association (ADA) 65th Annual Scientific Sessions and at the 41st Annual Meeting of the European Association for the Study of Diabetes (EASD):

The INSIGHT study was a Canadian, multicenter randomized trial designed to assess early insulinization using bedtime insulin glargine versus a standard oral agent strategy in 405 type 2 diabetic patients. Patients were randomized to either the addition of glargine insulin (with no change in oral therapy) or optimization of oral therapy (with no insulin). When provided with training in insulin initiation and a therapy and simple algorithm for patient use, general practitioners achieved glycemic targets more effectively with glargine than with standard lifestyle or oral agent therapy. General practitioners were comfortable with aggressive insulin use to achieve and sustain glycemic targets.

In a randomized, parallel-group, two-arm, open-label U.S. study of 253 oral monotherapy type 2 diabetic failures, the addition of insulin glargine to existing oral therapy resulted in a greater decrease in HbA1c levels and fewer adverse events than the addition of pioglitazone to existing oral therapy. However, rates of hypoglycemia were greater with insulin glargine than with pioglitazone.

Following the approval of OptiClik® for use with Lantus® by the relevant authorities, this medical device was launched in the United States and Japan in 2005. OptiClik® is a reusable pen which provides people with diabetes with a new and easy-to-use delivery option. Further launches are planned throughout 2006.

Lantus® has outperformed insulin market growth since it was first launched in Germany in 2000, followed by the United States in 2001, then the United Kingdom in 2002, and France in 2003. Overall, Lantus® has been launched in over 70 countries worldwide.

The largest insulin market after the United States is Germany followed by Japan. Since December 2003, Lantus® has been the leading insulin brand worldwide with sales exceeding 1 billion in 2005. The top three markets for Lantus® are the United States, Germany and the United Kingdom. (IMS sales Full Year 2005, retail only except for U.S. retail and hospital, All insulin).

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 can achieve a very good level of control with a low risk of hypoglycemia.

Amaryl® was first launched in 1995 and has been approved in about 100 countries worldwide. The key markets for Amaryl® are Japan (rank: #3), Germany (rank: #1) and Poland (rank: #2) (IMS sales December 2005, parallel trade sales re-allocated in Germany, oral antidiabetes market).

In the European countries, the Amaryl® active ingredient patent expired in December 2005. In the United States, where the equivalent patent also expired in 2005, sanofi-aventis has entered into a partnership with Prasco to offer a generic at the end of this product s U.S. patent protection. In December 2005, our generic achieved total prescriptions (TRx) monthly market share of 29.6% of the glimepiride molecule (IMS NPA).

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Oncology

Sanofi-aventis is a leading group 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 launched in 1995 and is currently marketed in over 100 countries.

Taxotere® is indicated for early stage and metastatic breast cancer, non-small cell lung cancer (NSCLC), and androgen-independent (hormone-refractory) metastatic prostate cancer.

Taxotere® is being studied extensively in clinical trials for safety and efficacy in head and neck and gastric cancers. On March 23, 2006, following a priority review, the FDA approved Taxotere® in combination with cisplatin and 5-fluorouracil for the treatment of patients with advanced stomach (gastric) cancer, including cancer of the gastro esophageal (GE) junction, who have not received prior chemotherapy for advanced disease.

This additional indication is also currently under review by the European Agency for the Evaluation of Medicinal Products (EMEA). The Agency s Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion, announced March 24, 2006, recommending approval in Europe of Taxotere® (docetaxel) Injection Concentrate in combination with cisplatin and 5-fluorouracil for the treatment of patients with metastatic stomach cancer, including the cancer of the gastro esophageal (GE) junction, who have not received prior chemotherapy for their metastatic disease.

In 2005, we continued our efforts to improve awareness of the effectiveness of Taxotere® in cancer patients. At the American Society of Clinical Oncology (ASCO) congress of 2005, based on the SWOG 9504 trial, Taxotere® demonstrated an impressive 29% five-year survival rate, as consolidation chemotherapy in stage IIIb advanced NSCLC patients, which is a unique position for Taxotere® in this setting.

At the San Antonio Breast Cancer Symposium, in December 2005, the Breast Cancer International Research Group (BCIRG) and sanofi-aventis announced the results from the first interim efficacy and updated safety analyses from the BCIRG 006 phase III breast cancer study, which demonstrated that Herceptin® (trastuzumab) combined with Taxotere®-based regimens significantly improves disease free survival for women with early HER2-positive breast cancer. Results from the BCIRG 006 study also demonstrated that a novel non-anthracycline-based regimen TCH with Taxotere®, platinum salt and Herceptin® (trastuzumab) reduces the risk of recurrence without increasing cardiotoxicity in patients with early stage HER2-positive breast cancer.

At the same meeting, Taxotere® also demonstrated for the first time, in a direct head-to-head study vs. a standard anthracycline-based regimen AC (doxorubicin / cyclophosphamide) in 1,016 women with early stage breast cancer, that by replacing the doxorubicin with Taxotere®, Taxotere® significantly improved five-year Disease Free Survival compared to AC regimen.

The ARD6562 phase II study of Taxotere® in the treatment of hormone refractory prostate cancer is ongoing in Japan. Results are expected in 2007.

The top four countries contributing to the sales of Taxotere® in 2005 were the United States, France, Germany and Japan in that order (based on net sales).

Eloxatine®

Eloxatine® (oxaliplatin) is an innovative platinum agent, and is currently the only agent indicated both for the treatment of metastatic colorectal cancer and for 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)

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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 prevent recurrences.

The development of Eloxatine® has led to major progress in the treatment of metastatic colorectal cancer. First, median survival has been prolonged to 20 months when Eloxatine® is used as a first-line treatment in combination with 5-fluorouracil (or 5-FU) and leucovorin (LV) (the FOLFOX regimen). Second, thanks to its demonstrated ability to reduce the size and number of liver metastases, Eloxatine® has allowed the complete surgical removal of hepatic metastases and has given the hope of a potential cure in a significant proportion of patients with initially unresectable liver metastases. 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® is now recognized as a cornerstone chemotherapy to which new targeted therapies (*e.g.*, monoclonal antibodies or small molecules) can be combined, with the hope of further increasing survival rate. Results from a cooperative group study (ECOG 3200) were presented at ASCO 2005 in the United States, showing that patients receiving bevacizumab in addition to FOLFOX4 had a 33% improvement in overall survival, compared to patients receiving FOLFOX4 alone.

Eloxatine® has also been developed for adjuvant treatment of colon cancer. Eloxatine® was the first anticancer agent to result in a significant improvement of the adjuvant treatment of colon cancer in a decade. Based on the results of the MOSAIC clinical trial presented for the first time at ASCO 2003, which studied the efficacy of Eloxatine® as an adjuvant treatment in over 2,200 patients, approval for adjuvant treatment was respectively granted by the European agency and the FDA on September 12, 2004 and on November 4, 2004. MOSAIC showed that the addition of Eloxatine® to the previous post-surgery reference chemotherapy of 5-FU/LV for colon cancer reduces the risk of recurrence by 23% when compared to the reference treatment alone. In 2005, results from a second large multicentric clinical trial conducted by the U.S. cooperative group NSABP were presented at ASCO. These studies showed a 21% reduction in risk of relapses, confirming the efficacy of Eloxatine® in the adjuvant setting. FOLFOX is now the standard treatment for stage III colon cancer patients who have undergone complete resection of the primary tumor.

Eloxatine® is being investigated in pancreatic cancer. Efficacy results of a large Phase III study (E 6201) led by the U.S. cooperative group study ECOG are expected in 2006.

A new liquid formulation (Eloxatine® Injection) was approved on January 31, 2005 by the FDA. This new formulation offers additional safety benefits and convenience to nurses since it involves fewer steps in the reconstitution of Eloxatine®. Sanofi-aventis plans to roll-out this formulation in a number of European countries in 2006.

Eloxatine® is in-licensed from Debiopharm and is marketed in nearly 70 countries worldwide. The top three countries contributing to our sales of Eloxatine® are, respectively, the United States, France and Germany (based on net sales).

Central Nervous System

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

Stilnox®/Ambien®/Myslee®

Stilnox® (zolpidem) is the worldwide hypnotic leader 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

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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. Two three-week placebo-controlled studies conducted in sleep laboratories, ZOLADULT and ZOLELDERLY, assessed the efficacy and safety of the controlled release formulation of zolpidem in the treatment of patients experiencing insomnia. The studies showed that the controlled release formulation of zolpidem improved sleep maintenance, sleep duration and the ability to fall asleep compared to a placebo. Based on these results, we obtained FDA market authorization in the United States and launched the product in September 2005 under the brand name Ambien CR . 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.

In January 2006, the FDA issued a written request for pediatric studies for Ambien®, and we are currently exploring the potential for a pediatric indication in the United States.

Stilnox® was first launched in 1988 in France and is marketed today in over 100 countries. In Japan, although launched only in December 2000, Stilnox® became the leading hypnotic on the market within three years of its launch. It is sold under the brand name Myslee® through our joint venture with Astellas.

Stilnox® is the leading hypnotic brand in its three largest markets: the United States, Japan and France. Generics have been available in France since January 2004. (IMS sales December 2005 retail + hospital, GERS for France - N5B1 (non barbiturate plain) + Trazodone (United States only))

Copaxone®

Copaxone® (glatiramer acetate) is an immunomodulating agent indicated for reducing the frequency of relapses in patients with relapsing-remitting multiple sclerosis (MS). This disease-modifying drug is characterized by an original and specific mode of action on MS. Clinical studies have shown that Copaxone® is more effective than placebo at two years, but also that it has a clinical efficacy over ten years both in reducing relapses and progression of disability. A significant effect on lesions has also been confirmed by nuclear magnetic resonance imaging (MRI).

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 Teva. 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.

More than 90,000 patients worldwide are treated with Copaxone®. The three leading countries for its use are the United States (rank: #2), Canada (rank: #2) and Germany (rank: #4) (IMS sales, December 2005)

Depakine®

Depakine® (sodium valproate) is a broad-spectrum anti-epileptic that has been prescribed for over 38 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.

We produce a wide range of formulations of Depakine® (syrup, oral solution, injection, entero-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

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stick packs, facilitating its use by children (the first Depakine® sustained release form for children), the elderly and adults with difficulties swallowing, has been approved in several European countries. It was commercialized for the first time in Austria in October 2004 and then in France and Germany in 2005. We plan to commercialize this new formulation gradually over the next few years as we register the product in additional countries.

Depakine® is marketed in over 100 countries, including the United States, where it is licensed to Abbott. In 2005, we received marketing approval in several European countries for Depakine Chrono and Chronosphere for use in the treatment of bipolar disorder.

Internal Medicine

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

Respiratory/Allergy

Allegra®/Telfast®

Allegra® (fexofenadine HCl) is an effective, powerful, long-lasting (12- and 24-hour) non-sedating prescription antihistamine for the treatment of seasonal allergic rhinitis (hay fever) and the skin condition chronic idiopathic urticaria (hives). It offers patients significant relief from allergy symptoms without causing drowsiness. Our top three markets for Allegra® in 2005 are the United States (rank: #1), Japan (rank: #1), and Australia (rank: #1). (IMS sales all channels December 2005).

We also market Allegra-D® 12 Hour, an antihistamine/decongestant combination product with an extended-release decongestant for effective non-drowsy relief of seasonal allergy symptoms, including nasal congestion. In July 2005, we introduced Allegra-D® 24 Hour, a once-daily formulation of the antihistamine/decongestant combination.

In September 2005, the FDA approved the U.S. New Drug Application (NDA) for a 180 mg once-daily dose for adult chronic idiopathic urticaria. An NDA for a pediatric indication was submitted in Japan in February 2004 and we are developing two new pediatric formulations: 30 mg orally disintegrating tablets and a 6 mg/ml oral suspension. The U.S. NDA for the pediatric suspension was filed in December 2005.

The top three markets for Allegra-D® 12 Hour and 24 Hour are the United States, Brazil, and Mexico. (IMS sales all channels December 2005)

In September 2005, Barr and Teva jointly launched a generic version of fexofenadine HCL 180mg, 60 mg and 30 mg to compete with Allegra®. Sanofi-aventis responded by entering into an agreement with Prasco Pharmaceuticals to launch an authorized generic of fexofenadine. In December 2005, the authorized generic product, marketed by Prasco, accounted for over 30% of fexofenadine prescriptions for the month. (IMS NPA)

Nasacort®

Nasacort® (triamcinolone acetonide) AQ Spray 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.

In April 2004, we received approval from the FDA for Nasacort® HFA Nasal Aerosol, the first intranasal corticosteroid dry-aerosol formulation approved in the United States that contains hydrofluoroalkane (HFA) rather than chlorofluorocarbons (CFCs).

Nasacort® HFA Nasal Aerosol will provide physicians and patients with a new option for those seeking a dry-aerosol formulation for the management of nasal allergy symptoms. It replaces Nasacort® Nasal Inhaler, which was taken off the market in July 2003 to comply with Environmental Protection Agency (EPA) and FDA requirements intended to protect the ozone layer, which required the removal of nasal inhalers containing CFCs from the U.S. market.

Our leading markets for Nasacort® AQ Spray are the United States (rank: #3), France (rank: #2) and Turkey (rank: #2). (IMS sales December 2005 all channels GERS for France)

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Urology

Xatral®

Xatral® (alfuzosin) belongs to the alpha1-blocker class of medications, and was the first product of the class to be indicated uniquely and specifically for the treatment of the symptoms of benign prostatic hyperplasia (BPH), as well as the first marketed product capable of acting selectively on the urinary system. Xatral® (extended release formulation) does not require dose titration, and shows good tolerability, particularly cardiovascular tolerability. Active from the first dose, it provides rapid and lasting symptom relief; improving 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 PDE5 inhibitor were released in 2005 and will be 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® for the management and prevention of the most severe complication of BPH: acute urinary retention (AUR).

The results of the first trial (the ALFAUR study) showed that Xatral® doubles the probability of restored capacity to urinate normally after an episode of AUR in conjunction with catheter insertion and reduces the need for BPH surgery up to six months after. These are the first published results that demonstrate the capacity of Xatral® to manage and prevent acute urinary retention. Since 2003, we have obtained authorizations of this extension of the indication in 56 countries worldwide including 16 European countries.

BPH is also widely known to be linked with various degrees of sexual dysfunction. The results of another international trial with over 800 patients have shown that Xatral® preserves sexual function, particularly ejaculatory function, in patients suffering from BPH.

We also completed Phase IIb in 2005 and will begin Phase III clinical trials of the once-daily formulation of Xatral® in 2006 for the treatment of BPH in Japan.

Since Xatral® was launched in 1988 in France, we have constantly worked on optimizing its formulation. The new once-daily formulation of Xatral® (branded Uroxatral® in the United States) has now been registered in over 90 countries and is marketed worldwide except in Australia and Japan. Our leading markets for Xatral® are France (rank: #1), the United States (rank: #4) and Italy (rank: #3). (IMS sales December 2005 GERS for France, all channels except for Italy retail).

Osteoporosis

Actonel®/Optinate®/Acrel®

Actonel® (risedronate sodium) is a bisphosphonate that helps prevent bone loss by inhibiting bone resorption. Actonel® 5 mg daily is indicated for the prevention of postmenopausal osteoporosis (PMO) in Europe and for the treatment of PMO in Europe and the United States. Actonel® 35mg once-a-week is indicated for the prevention and treatment of this disease in both Europe and the United States. Actonel 5mg daily is indicated for the treatment 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® 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 in just six months (Roux et al.). Data shows that Actonel® is effective in preventing bone loss and preserving trabecular architecture within one year of treatment, an effect that may contribute to the early reduction in risk of vertebral fracture observed with Actonel®. Actonel® also stands out in that it provides proven fracture protection at vertebral and non-vertebral sites (non-vertebral fracture reduction based on a composite endpoint of the following sites: hip, wrist, humerus, clavicle, leg and pelvis).

Actonel® is in-licensed from Procter & Gamble Pharmaceuticals (P&G) and is co-marketed by sanofi-aventis and P&G through the *Alliance for Better Bone Health*. In Japan, Actonel® was 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.

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The top four markets for Actonel® are the United States, Canada, France and Germany.

Other Pharmaceutical Products

In addition to the top 15 pharmaceutical products of sanofi-aventis global portfolio, a wide range of products exists, which includes prescription drugs, products sold over the counter (OTC) and generic drugs. They represent a significant part of our pharmaceutical activity (36% of 2005 worldwide net sales). Depending on the affiliates, these products can be strategic products for local markets. Where they have important growth potential they generally receive targeted promotional investments. On the other hand, if the products potential is more limited, the approach will be to capitalize on current prescriptions. Due to their presence on the market for several years, these products have strong brand recognition and are known by healthcare professionals and patients as much for their effectiveness as for their safety.

Human Vaccines Activity

Our subsidiary sanofi pasteur is a fully integrated vaccine business offering the broadest range of vaccines in the industry. In 2005 sanofi pasteur immunized over 500 million people against 20 serious diseases and generated net sales of 2,062 million.

Based on our estimates, sanofi pasteur is a world leader in the vaccine industry and holds a leading position in most countries. In the United States and Canada, which account for approximately 50% of the worldwide vaccines market, sanofi pasteur is the market leader with a 28% market share.

In 2005, North America accounted for 54% of sanofi pasteur s global sales activity (global sales activity is defined as the sum of consolidated net sales plus 100% of Sanofi Pasteur MSD sales, but excluding what sanofi pasteur sells to Sanofi Pasteur MSD).

In Europe, our vaccines business are marketed by Sanofi Pasteur MSD, a 50-50 joint venture between sanofi pasteur and Merck & Co, which provides vaccines to 19 countries. With a 36% market share in 2005, Sanofi Pasteur MSD was the market leader in Europe overall, and in particular in France and the United Kingdom. In 2005, sales of Sanofi Pasteur MSD, which are accounted for using the equity method, were 688 million.

Sanofi pasteur has established a leading position in Latin America, has been expanding its presence in Asia, particularly in China and Japan, and is very active in international publicly funded markets such as UNICEF; it also has a significant activity in other developed, middle income and emerging markets throughout the world.

Main Areas

Pediatric Combination and Polio Vaccines

The components of these vaccines vary due to diverse immunization schedules throughout the world. Protecting against up to five diseases in a single immunization, this group of products is anchored by acellular pertussis components in general and by the trivalent vaccine Daptacel® in particular. Daptacel® protects against pertussis, diphtheria and tetanus. It was launched in the United States in 2002 and has become a strong sales contributor due to its synergy with immunization schedules. Act-HIB® for the prevention of *Haemophilus influenzae* type b, is also an important growth driver within the pediatric product line. Pentacel® is a vaccine against five diseases (pertussis, diphtheria, tetanus, polio and *Haemophilus influenzae* type b) that is approved in nine countries and has been a standard of preventive care in Canada since its launch in 1997. Pediacel®, another acellular pertussis-based pentavalent vaccine, was launched in the United Kingdom in 2004 and several other EU countries in 2005.

Sanofi pasteur is one of the world s leading developers and manufacturers of polio vaccines, both oral (OPV) and inactivated (IPV). We expect the use of inactivated polio vaccines (IPV) to increase as the goal of global polio eradication is nearly reached 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

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global preferred partner with both oral polio and IPV vaccines. In March 2005, sanofi pasteur developed the first new polio vaccine in nearly 30 years for use in eradication. The company s Monolavent Oral Polio Vaccine - 1 was subsequently licensed by the French regulatory authorities (AFSSAPS). This new vaccine has first been used in Egypt in 2005 as part of a new WHO strategy to end polio transmission. Egypt is no longer a polio endemic country.

Influenza

With more than a 45% share of the 1.3 billion influenza vaccine market in 2004, sanofi pasteur is the world leader in the production and marketing of influenza vaccines. Since 1995, sales of the influenza vaccines Fluzone® and Vaxigrip®/Mutagrip® have more than tripled and annual production capacity has been increased to 165 million doses to better meet demand. We expect global demand for influenza vaccines to grow strongly within the next decade, due to increasingly broad government immunization recommendations. Health authorities, medical professionals and the public are paying more attention to the potential threat of an avian influenza pandemic, which is also expected to contribute to an increase in demand for influenza vaccines in general. In 2005, we initiated a $160 million investment in the United States for a brand new influenza vaccine manufacturing facility, which will double our production capacity there. This will help meet additional influenza vaccine demand from both inside and outside the United States. In April 2005, sanofi pasteur and the U.S. Health and Human Services Department (HHS) entered into a five-year agreement to speed the development of a production process for new cell culture influenza vaccines in the United States and to design a U.S.-based cell-culture vaccine manufacturing facility. A 160 million investment has also been approved for a formulation and filling facility in Val de Reuil, France, to boost filling capabilities, mainly for influenza vaccines. In recent years, influenza vaccine demand has experienced strong growth in many other countries, including China, Korea and Mexico, and this trend is expected to continue over the next several years.

Adult and Adolescent Boosters

The incidence of pertussis (whooping cough) is on the rise globally, affecting both children 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®, which is the first trivalent adolescent and adult booster against diphtheria, tetanus and pertussis, was licensed by the FDA in June 2005 and launched in the United States in July 2005 (see Vaccines Research and Development below). Adacel® became the standard of care in Canada in 2004 where the majority of provinces provide routine adolescent immunization. This product will play an important role in efforts to better control pertussis by not only preventing the disease in adolescents and adults, but also by breaking the cycle of transmission in infants too young to be immunized or only partially vaccinated. Additionally, the Tetanus-diphtheria booster, Decavac®, has been a strong growth driver in this category in the United States.

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 United States. In January 2005, Menactra®, a conjugate vaccine that is expected to offer a longer-lasting immune response and a boostable memory response, was approved by the FDA for use in adolescents and adults aged 11-55 years. One month later, the U.S. Advisory Committee on Immunization Practices (ACIP) recommended immunization with the Menactra® vaccine for young adolescents at the pre-adolescent visit (11-12 years old), adolescents at high-school entry (15 years old) and college freshmen living in dormitories. To protect younger segment of the population, sanofi pasteur filed a supplemental application with the FDA in March 2005 to amend the vaccine s license to include children aged two through 10 years. Sanofi pasteur also submitted for licensing of the vaccine in Canada in 2005 and 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.

Travel/Endemic Vaccines

Sanofi pasteur s Travel/Endemic vaccines provide the widest range of traveler vaccines in the industry, and include hepatitis A, typhoid, rabies, yellow fever, Japanese encephalitis, cholera, ETEC, and anti-venoms. These

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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 militaries and travelers to endemic areas. As the global market leader in most of these vaccines, sanofi pasteur s Travel/Endemic franchise has provided stable, profitable growth. Additionally, sanofi pasteur has several lifecycle and new vaccine projects in development, including vaccines for Dengue Fever and Malaria, which are major burdens of disease-endemic areas in Asia, South America and Africa, and the leading causes of fever amongst travelers.

Research and Development

We have two Research and Development (R&D) organizations: one for our pharmaceutical activity (Scientific and Medical Affairs) and the other dedicated to our human vaccines activity, sanofi pasteur.

The objective of sanofi-aventis R&D organizations is to discover, develop, register and launch highly innovative compounds answering major unmet medical needs worldwide. They include a global force made up of over 17,600 people working in 28 research and development centers on three continents.

Pharmaceutical Research and Development

In 2005, the first full calendar year for sanofi-aventis, our large R&D organization was integrated and, on top of smooth progress for the projects in our portfolio, achieved significant goals with two major submissions in the United States and Europe (rimonabant and dronedarone), an important approval in the United States (zolpidem CR®), and approvals of several new indications for already-marketed products (*e.g.* Allegra®, Taxotere®, Eloxatine®, Ketek® and Lantus®). Furthermore, Plavix® was approved for marketing in Japan on January 23, 2006.

Global and Focused Organizations: Discovery and Development

Discovery Research

In 2005, Discovery Research continued its efforts to provide Development with a pipeline of high quality, innovative drugs that fulfill unmet medical needs or provide improved treatments for patients.

We benefit from the excellence of our scientists in six major therapeutic areas (Cardiovascular Diseases, Thrombosis & Angiogenesis, Metabolic Diseases, Central Nervous System Diseases, Oncology and Internal Medicine), with our activities currently targeting 12 out of the 16 diseases / conditions identified as demonstrating pharmaceutical gaps according to the World Health Organization.

In 2005, Discovery Research enriched the Development pipeline by entering 11 new molecules into Development:

AVE8680, inhaled IKK-beta inhibitor, for the treatment of pulmonary inflammatory disorders (collaboration with Millennium),

SSR106462 / CEP11981, a Tie2 / VEGFR-2 tyrosine kinase inhibitor, in oncology (collaboration with Cephalon),

SAR102779, a NK2 antagonist, for the treatment of major depressive disorders and generalized anxiety disorders,

SAR7226, a SGLT1/2 (sodium dependent glucose transporters) inhibitor, for the treatment of diabetes,

SAR97276, a choline uptake inhibitor, for the treatment of malaria,

SAR3419 (HuB4-DM4), a Tubulin inhibitor, DM4, coupled to anti-CD19 humanized monoclonal antibody, for the treatment of B cell lymphomas and leukemias (collaboration with Immunogen),

SAR502250 (UDA-680), a Tau Phosphorylating Kinase I (GSK-3b) inhibitor, for the treatment of Alzheimer s disease and type 2 diabetes (collaboration with Mitsubishi),

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SAR21609, a toll-like receptor 9 agonist, for the treatment of asthma including virus induced asthma exacerbation (collaboration with Coley Pharmaceuticals),

SAR501788, a peripheral benzodiazepine receptor ligand, for the treatment of sensory and motor neuron degeneration,

SAR351034, a Peroxisone Proliferator Activated Receptor (PPAR) agonist, for the treatment of dyslipidemia and type 2 diabetes in the context of metabolic syndrome, and

SAR389644C, a DP antagonist, for the treatment of allergic rhinitis and asthma.

Furthermore, two new molecules entered development in early 2006:

SAR 377142, an oral Xa inhibitor, for the prevention/treatment of thromboembolic diseases, and

SAR 114646, an anti arrhythmic agent, for the treatment of atrial and ventricular arrhytmias.

Among the 11 compounds that entered development in 2005, we consider that five products are first-in-class (see Portfolio): AVE8680A, SAR7226, SAR97276, SAR3419A, and SAR502250.

Sanofi-aventis Discovery Research now combines the skills of around 3,000 people in a coherent global organization in which each scientist contributes positively his/her multidisciplinary and cultural approach to our drug discovery effort. Our aim is to continue to synergistically capitalize upon the unique skill-sets of our scientists so as to maintain the necessary high-quality research that will fulfill the expectations of our top management, shareholders and, above all, patients who are in need of new drugs.

Development

Sanofi-aventis development structure relies on a strong matrix organization that leads and coordinates the efforts and expertise of representatives from all functions, and at all stages of development, from the preclinical stage to marketing. The members of the Development team work together to register and deliver innovative new medicines to patients worldwide, while meeting critical strategic, technical and time-to-market requirements, in accordance with our high standards of quality and ethics.

One major principle of our matrix organization is the continuity of development from the very beginning of a molecule s development (when it enters Development from Discovery) to the end of development (until the project is terminated or until the last potential approval is obtained). A project is defined by one molecule, even if multiple indications are possible. When a molecule enters development, a project team is formed with representatives from all relevant functions (including pharmacologists, clinicians, chemists, toxicologists, regulatory affairs specialists, marketing specialists and many others) who work together throughout the life of the molecule in development. Development ends when the last potential indication has been approved by Regulatory Authorities. Throughout development, our global organization aims at strategic and operational excellence, two key success factors.

In 2005, several hundred clinical trials were up and running in more than 60 countries for our projects under clinical development (including life cycle management projects), thanks to the consolidation and growth of our International Clinical Development organization. Most studies were managed through the in-house Clinical Research Units (CRU) network that consists of 26 units (covering, with their satellites about 40 countries), involving three of them created in 2005: Korea, China and Turkey. Korea was set up in January 2005 and particularly involved in thrombosis, cardiology, oncology and metabolism trials. The Turkish CRU was created early 2005 and is involved in three international clinical trials (ExTRACT, Origin and a study on Actonel®) including more than 900 patients in 32 centers. The Chinese CRU was created on June 1, 2005. Further to the mega-trial CCS2/COMMIT with Plavix® in acute myocardial infarction, Chinese clinical centers have been involved in two large international clinical trials: Extract (with Lovenox® in acute coronary syndromes) and Origin (with Lantus® in diabetes). The involvement of China will be considered for other studies in 2006, mainly in cardiology, diabetes, metabolic disorders, oncology and neurology.

As regards disclosure of clinical trial information, the research-based pharmaceutical industry with the participation of sanofi-aventis, committed in January 2005 to increasing the transparency of sponsored clinical

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trials. Practitioners, patients and the community will benefit from broader distribution of clinical results. In addition, sanofi-aventis, in compliance with this policy, has taken the initiative of posting all clinical trials it, sponsors, other than exploratory trials, in a free, publicly accessible clinical trial registry, within three weeks of the initiation of patient enrolment (unless there are alternative national requirements).

Portfolio

The research and development process historically takes from 10 to 15 years from discovery to initial product launch and is conducted in various stages. During the pre-clinical stage, research scientists perform pharmacology and toxicology studies on various animals. Before testing on humans, an application for the compound must be filed with and approved by the requisite regulatory authorities. Testing on humans is performed in different clinical phases to demonstrate the safety and efficacy of a new compound:

Phase I. In clinical phase I, studies are performed on healthy human volunteers to obtain information concerning safety, preliminary dose-ranging, pharmacokinetics and preliminary interaction with other medications.

Phase IIa. In clinical phase IIa, studies are performed to research the pharmacological activity of the dose range determined in the phase I studies and/or to assess preliminary therapeutic activity in patients.

Phase IIb. In clinical phase IIb, the aim is to determine the risk/benefit ratio, *i.e.*, to demonstrate the clinical activity and to determine the optimal dose in a larger and more varied population.

Phase III. In clinical phase III, we verify the clinical efficacy of the compound on a large population of patients (usually between 3,000 and 5,000 volunteers). These studies involve control groups taking a reference compound or a placebo (an inactive compound identical in appearance to the study compound).

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

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A Rich, Innovative and Balanced R&D Portfolio

The table below shows the composition of our R&D portfolio at the end of 2005:

	Preclinical	Phase I	Phase IIa	Phase IIb	Phase III	Launched / LCM
Cardio-vascular	AVE0657 AVE3085 AVE4454 AVE4890 SAR114646	HMR1069 AVE1231 AVE9488	AVE0118 ataciguat	XRP0038 SSR149744 AVE7688 SL650472	Multaq® **	Tritace® Aprovel®
Thrombosis	AVE6324 SSR128428 SSR128429 SAR 377142	AVE3247	AVE5026	otamixaban SR123781 SSR126517	idraparinux	Lovenox® Plavix®
Metabolic disorders	AVE0897 SAR7226 SAR351034 AVE9423	AVE5376 SSR162369 AVE5530 AVE8134	AVE1625* AVE0847 AVE2268	SR147778* AVE0010	rimonabant**	Amaryl® Lantus® Apidra®
Oncology	SSR106462/CEP11981 SAR3419 AVE1642 SSR 97225 SSR 128129 SSR244738 SSR 250411	AVE8062 AVE9633 SSR125329 CEP7055	XRP6258 Uvidem® AVE0005	SR31747	XRP9881 tirapazamine xaliproden* alvocidib	Eloxatine® Fasturtec® Taxotere®
Central Nervous System	SAR102779 SAR501788 SAR502250 AVE8112 AVE8488 SSR101010 SSR103800 SSR126374 SSR180711 SSR241586	AVE9897* SSR125543 SSR411298 SSR504734 SSR180575 SR147778*	HP184 AVE1625* SSR149415	M100907 SR57667	teriflunomide SR58611 xaliproden* saredutant eplivanserin rimonabant** SSR591813	Rilutek® Depakine® Stilnox® Ambien CR
Internal Medicine	SAR389644 SAR21609 SAR97276 AVE8680 AVE0675 AVE8923	XRP2868 AVE9897* ferroquine SSR126768 SSR150106 AVE1701	icatibant SSR240600 pleconaril SSR240612	SR140333 ciclesonide/ formoterol	Alvesco®** SR121463	Arava® Allegra® Ketek® Actonel® Xatral® Flisint® (fumagillin)

* *Compounds appearing in more than one therapeutic area*
** *NDAs have been submitted for these products*

Sanofi-aventis Pharmaceutical Scientific and Medical Affairs are currently developing 106 compounds, in six therapeutic areas (these figures do not include the vaccines portfolio; for details of this portfolio, please refer to Vaccines Research and Development below). We believe this is one of the strongest and most promising R&D portfolios in the pharmaceutical industry, particularly strong in the CNS and oncology therapeutic areas, where the needs for better drugs to treat neurodegenerative diseases, dementia and psychosis are still considerable. The portfolio is well balanced throughout all our therapeutic areas. With 60 compounds in early development (preclinical and phase I), and 46 in late development (phase II and III), our pharmaceutical portfolio is also well balanced in terms of phase distribution, with a quite significant reservoir of compounds in the early phases.

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The sanofi-aventis R&D portfolio is particularly innovative, as indicated by the number of first-in-class new molecular (or biological) entities in this portfolio. A molecule is considered as first-in-class if, at the time of its entry into development, to our knowledge, no other active substance with the same mode of action is under active preclinical or clinical development or already on the market. By the end of 2005, 42 products (small molecules) are first-in-class in our portfolio.

Sanofi-aventis Scientific and Medical Affairs Achievements in 2005

The strength of the sanofi-aventis portfolio is illustrated through the key achievements and project highlights of our R&D in 2005.

In 2005, 11 new compounds have entered preclinical development (see Discovery Research). Also, another compound re-entered the oncology development portfolio, alvocidib (HMR1275), a cyclin-dependent kinase inhibitor, for which phase III studies in chronic lymphocytic leukaemia will be initiated.

In 2005, 12 compounds entered phase I, while four phase II programs have started and nine phase III/IIIb programs have been initiated.

In terms of regulatory submissions, two major NDAs were submitted in April 2005 in the United States and Europe for rimonabant (obesity, metabolic disorders and smoking cessation), and in June 2005 for dronedarone (atrial fibrillation). Furthermore, the mutual recognition process for Zolpidem MR was initiated in Europe in 2005.

Several sNDAs were submitted in 2005 in the United States and in Europe for major products like Actonel®, Allegra®, Aprovel®, Taxotere® (gastric cancer, granted priority review in the United States), or Plavix® (acute myocardial infarction). In Japan, the amiodarone IV (Ancarone®) dossier was submitted, as well as a new formulation for Lantus®.

As far as regulatory approvals are concerned, Ambien CR was approved and launched in the United States in 2005. One marketing authorization was obtained in France for an orphan drug, Flisint® (fumagillin), a very potent treatment for a very rare disease (microsporidiosis in severely immuno-compromised patients).

Several sNDAs were granted in the United States, Europe or Japan to major products including Taxotere®, Eloxatine®, Allegra® or Lantus®: details are given below under Project Highlights.

Furthermore, in Japan, the approval of Plavix® was obtained on January 23, 2006.

Project Highlights

Life cycle management development programs for our marketed products are described above under Major Products.

Cardiovascular

Certain of our principal compounds in the fields of cardiovascular medicine currently in phase IIIb, phase III or phase IIb clinical trials are described below.

Multaq® (Dronedarone SR33589, atrial fibrillation; phase III). Amiodarone, which we have marketed since the late 1960s under the brand name Cordarone®, is a current reference anti-arrhythmic. With dronedarone, a potential successor to Cordarone®, our goal is to develop a new treatment with the efficacy of amiodarone, but with an improved safety/tolerability profile. The first indication being developed for dronedarone is the prevention of recurrences of atrial fibrillation, the most common cardiac rhythm disorder. The usual treatment for acute atrial fibrillation is an external electric shock to the heart, which is then generally followed by an anti-arrhythmic pharmacotherapy to avoid recurrences, which are extremely common. The EURIDIS (Europe) and ADONIS (North and South America, Australia and South Africa) phase III trials, involving 1,245 patients with atrial fibrillation have confirmed the good efficacy and safety of dronedarone as an anti-arrhythmic drug, particularly with the absence of any pro-arrhythmic effect. Based on these data, a registration file has been submitted in Europe and in the United States and is currently under review by Health Authorities.

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SSR149744C (atrial fibrillation; phase IIb). Besides the improved tolerability as compared to amiodarone, SSR149744C has a different metabolic profile from amiodarone and is therefore expected to be devoid of the drug interactions commonly described with amiodarone. The targeted indication for SSR149744C is atrial fibrillation. SSR149744C is in phase IIb since December 2004.

NV1FGF (XRP0038, non-viral fibroblast growth factor 1, phase IIb) is an injectable non-viral DNA plasmid and gene therapy-based approach for the promotion of angiogenesis in peripheral arterial disease (PAD). Following encouraging results in phase IIb with statistically significant prolongation of the time to amputation in patients with critical limb ischemia, XRP0038 development will continue in this indication in phase III in 2006.

Thrombosis

There are four compounds that are currently in later-stage development in thrombosis:

Idraparinux sodium (SR34006, thromboembolic events; phase III). Idraparinux sodium is a selective indirect inhibitor of coagulation factor Xa with a long duration of action. It is a synthetic pentasaccharide. The VAN GOGH phase III program is investigating the efficacy and safety of idraparinux sodium in the long-term treatment of thromboembolic events in patients suffering from deep-vein thrombosis or pulmonary embolism and is progressing as planned. In the AMADEUS program studying idraparinux sodium in comparison to Vitamin K antagonists in the prevention of thromboembolic events associated with atrial fibrillation, a substantially lower incidence of events than initially expected was observed. As a result, sanofi-aventis has decided in agreement with the Steering Committee and the DSMB to make no further recruitments in the AMADEUS program. The principal reason was the very large number of patients that would be required in order to show statistical significance.

SSR126517 (thromboembolic events, phase III to start second quarter of 2006). SSR126517 is a neutralizable selective inhibitor of coagulation Factor Xa. It has the same pentasaccharidic structure as idraparinux, with the addition of a biotin hook to allow quick and efficient fishing by its specific neutralizing agent, avidin. It demonstrated similar anticoagulant, pharmacokinetics and antithrombotic properties to idraparinux. Based on this similarity to idraparinux we plan to start a bridging clinical development including phase III program in patients with pulmonary embolism and deep vein thrombosis in the second quarter of 2006.

SR123781 (Acute coronary syndrome; phase IIb). SR123781A is a synthetic hexadecasaccharide. It includes two functional domains, an antithrombin binding domain, and a thrombin binding domain, responsible for its dual anticoagulant activity via indirect inhibition of coagulation factors Xa and IIa. Based on its demonstrated potent antithrombotic activity in animal models, it is currently being studied in phase IIB in patients with acute coronary syndromes treated with an invasive strategy.

Otamixaban (XRP0673, Acute coronary syndrome; phase IIb). Otamixaban is an injectable non-saccharidic synthetic direct inhibitor of coagulation factor Xa. It exhibits a fast on- and offset of action. It is being investigated in patients undergoing cardiac catheterization.

Metabolic Disorders

Our main compounds currently in late-stage development for metabolic disorders are described below.

Acomplia® (Rimonabant, SR141716), metabolic syndrome and weight management, smoking cessation; phase III). Rimonabant is the first in a new class of therapeutics called selective CB-1 receptor blockers. CB-1 receptors were found first in the brain and have recently also been identified in several other human tissues, including adipocytes. They are part of the endocannabinoid system, which is critically involved in the regulation of body mass and body weight, lipid metabolism and insulin resistance. The endocannabinoid system is also involved in the sensitivity to positive re-inforcers such as nicotine.

Rimonabant has completed a phase III program in obesity, cardiometabolic risk management and related disorders like type 2 diabetes and dyslipidemia (the RIO program: rimonabant in obesity) as well as a program in smoking cessation (STRATUS program). In 2005, registration dossiers were submitted in the United States and Europe. On February 17, 2006, an approvable letter for the

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weight management indication and a non-approvable letter for the smoking cessation indication were received from the FDA. Sanofi-aventis continues to work closely with the FDA on this matter.

AVE0010 (Type 2 diabetes mellitus), our injectable GLP-1 agonist, entered Phase IIb in patients with Type 2 diabetes mellitus. Compounds that lead to increased circulating levels of GLP-1 have the potential not only to lower blood glucose but also rejuvenate the insulin-producing beta cell. AVE0010 was licensed in from Zealand Pharma.

Oncology

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

Tirapazamine (SR259075, head and neck cancer; phase III). Tirapazamine is an anti-cancer agent activated under hypoxic conditions to promote the destruction of resistant hypoxic cells. This innovative mechanism of action is hypothesized to decrease the rate of relapse in tumors associated with hypoxia (*i.e.* head and neck cancer). Phase III trials on tirapazamine in combination with cisplatin and radiation in head and neck cancer are ongoing. Exploratory studies in other tumors associated with hypoxia are also ongoing.

Xaliproden (chemotherapy induced neuropathy; phase III). Xaliproden is an orally active neurotrophic agent which is currently being studied in phase III trials for the treatment of chemotherapy-induced neuropathy.

XRP9881 (metastatic breast cancer failing taxane therapy; phase III). XRP9881 is a new taxane derivative that has been designed to overcome resistance to existing taxanes, docetaxel and paclitaxel. In phase II, XRP9881 has proved to be active on metastatic breast tumors progressing after taxane therapy. XRP9881 has also been shown to cross the blood-brain barrier, and therefore could potentially be active on brain metastasis.

Alvocidib (HMR1275, chronic leukocytic leukaemia; Phase III). Alvocidib is a novel cyclin-dependent kinase inhibitor. Development was terminated by Aventis in 2004 due to lack of clinical efficacy of the tested regimen. Results from a Phase I/II study in patients with refractory chronic leukocytic leukaemia conducted at Ohio State University under an agreement with the U.S. National Cancer Institute demonstrated a 43% partial response rate with overall survival after 12 months when alvocidib was administered using a novel dosing regimen of a 30 minute bolus followed by 4-hour infusion. Based on these results, development was re-initiated using the bolus/infusional regimen in hematological malignancies.

Central Nervous System

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

SR58611 (depression; phase III). SR58611 is a beta-3 adrenergic receptor agonist. This substance stimulates neuronal activity in a specific region of the prefrontal cortex and could give rise to a new class of anti-depressants. In a phase II trial in patients

suffering from severe depression with melancholic features, SR 58611 was observed to be superior to fluoxetine, a reference treatment, and was well tolerated. A Phase III program in depression is ongoing, moreover a phase III clinical program in General Anxiety Disorder started in 2005.

Saredutant (SR48968, depression; phase III). Saredutant is an NK2 receptor antagonist developed for the treatment of Major Depressive Disorders. The patient inclusion of the two first phase III clinical trials have been completed.

Teriflunomide (HMR1726, multiple sclerosis; phase III). Teriflunomide is a dihydroorotate dehydrogenase inhibitor. An international phase III development program is ongoing.

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Xaliproden (SR57746, Alzheimer s disease, neuropathy; phase III phase II). Xaliproden is a non-peptide compound that activates the synthesis of endogenous neurotrophins. Two phase III studies in Alzheimer s disease are ongoing. Xaliproden is also studied in the oncology area (see above).

SSR591813 (smoking cessation; phase III). This nicotinic partial agonist is being developed for smoking cessation. Results of phase IIb showed a clear evidence of dose response. Treatment with SSR591813 was associated with a greater percentage of subjects who achieved the primary efficacy criterion (4-week prolonged abstinence, compared to placebo).

SR57667 (Alzheimer s disease, Parkinson s disease; phase IIb). SR57667B, like xaliproden, is a non-peptide compound that activates the synthesis of endogenous neurotrophins. One Phase II study is ongoing in Alzheimer s disease. Two phase II studies are ongoing in Parkinson s disease.

Eplivanserin (SR46349, $5HT_{2A}$ antagonist; phase III). The drug is being developed for the treatment of insomnia characterized by difficulties maintaining sleep (or sleep maintenance insomnia). A worldwide phase III program has started in November 2005 in patients with chronic primary insomnia.

M100907 ($5HT_{2A}$ antagonist; phase IIb). This second $5HT_{2A}$ antagonist is being developed for the treatment of sleep maintenance insomnia. The phase IIb program is now completed.

HP 184 (spinal cord injury; phase IIa). HP 184 is a potassium channel and use-dependent sodium channel blocker. A first Phase II study showed improvement in ASIA Total Motor Score (a measure of sensory and motor function impairment) and confirmed tolerability in patients with spinal cord injury. A second phase II study is ongoing with the goal to treat 240 patients globally.

Negative results for Osanetant, which was in Phase IIb, led us to stop the development of this compound.

Internal Medicine

Certain of our principal compounds in the field of Internal Medicine currently in clinical trials are described below.

Alvesco® (Ciclesonide, XRP1526 asthma NDA approvable). The Alvesco® metered dose inhaler is being developed jointly with our partner Altana Pharma. Sanofi-aventis is conducting clinical studies to respond to the FDA s questions from review of the Alvesco® NDA, and a response to the approvable letter is planned for submission in the first quarter of 2007.

AVE2635 (Ciclesonide/Formoterol asthma Phase IIb). Clinical studies are ongoing with the dry-powder inhaler combination of ciclesonide and formoterol. Phase IIb studies will be completed in the second quarter of 2006.

Ketek® (HMR3647 Ketolide antibiotic). Ketek® is approved for respiratory tract infections (RTI s: Community acquired pneumonia; acute exacerbation of chronic bronchitis; acute bacterial sinusitis; tonsillitis and pharyngitis). The new reduced size tablet formulation (400 mg in the United States and The European Union, 300 mg in Japan) was approved during 2005. Our current development program includes clinical studies in the United States, Europe and Japan to gain approval for pediatric RTI s.

Satavaptan (SR121463, vasopressin V2 receptor antagonist; phase III) is a pure aquaretic compound developed for the treatment of dilutional hyponatremia. The double blind part of Phase III program in patients with syndrome of inappropriate antidiuretic hormone secretion (SIADH), showing a rapid, statistically significant and clinically relevant correction of hyponatremia in comparison with placebo, has now been completed. Efficacy in correcting hyponatremia associated with cirrhotic ascites has also been demonstrated. In addition, based on positive results of the Phase IIb program in cirrhotic patients, indicating a potential for a better control of the ascites, in co-administration with standard treatment, through a decrease in weight or a reduction of the paracenthesis, a phase III program is to be implemented in 2006.

Targeted Partnerships to Support the Development of Innovative Products

Through partnerships and alliances established with biotechnology firms and other pharmaceutical groups, sanofi-aventis is able to access new technology and to extend or strengthen existing areas of research.

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Discovery Research

Two types of partnerships are employed to boost Discovery Research:

Technological partnerships giving sanofi-aventis teams access to new technology and extending their research and skills areas. Examples include:

GeneLogic (Gaithersburg, Maryland, U.S.): two global licenses to use toxicogenomic technologies, enabling access to expression profiling databases.

Amphora (Durham, North Carolina, U.S.): an agreement was signed in 2004 on the screening of specialist chemical libraries using microfluid-based compound profiling.

Elan (Dublin, Ireland) license to NanoCrystal formulation technology, which can assist with formulation and improve compound activity and final product characteristics.

Partnerships on innovative products, to maximize opportunities of exploring new leads in our therapeutic areas of excellence:

Millennium (Cambridge, Massachusetts, U.S.): validating novel biological targets in the field of inflammation and rapidly taking high value-added compounds forward to the development phase.

Immunogen (Cambridge, Massachusetts, U.S.): identifying and developing naked antibodies or immunoconjugates (monoclonal antibodies associated with an anti-cancer agent) in oncology. In March 2005, the anti-CD33 TAP (huMy9-6-DM4, AVE9633) was advanced into clinical testing.

Coley (Wellesley, Massachusetts, U.S.): global license and collaboration agreement on research into CpG oligonucleotides, which act as immunomodulators, for the treatment of certain respiratory disorders. Phase I clinical trial has been conducted with AVE 7279. A second-generation drug candidate, AVE 0675, has been selected for further clinical development.

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

Genfit (Lille, France) profiling and studying the mechanism of action of PPAR-family related drugs.

As part of the Impact Malaria program, three cooperative programs were continued in 2005. Ferroquine, co-developed with the *Université Scientifique et Technique de Lille* (France), is currently in phase I of clinical development.

Sanofi-aventis is engaged in numerous partnerships with academic institutions, such as research collaborations with INSERM and CNRS in France, with Frankfurt University in Germany, and with Harvard Medical School in the United States.

International development

Cephalon (Frazer, Pennsylvania, U.S.): discovery and development of innovative small compounds able to inhibit tyrosine kinase pathways by blocking Vascular Endothelial Growth Factor (VEGF) receptors and thus inhibiting angiogenesis. Angiogenesis, or the development of capillary blood vessels, is a crucial mechanism in tumor development.

Regeneron Pharmaceuticals Inc. (Tarrytown, New York, U.S.): joint development of a recombinant fusion protein, the VEGF Trap, that produces soluble decoy-receptors which bind to VEGF, stopping it from stimulating the natural VEGF receptor and thus preventing angiogenesis. Clinical phase I trials are ongoing.

Immuno-Design Molecule, Inc. (IDM) (San Diego, California, U.S.): cooperation agreement on the development and marketing of immunological treatments for cancer. The purpose of the agreement is to develop autologous cell vaccines, using cellular therapy technology based on monocyte maturation using Interleukin-13. The therapeutic vaccine Uvidem, developed under the agreement, is currently in phase II trials for the treatment of melanoma in the United States.

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License Agreements

Zealand: ZP10 is a glucagon-like peptide 1, or GLP-1, receptor agonist, intended to treat type 2 diabetes. The first Phase II clinical study on ZP10 was completed in 2005.

Ajinomoto: AVE 8062 is an antivascular agent for the treatment of solid tumors currently in clinical trials.

For other products developed under other research agreements with various pharmaceutical companies, such as Alvesco® (Altana AG) and Actonel® (P&G) see Project Highlights/Internal Medicine for Alvesco® and Pharmaceutical Activity /Internal Medicines for Actonel®.

Vaccines Research and Development

Our human vaccines R&D remains focused on the development of new preventive vaccines, one particular area of research covers novel therapeutic vaccines targeting diseases such as HIV and cancer.

Sanofi pasteur R&D Pipeline

The table below shows the composition of our Research and Development Portfolio.

Preclinical	Phase I	Phase IIa	Phase IIb	Phase III	Launched/ LCM
DTP-HepB-Hib*			DTP-HepB-Polio-Hib*	DTP-HepB-Polio-Hib*	Pediacel® D,T,P, Polio, Hib*
Meninge A,C,Y,W Infant	Meninge B		Menactra®	Menactra®	Menactra®
Meningitis in infants	**Meningitis B in infants**		toddler **1-2 Years**	***Meningitis in **2-10 Years**	Meninge A,C,Y,W
Pneumo					**Meningitis in 11 to 55 Years**
Meningitis & pneumonia in infants		Flu		Pentacel *** D,T,P, Polio,	Adacel®

	Flu Pandemia	**New Formulation**	Flu Micro-injection	Hib*	DTP* booster
Flu Cell	**H5 & other types**				11-64 Years
Influenza (new	**Experimental**		**New Delivery**		
production method)	**vaccines**				
			Flu Infants		
Rabies			**Influenza in 6 weeks to**		
Improved		Dengue	**6 months of age**		
formulation		**Mild-to-severe**			
		Dengue Fever			
Yellow Fever					
Improved		HIV Therapeutic			
formulation		**ART interruption**		HIV (Thailand)	
				Prevention of	
Melanoma				**infection Proof of Concept**	
Tumor antigen					
administered					
through viral vector					
Treatment of					
stage III & IV					
Colorectal					
Tumor antigen					
administered		CMV			
through viral vector		**Prevention of**			
Treatment of		**congenital infection**			
stage III & IV					
Malaria					
Prevention of					
P.falciparum Malaria					

* D=Diphtheria, T= Tetanus, Hib=H influenzae b, HepB=Hepatitis B, P = Pertussis
** Compounds appearing in more than one therapeutic area
*** NDAs have been submitted for these products

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Project Highlights

Influenza

We are developing a new formulation and applying new technologies including new delivery modes and new manufacturing processes with the aim to increase efficacy, acceptance or both. We are very active in pandemic preparedness.

A new delivery program based on the administration of Flu vaccine by Intra Dermal (ID) route using an innovative microinjection system is being developed in partnership with Becton Dickinson. Phase II studies were conducted in 2005 and Phase III clinical trials will be initiated in 2006.

A new formulation has been developed with the aim of improving vaccine effectiveness in the elderly population. This project is currently in Phase II.

New technology using a cell-based system, instead of the classic egg-based manufacturing process, has been developed under contract with the U.S. Government (under *HHS* supervision) and in partnership with Crucell. This program is aimed at both inter-pandemic and pandemic vaccines. A Phase I study will be initiated in 2006.

An extension of indication will be sought for the pediatric population in the United States. This project is currently in Phase II.

Pandemic Preparedness A very active program for pandemic preparedness has been launched in both Europe and the United States. In the United States, activities are conducted under U.S. Government contracts. These activities concern year-round egg supply, clinical batch formulation and stockpiling of H5N1 vaccine. In Europe, activities include clinical batch production, clinical studies and core dossier submission for registration with the EMEA. The first clinical studies using H5N1 vaccine were completed in 2005.

Pediatric & Adolescent/Adult Booster Combination Vaccines

A number of pediatric vaccines are in development. Tailored for specific markets, they are aimed at protecting against 5 or all 6 of the following diseases: diphtheria, tetanus, pertussis, poliomyelitis, *Haemophilus influenzae* type b and hepatitis B.

Pentacel a pentavalent pediatric vaccine protecting against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis, and *Haemophilus influenzae* type b disease for the U.S. market was filed with the FDA in 2005.

Pediacel® another pentavalent pediatric vaccine protecting against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and *Haemophilus influenzae* type b disease for the EU markets, was licensed in the Netherlands and Portugal in 2005 (after being licensed in the United Kingdom in 2002).

Two hexavalent pediatric vaccines protecting against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and *Haemophilus influenzae* type b disease are in development. One has completed Phase II development stage and will enter the Phase III development stage in 2006.

Adacel® a trivalent vaccine protecting adolescents and adults against diphtheria, tetanus, and pertussis. Marketed in Canada and Germany. This product has been approved by the FDA and was launched in the United States in July 2005. In 2006, we will focus on efforts to extend its indications (primarily the pre-school booster indication) in countries where the product is already marketed, and to gain new licenses.

Meningitis Program

Neisseria meningitidis has been a leading cause of meningitis in the United States, Europe and elsewhere, striking the very young as well as adolescents. There are five serogroups that contribute to the vast majority of the incidences of the disease worldwide: A, C, W-135, Y and B. A polysaccharide vaccine comprised of serogroups A, C, W-135 and Y, Menomune®, has been a valuable product for many years. In 2005, a conjugate-based vaccine, Menactra®, was licensed in the United States for indications against invasive meningococcal diseases in patients aged 11-55 years. As a conjugate vaccine, Menactra® is expected to provide a longer immunity than the polysaccharide vaccine. Ongoing projects related to Menactra® have the primary focus of decreasing the age at which one can first receive this vaccine. In 2005, a supplement to the Menactra® license was submitted to the FDA to lower the indication to two years of age, effectively increasing the age range of 2-55 years. This

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supplement is pending and expected to be approved in 2006. In parallel, activities are ongoing to license this vaccine worldwide. In 2005, an application was filed in Canada and approval is expected in 2006. Submission to the European Union is targeted for early 2007. Additional international filings will subsequently occur.

Menactra® Toddler The project is aimed at further lower the age of administration below two years of age. This vaccine entered into a Phase I study at the end of 2004 and will enter Phase III in 2006.

Meninge Infant Targets the infant primary/booster series schedule for introduction of a meningococcal vaccine. The primary focus of this project is to evaluate optimal conjugation chemistries.

Meningitidis B Cross-reactivity between the polysaccharide and human tissues prevents using the same approach as used for the other serogroups. Sanofi pasteur s approach is to identify conserved components of the bacterial membrane that provide wide protective coverage. A Phase I study evaluating this approach was initiated in 2005.

Pneumococcal Program

Streptococcus pneumoniae is the leading etiological agent of severe infections such as pneumonia, septicemia, meningitis and otitis media and causes over 3 million deaths per year worldwide, of which a million are children. The problem of antimicrobial resistance in *Streptococcus pneumoniae* has complicated the treatment of pneumococcal disease and further emphasized the need for vaccination to prevent large-scale morbidity and mortality. Sanofi pasteur has 2 projects in its pneumoccal program.

Conjugate Vaccines have proven effective. Sanofi pasteur has long been active in the field. Our current approach should enter the clinic at the end of 2006.

Protein Vaccine Conserved pneumococcal proteins (as opposed to the polysaccharides) are frequently involved in the pathogenesis of infections. As with the meninge B approach, these proteins are considered to be components for future vaccines as they cover many more serotypes of *Streptococcus Pneumoniae*. They are less variable than the capsular polysaccharides and are more likely to elicit an immune response in children. Clinical development is expected to start at the end of 2006.

New vaccine targets

Dengue

Dengue fever is growing in epidemiological importance, linked with global socio-climatologic changes, and is a major medical and economic burden in endemic areas in Asia, Latin America, the Pacific and Africa and one of the leading causes of fever among travelers. We are undertaking multiple approaches to develop a vaccine covering the four viral serotypes of Dengue fever in order to prevent this disease and its severe complications (hemorrhagic fever). The sanofi pasteur Dengue fever vaccine project has now entered Phase II following promising phase I results. Vaccination will target people living in affected areas as well as travelers to these regions.

Malaria

The sanofi pasteur malaria vaccine project is in the pre-clinical stage and will benefit from the malaria partnership network and vaccine adjuvant technology developed in-house.

Chlamydia trachomatis

Chlamydia trachomatis is the most commonly reported sexually transmitted bacterial pathogen and produces serious morbidity and long-term sequels, especially in women. Chlamydia-host immunobiology is characterized by acute infection followed by immunity or by persistent infection that is associated with tissue damage and disease sequels. The *Chlamydia trachomatis* project goal is to develop a recombinant protein vaccine for prophylactic vaccination against the *Chlamydia trachomatis* sexually transmitted infection. The target population is pre-sexually active women, 11 to 14 years of age. At present the project is at the exploratory stage.

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Cancer

A development program is focusing on colorectal and melanoma cancers, seeking specifically to activate the immune system to destroy cancer cells. Phase I clinical studies using the proprietary ALVAC technology in patients with melanoma and colorectal cancer showed a favorable safety profile.

Melanoma

The incidence and mortality of cutaneous malignant melanoma have risen dramatically over the past several decades and combating melanoma remains an unmet medical need. There is evidence that suggests that manipulation of the immune response against melanoma may be therapeutic. During 2005, clinical and research grade new generation melanoma multiantigen vaccine candidates have been engineered and preclinical immunologic validation was initiated.

Colorectal Cancer

Colorectal cancer is the most common cancer of the gastrointestinal tract and the second leading cause of cancer-related morbidity and mortality, with approximately 300,000 new cases and 200,000 deaths in Europe and the United States each year. A multiantigen therapeutic vaccine is being developed, incorporating several tumor-associated antigens highly specific to colorectal cancer, as well as a co-stimulatory component to enhance immune activation. New antigens for the colorectal vaccine from recently established collaborations are currently being evaluated.

Both our cancer vaccine programs use the ALVAC technology: an avian pox virus is used as the vector tumor-associated antigens to deliver to the immune system and elicit a cell-mediated immune response aimed at controlling or destroying malignant cells.

HIV

Sanofi pasteur has been a pioneer in HIV vaccine research with a long-standing research program as well as partnerships with leading government agencies and pharmaceutical companies. Sanofi pasteur is exploring both prophylactic and therapeutic approaches to developing vaccines to combat HIV.

HIV Immunotherapy

Vaccine-based HIV immunotherapy aims to present critical HIV antigens in a novel way, thus triggering an HIV-specific immune response capable of controlling viral replication. The goal of immunotherapy is to provide HIV patients with the option of interrupting antiviral therapy in order to maintain treatment options, relieve side effects and improve patient quality of life. Sanofi pasteur s approach is based on two candidates: recombinant Tat toxoid, and the recombinant canarypox vector expressing HIV genes. The goal is to elicit antibodies to block Tat secreted by HIV-infected cells since Tat is involved in the replication of the virus and in its immunosuppressive effects. The canarypox vector, ALVAC-HIV, is designed to elicit cell-mediated immune response that would kill HIV-infected cells. Pilot clinical studies have been conducted and support further development to determine the best treatment modality for this approach.

HIV Prophylactic Vaccine

The development of an effective prophylactic vaccine for human immunodeficiency virus has been an elusive target since the discovery of the virus 20 years ago. However, until an efficacy trial is undertaken, the evaluation of candidate vaccines relies on anecdotal criteria derived from other clinical settings, such as the immunologic responses found in HIV-1 infected long-term non-progressors and in HIV-1 and non-human primate vaccine studies. A recombinant canarypox vaccine, ALVAC-HIV is currently in phase III in Thailand. The trial is a collaboration between the U.S. Army, the National Institute of Allergy and Infectious Diseases of the NIH, the Ministry of Public Health of Thailand, sanofi pasteur and Vaxgen. In 2005, the enrolment of more than 16,000 volunteers was completed. A 2.5 year follow-up is now underway. A similar approach using a recombinant virus to elicit HIV-specific CD8 response is being applied in Europe where a Phase I trial sponsored by the EuroVacc Foundation (EuroVacc 02) has been completed.

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Important Partnerships

Sanofi pasteur has concluded important partnerships in 2005 with:

- Becton Dickinson (broad field micro-injection technology)
- HHS/ NIH (Flu 4 RPF s for pandemia)
- EISAI (broad field TLR adjuvant)
- Agensys (Colorectal cancer antigens)

Production and Raw Materials

Our principal manufacturing processes consist of three stages: the manufacture of active ingredients, the incorporation of those ingredients into products designed for use by the consumer and packaging. At each of these three stages, we need to purchase a variety of raw materials. When possible, we have a policy of maintaining multiple sources of supply for these materials. In a few cases, some raw materials may be in short supply. Nonetheless, we have not experienced any material difficulty in obtaining a sufficient supply of raw materials in recent years and believe that we will be able to obtain supplies in sufficient quantities in the future. We do not believe the Group is exposed to any material risks related to the volatility of the prices of raw materials that we outsource.

We generally develop and manufacture the active ingredients that we use in our products. We have a general policy of producing the active ingredients for our principal products at our own plants rather than outsourcing production. Even though we must outsource certain production elements, we are committed to this general principle, which reduces our dependency on key suppliers.

The production of the active ingredients used in Stilnox®, Kerlone®, Xatral®, Solian® and Tildiem® is outsourced to Dynamit Nobel, a company to which we sold the related facilities in 2001. Under our current outsourcing agreement, we are required to purchase 50% of our manufacturing requirements of the ingredients for Stilnox®, Xatral® and Solian® and all of our manufacturing requirements of the ingredients for Kerlone® and Tildiem® from these facilities through December 31, 2007.

Among our other key products, we also depend on third parties in connection with the manufacture of Eloxatine®. Under the terms of our license agreement, we purchase the active ingredient from Debiopharm, and the production of the finished product is outsourced to two manufacturers. We have scheduled to transfer the manufacture of the liquid form of Eloxatine® to our facility in Dagenham (United Kingdom). Routine production will occur end of 2006.

In addition, we work with external manufacturers mainly for several small products. These subcontractors are required to follow our guidelines in terms of quality, logistics and other criteria. Our main subcontractors are Patheon, Famar, LCO, Haupt and Sofarimex.

Under our partnership with BMS, a multi-sourcing organization is in place for Plavix® and Aprovel®. For both products, pharmaceutical production is performed partly in sanofi-aventis plants and partly in BMS plants. For active ingredient production, a double-sourcing approach has been put in place for Aprovel® involving sanofi-aventis, BMS and sub-contractors plants.

In mid-2004, we sold the chemical manufacturing plant at Villeneuve-la-Garenne to PCAS. As a consequence we now outsource a part of the chemical activity linked with Lovenox® to PCAS (early stages of chemical synthesis), pursuant to a six-year outsourcing agreement.

In connection with the acquisition of Aventis, we divested our interests in Arixtra® and Fraxiparine®. Our facility at Notre-Dame de Bondeville, which produces those two products, was sold to GlaxoSmithKline on September 1, 2004. This plant also manufactures other products like Elitek®, Tranxene®, and Depakine® under a supply agreement until September 2009.

Each stage of the manufacturing process is carried out under carefully controlled conditions and is regulated by applicable legislation and regulatory authorities, including for facilities that produce products marketed in the United States. Wherever possible, we seek to have multiple plants approved for the production of key active ingredients and finished products.

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Our main European production facilities are located in France, Germany, Italy, Spain, the United Kingdom and Hungary. In North America, we run two facilities in the United States (Kansas City and Saint Louis) and one in Canada (Laval). We have one plant in Japan (Kawagoe) and additional facilities located in many other countries around the world, including in Northern Africa, Eastern Europe, Asia and Latin America.

All of our facilities are Good Manufacturing Practices (GMP) compliant in accordance with international guidelines. Our main facilities are also FDA approved, including, our facilities in Ambarès, Tours, Le Trait, Maisons-Alfort and Compiègne in France, Dagenham and Holmes Chapel in the United Kingdom, Frankfurt in Germany, Saint Louis and Kansas City in the United States and Laval in Canada.

To carry out the production of human vaccines, sanofi pasteur has a large industrial operations network with sites located in North America and Europe as well as in emerging markets: China, Thailand and Argentina.

A more detailed list of our manufacturing sites is set forth below under Property, Plant and Equipment .

Markets

Marketing and Distribution

The combination of Sanofi-Synthélabo and Aventis into sanofi-aventis has reinforced our Group s international footprint and our marketing strength in a number of key markets.

We have a commercial presence in approximately 100 countries, and our products are available in more than 170. Our top five markets in terms of net sales are, respectively, the United States, France, Germany, Italy and Japan.

A breakdown of our sales by geographic market is presented in Item 5. Operating and Financial Review and Prospects Results of Operations Year Ended December 31, 2005 Compared with Year Ended December 31, 2004 . Accounting for over 49% of global prescription drug sales, the United States is the world s largest pharmaceutical market and our single largest national market. In 2005, we generated 35% of our net sales in the United States. In Europe, our leading markets are France, Germany, Italy, Spain and the United Kingdom. Japan, the world s second-largest national pharmaceutical market, accounted for 3.8 % of our net sales in 2005.

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

We have a global sales force of 35,000 representatives, including approximately 12,400 in Europe, 9,400 in the United States, 1,600 in Japan and 1,600 in China. The precise composition by therapeutic area fluctuates according to business needs and in line with each country s key

products. In our major markets, we deploy dedicated sales forces specialized in areas such as oncology, metabolism and cardiovascular diseases.

Our 35,000 medical sales representatives, who work closely with health care professionals, use their expertise to promote and provide information on our drugs. These representatives embody the Group s values on a day-to-day basis and are required to adhere to a code of ethics. This commitment extends to promoting and providing information not only on the latest therapeutic advances but also on all our traditional products, which provide the foundation for satisfying major therapeutic needs. The quality of our sales force teams is recognized by our customers, as highlighted in the United States by the results of the Health Strategies Fall 2005 SFE monitor survey. In this survey, sanofi-aventis enhanced its high ranking: both in its ability to access customers and inform them about its products, and in effectiveness of sales calls, in terms of delivering useful content to customers.

Beyond direct promotion by our sales forces, and as most pharmaceutical companies do, we also market and promote our products to physicians through a variety of advertising, public relations and promotional tools. We regularly advertise in medical journals and exhibit at major medical congresses. In some countries, some of our products are also marketed directly to consumers by way of television, radio, newspapers and magazines. Not all products are marketed through all media channels. National advertising campaigns are used to enhance

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awareness of conditions such as deep vein thrombosis, osteoporosis, uncontrolled diabetes, influenza and peripheral arterial disease in markets such as Germany, France and the United States. Some major campaigns took place in 2005, such as a direct-to-consumer campaign in the United States on the importance of compliance with medical recommendations related to a drug treatment.

Although we market most of our products with our own sales forces, we have entered into and continue to form partnerships to co-promote/co-market certain products in specific geographic areas. Major arrangements currently include an agreement with BMS for the cardiovascular drugs Aprovel® and Plavix®, P&G for the osteoporosis drug Actonel® and Teva Pharmaceuticals for the multiple sclerosis drug Copaxone®. More details on these alliances are provided below under Alliances .

Our human vaccines are sold and distributed through multiple channels, including physicians, pharmacies and distributors in the private sector, and governmental entities and Non-Governmental Organizations (NGOs) in the public and international donor markets, respectively.

Alliances

In 2005, we had three major alliances through which four of our top 15 products were marketed. The first, with Bristol-Myers Squibb, or BMS, governs the development and marketing of Plavix® and Aprovel®. The second, with Procter & Gamble Pharmaceuticals, or P&G, governs the development and commercialization of Actonel®. The third is a marketing agreement with Teva Pharmaceuticals regarding Copaxone®.

The financial impact of our principal alliances on our financial condition or results of operations is significant and is described in detail under Item 5. Operating and Financial Review and Prospects Overview Financial Presentation of Alliances .

Bristol-Myers Squibb

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

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

Co-marketing: Each company markets the products independently under its own brand names.

Exclusive Marketing: One company has the exclusive right to market the products.

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

Under the alliance arrangements, there are two territories, one under our operational management and the other under the operational management of BMS. The territory under our operational management consists of Europe and most of Africa and Asia, while the territory under the operational management of BMS consists of the rest of the world excluding Japan. In Japan, Aprovel® is under development through agreements between BMS and the Japanese pharmaceutical company Shionogi Pharmaceuticals. The BMS alliance does not cover rights to Plavix® in Japan.

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

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

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

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

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

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

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

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

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

Procter & Gamble Pharmaceuticals

We in-license Actonel® from Procter & Gamble Pharmaceuticals. An alliance with P&G was concluded in April 1997 for the co-development and marketing of Actonel®. The 1997 agreements were amended in October 2004 following the acquisition of Aventis by sanofi-aventis.

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

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

*Co-promotion Territor*y: The product is jointly marketed through the alliance arrangements under the brand name Actonel® with sales booked by P&G. The co-promotion territory includes the United States, Canada, France, Germany, the Netherlands, Belgium and Luxemburg.

Secondary Co-promotion Territory: The product is jointly marketed through the alliance arrangements under the brand name Actonel® with sales booked by sanofi-aventis. The secondary co-promotion territory includes the United Kingdom, Ireland, and since mid-2005, Sweden, Finland, Greece Switzerland, Austria, Portugal and Australia. P&G may also at a later date exercise an option to co-promote the product in Denmark, Norway, Mexico and/or Brazil.

Co-marketing Territory: Each company markets the products independently under its own brand name. Italy is currently the only country in this territory; the product is sold in Italy under the brand name Actonel® by P&G and under the brand name Optinate® by sanofi-aventis.

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

Teva Pharmaceuticals

We in-license Copaxone® from Teva Pharmaceuticals (Teva) and market it through an alliance agreement with Teva, which was originally concluded in December 1995, and amended several times, most recently on December 22, 2005.

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

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

Exclusive Marketing: We have the exclusive right to market the product. This system is used in a number of European countries (Spain, Portugal, Italy, Greece, Finland, Denmark, Sweden, Norway, Iceland, Ireland, Luxemburg, Poland, Lichtenstein and Switzerland), Australia and New Zealand.

Co-promotion: The product is marketed through the alliance arrangements under a single brand name. We use the co-promotion system in Germany, the United Kingdom, France, the Netherlands, Austria, Belgium and the Czech Republic.

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In the United States and Canada, Copaxone® is sold and distributed by sanofi-aventis but marketed by Teva. Following the expiration of an agreement in March 2008, Teva will assume the Copaxone® business, including sales of the product, in the United States and Canada.

Competition

The pharmaceutical industry in which we operate is highly competitive. Over the last few years, the pharmaceutical industry has experienced increased vertical and horizontal consolidation.

In addition to the consolidation, significant changes in marketing conditions are occurring in the European, U.S. and Japanese pharmaceutical markets, including decreased pricing flexibility, increased cost control measures, and the impact of managed care, especially with respect to product selections and pricing concessions. As a result of these factors, the breadth of products that we offer and our distribution capabilities have become increasingly important.

The pharmaceutical market is generally defined by three types of competition:

- competition among pharmaceutical companies to develop new patented pharmaceutical products for a specific therapeutic indication;
- competition among existing patented pharmaceutical products for a specific therapeutic indication; and
- competition between original products and bioequivalent generic products following the loss of patent protection. Generics competition has been more intense in the past few years and several major pharmaceutical companies including Novartis through its generic division Sandoz are investing substantially in this segment.

We compete with other pharmaceutical companies to develop new and innovative pharmaceutical products. We may develop new technologies and new patented products entirely internally, or we may enter into collaborative R&D arrangements in order to access additional new technologies. When we decide to have access to new technologies through outside R&D collaborative arrangements, we compete directly with large pharmaceutical companies.

Our prescription drugs compete in all our major markets primarily against other branded, patented drugs from large national and international pharmaceutical companies, *e.g.*, Novartis in hypertension and oncology, Pfizer in antibiotics, oncology and allergy, AstraZeneca in cardiovascular and oncology, BMS in oncology, Boehringer-Ingelheim in atherothrombosis and benign prostatic hyperplasia, Eli Lilly in osteoporosis, diabetes, and oncology, GlaxoSmithKline in oncology, allergy and thrombosis, Merck & Co. in hypertension, osteoporosis and benign prostatic hyperplasia, Abbott in benign prostatic hyperplasia, Novo Nordisk in diabetes and Roche in oncology. In the human vaccines business, we compete primarily against GlaxoSmithKline, Merck & Co., Wyeth and Novartis through its subsidiary Chiron.

Note: The following market share and ranking information is based on sales data from IMS Health MIDAS and GERS (France), retail and hospital, for the full year 2005, in constant euro.

While we believe 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). 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 prepare a reconciliation of consolidated net sales data to developed sales as defined in Item 5 Operating and Financial Review and Prospects Presentation of Net Sales Developed Sales , IMS net sales have been adjusted as follows:

IMS consolidated net sales as presented:

(i) include sales as published by IMS (excluding sales generated by the Vaccines business), equating to the scope of our pharmaceutical operations;

(ii) include adjustments to data for Germany, to reflect the significant impact of parallel imports;

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(iii) include IMS sales of products sold under alliance or license agreements which we recognize in our consolidated net sales but which are not attributed to us in the reports published by IMS;

(iv) exclude IMS sales for products which we do not recognize in our consolidated net sales but which are attributed to us by IMS.

The scope of IMS developed sales includes:

(i) IMS consolidated net sales as defined above; and

(ii) IMS sales of products that we include in our developed sales but which are not included in the scope of IMS consolidated net sales.

Products market shares are calculated based on referenced market definitions specified internally and on the basis of IMS consolidated sales unless specified otherwise.

United States

Sanofi-aventis ranks eighth based on IMS-consolidated sales and fourth based on IMS-developed sales. Our market share in this market is 4.4% based on IMS-consolidated sales and 6.0% on IMS-developed sales.

In 2005, our top-selling products in the U.S. were Lovenox®, Plavix®, Stilnox® under the brand name Ambien® and Allegra®. These two last ones faced major events in September 2005 with the launch of the new controlled-release formulation of Ambien® (Ambien CR) and the market entry of generic versions of fexofenadine HCI.

France

Sanofi aventis is the leading pharmaceutical company in France with a market share of 16.4% based on IMS consolidated sales. Plavix®, Lovenox® and Taxotere® are leading brands in their market.

Germany

The Group has a market share of 6.7% in IMS consolidated sales and 7.6% in IMS developed sales. Our largest products are Plavix®, Lovenox® and Insuman®.

Japan

In Japan, sanofi-aventis has a market share of 1.7% based on IMS-consolidated sales and 1.9% on IMS-developed perimeter and ranks 17th in both perimeters. Our top-selling products were Allegra®, Amaryl® and zolpidem under the brand name Myslee®.

In July 2005, we announced an agreement with Daiichi under which sanofi-aventis Japan would recover all Japanese rights to Plavix®. Sanofi-aventis and Daiichi agreed to collaborate in the future in the areas of manufacturing and co-promotion to ensure the success of Plavix® in Japan, which we currently expect to launch in 2006.

We also face competition, which can be significant, from generic prescription products. Generic products typically enter the market as patent protection and regulatory exclusivity expire. More details on such challenges are provided under at Item 8. Financial Information Consolidated Financial Statements and Other Financial Information Information on Legal or Arbitration Proceedings and at Note D.22(b) to the consolidated financial statements included in Item 18 of this annual report. In addition, a competitor who has otherwise received all relevant regulatory approvals for its proposed generic product, may choose to launch its product before either the patent expiration date or the decision of a court in a legal challenge to the patent. Such launches are said to be at risk for the promoter of the generic product because of the risk it will be required to pay substantial damages to the owner of the original product. See Item 3. Risk Factors . If we are unable to protect our proprietary rights, we may fail to compete effectively or operate profitably. This was the case in September 2005 when Teva and Barr launched a generic of fexofenadin HCI before the expiration of the U.S. patents and while patent litigation against these companies remains pending.

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Sanofi-aventis also faces competition from over-the-counter (OTC) products which pharmacies sell without a prescription, generally at a price lower than the price of drugs sold only with a doctor s prescription.

Another competitive issue facing pharmaceutical manufacturers is the increasing incidence of parallel trade, also known as re-importation, which takes place when drugs sold abroad under the same trade name as in a domestic market are then imported into the domestic market by parallel traders, who may repackage and/or resize the original branded product or offer products for sale by alternative means, such as by mail or the internet. The rationale for parallel trade lies in economic advantages arising from different prices for the drugs due to different sales costs, market conditions (*e.g.*, intermediate trading stages) and tax rates or because of national regulation of prices. There are indications that parallel trade is affecting markets in several regions, mostly in European countries.

Regulation

The global pharmaceutical industry is highly regulated. National and supranational regulatory authorities administer numerous laws and regulations covering the testing, approval, labeling, manufacturing, importation, exportation, labeling and marketing as well as post-marketing commitments of drugs, and also review the quality, safety and efficacy of pharmaceutical products. Of particular importance is the requirement to obtain regulatory approval for a pharmaceutical product from a country s national regulatory authority before such product may be marketed in that country and also to maintain the dossier thereafter. These regulatory requirements are a major factor in determining whether a substance can be developed into a marketable product and the amount of time and expense associated with such development.

The submission of an application to a regulatory authority does not guarantee that a license to market the product will be granted. Furthermore, each regulatory authority may impose its own requirements and may refuse to grant, or may require additional data before and also after granting, an approval, even though the relevant product has been approved in one or several other countries. Regulatory authorities also have administrative powers that determine product recalls, seizure of products and other sanctions.

Europe, the United States and Japan all have very high standards for technical appraisal. Approval takes usually one to two years but may vary by country, from six months to, in some cases, several years from the date of application, depending on the quality of data produced, the degree of control exercised by the regulatory authority, the review procedures, the nature of the product and the condition to be treated.

In recent years, intensive efforts have been made among the United States, the European Union and Japan to harmonize registration requirements. Many pharmaceutical companies are now able to prepare and submit a common technical document (CTD), that can be used in each jurisdiction for a particular product with only local or regional adaptation.

However, the requirement of many countries (including Japan and several Member-States of the European Union) to negotiate selling prices or reimbursement levels with government regulators can substantially extend the time to market after initial approval to market is granted. While marketing authorizations for new pharmaceutical products in the European Union have been substantially centralized with the European Agency for the Evaluation of Medicinal Products (EMEA), pricing and reimbursement remains a matter of national competence. See(Pricing), below.

In the European Union, there are three main procedures by which to apply for marketing authorization: the Centralized Procedure, the Mutual Recognition Procedure and the decentralized procedures.

The Centralized Procedure is compulsory for medicinal products derived from biotechnology and is also available at the request of companies for other innovative products. In the Centralized Procedure the license application is submitted directly to the European Agency for the (EMEA). The application is evaluated by the Committee for Medicinal Products for Human Use (CHMP). The European Commission makes the final binding decision. Once granted, an approval via the Centralized Procedure is valid throughout the European Union without further action and the drug may be marketed within all EU Member States.

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The Mutual Recognition Procedure operates by having one country (*i.e.* the Reference Member State (RMS)) carry out the primary evaluation of a new compound. Once the first license is granted by the RMS other EU Member States (Concerned Member States or (CMS)) then must decide whether they will accept or reject the approval granted by the RMS.

The Decentralized Procedure applies to products which have not yet obtained a marketing authorization in a European Member State. The key procedural difference compared to the Mutual Recognition Procedure is that an initial marketing authorization is not issued by the RMS. All the Concerned Member States (CMS) can be involved early in the process by contributing to the draft assessment report. As compared to MRP, more opportunities exist for discussion and consensus to be reached leading to closure of the procedure at a several possible points.

The EMEA has introduced a series of initiatives aiming at improving the openness and the transparency of its activities, such as procedures dealing with the publication of the European Public Assessment report which will now be more detailed. New initiatives are proposed with regards to the publication of Questions and Answer documents and of Safety Bulletins for medicines for human use.

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

In the United States, applications for drug registration are submitted to and reviewed by the FDA. The FDA has broad regulatory powers over all pharmaceutical products that are intended to be, and which are, commercialized in the United States. To commercialize a product in the United States a New Drug Application is filed with the FDA with data that sufficiently demonstrate the drug s quality, safety and efficacy. Approval for a new indication of a previously registered drug requires the submission of a supplemental NDA (sNDA).

Pharmaceutical manufacturers have committed to publish protocols and results of clinical studies performed with their compounds in publicly accessible registries (Clinical Trials Registry and Clinical Trial Results Registry). See Research and Development Pharmaceutical Research and Development Global and Focused organizations : Discovery and Development Development above.

Generic drug manufacturers may file an Abbreviated NDA (ANDA). These applications are abbreviated because generic manufacturers, except for the quality part of the dossier, need only to demonstrate that their product is bioequivalent (*i.e.*, that it performs in the same manner as the innovator s product). Consequently, the length of time and cost required for development of such product is considerably less than for the innovator s drug. See Patents, Intellectual Property and Other Rights , below, for additional information. The ANDA procedures in the United States can be used for pharmaceutical products classified as drugs , but are not currently available for other product categories including vaccines.

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

In Japan, the regulatory authorities can request bridging studies to verify that foreign clinical data are applicable to Japanese patients and also require data to determine the appropriateness of the dosages for Japanese patients. These additional procedures have in the past created

differences of several years in the registration dates of some of our products in Japan compared to our other major countries.

Pricing

In most markets in which we operate, governments exercise some degree of control over pharmaceutical prices. The nature of these controls and their effect on the pharmaceutical industry vary greatly from country to country. In recent years, national healthcare reimbursement policies have become more stringent in a number of

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countries in which we do business as part of an overall effort to reduce the cost of healthcare. Different methods are applied to both the demand and supply side to control pharmaceutical costs, such as reference pricing, patient co-payment requirements, reimbursement limitations and volume containment measures, depending on the country.

We believe that the governments in many markets important to our business will continue to enact measures in the future aimed at reducing the cost of pharmaceutical products to the public. It cannot be predicted with certainty what future effects the various pharmaceutical price control efforts will have on our business. These efforts could have significant adverse consequences for the pharmaceutical industry as a whole and, consequently, also for sanofi-aventis. Increasing budgeting and price controls, the inclusion of patent protected drugs in national reference price systems and approved drug lists and other similar measures may continue to occur in the future.

United States

In the United States, the initiation of the new Medicare Part D drug benefit program, combined with Medicaid, establishes the federal government as almost equal to the private health insurance sector in terms of total drug reimbursement. The Medicaid program requires that pharmaceutical manufacturers pay rebates to individual states on Medicaid reimbursed pharmaceutical products so that the Medicaid program receives the manufacturer s best price or a minimum discount provided by law. Individual state governments are actively seeking ways to further reduce the cost of pharmaceutical products by exerting more formulary control of available products in the program through a discount bid process as well as the historical preference for generic product usage. However, the estimated total drug spend in Medicaid has been reduced by 50% due to the shift of the dual Medicare/Medicaid eligible patients to Part D. The new Part D program is implemented through third party market drug benefit providers utilizing formulary design and a discount bid process to attain access similar to the private sector. Benefit Managers, both in Part D as well as for the private sector plans, dynamically manage the formulary process and products in order to control overall cost trends. Further attempts to reform Medicaid and Medicare may occur, due to the U.S. government motivation to keep costs down via future pricing and reimbursement constraints. Private sector plans will continue to pressure prescription cost increases by greater generic utilization and cost shifting to the beneficiaries.

France

In France, the government regulates prices of new prescription and non-prescription drugs and price increases and decrease for existing drugs. A new reference pricing system was introduced in France in July 2003 under which the government reimburses some off-patent products only up to a certain level (generic price or the so-called reference price) with patients paying the remainder if the original brand does not cut its price to the level of the reference price. In addition, the French health ministry de-listed several products deemed to have insufficient medical benefit. In return, the government introduced the principle of a fast-track procedure to set prices and provide reimbursement for new innovative drugs. This measure could extend by many months the duration of commercialization for drugs under patent protection. In July 2004, the French Parliament passed a Health Insurance Bill (Projet de Loi Relatif à l Assurance Maladie) with the objective to reduce costs by around 10 billion per year and to raise additional revenues totaling 5 billion per year. A major impact on the pharmaceutical industry will be that, if health insurance spending on drugs increases by more than the government s target of 3% in 2004 and 1% per annum in subsequent years, the pharmaceutical industry will be required to pay rebates equivalent to up to 50% up to 1.5%, 60% up to 2% and 70% of the excess. Beginning January 1, 2005, a new organization, the High Authority for Health (Haute Autorité de la Santé), will evaluate medicines and other forms of treatment, offer recommendations on what the health insurance system should reimburse, and issue guidelines on good clinical practice. On 23 November 2005 the Parliament approved the Social Security Finance Act for 2006, which provides for some cost containment measures for medicines, inter alia:

Increase from 0.6% to 1.76% of the special tax on reimbursed medicines sales;

Price reduction for generics groups (a generic group consists of the brand product and its copies) by 15% or 25% for molecules that have been off-patent for more than two years;

De-listing of products with insufficient medical value and reduction of the reimbursement rate from 35% to 15% for veinotonics.

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Japan

The Ministry for Health, Labor and Welfare (MHLW) controls the pricing of pharmaceutical products in Japan. The MHLW determines the drug reimbursement price paid by the National Health Insurance (NHI) to medical institutions. The NHI drug reimbursement price is determined for each prescription drug by the MHLW. Since the price at which medical institutions purchase drugs can be set at a lower price than the reimbursement price through negotiation with wholesalers, a gap may exist between the selling price and the NHI drug price. Periodically (every two years in principle), the MHLW carries out a revision of drug reimbursement prices aimed at bringing NHI prices closer to the market prices. The latest pricing round in April 2004 averaged a decrease of 4.2%, which was the lowest in two decades. Having implemented wide-ranging reforms to its healthcare system over a three-year period, Japan s new Pharmaceutical Affairs Law (PAL) was finally completed in April 2005. The government has since recognized the need for reforms to its pricing and reimbursement system in light of the country s demographic problems. The reforms include raising co-payments from 20% to 30% for the elderly, and promoting generic substitution by changing a prescription. The April 2006 price cuts average of 6.7% which was caused by the increasing purchasing power.

Germany

Since the late 1980s, the German government has imposed a wide range of supply- and demand-side restrictions intended to curb the level of overall spending on pharmaceuticals. A reference pricing system that requires patients to pay the difference between the actual price of the prescribed drug and the reference price has been in existence since 1989. In practice, patients are generally not willing to pay the difference. As a result, pharmaceutic