

SANOFI-AVENTIS  
Form 20-F  
March 04, 2009  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 20-F**

(Mark One)

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

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2008

OR

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

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

For the transition period from            to

Commission File Number: 001-31368

**Sanofi-Aventis**

(Exact name of registrant as specified in its charter)

N/A

(Translation of registrant's name into English)

Edgar Filing: SANOFI-AVENTIS - Form 20-F

France

(Jurisdiction of incorporation or organization)

174, avenue de France, 75013 Paris, France

(Address of principal executive offices)

**Karen Linehan, General Counsel. 174, avenue de France, 75013 Paris, France. Fax: 011 + 33 1 53 77 43 03**

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

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

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

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

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

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

**common stock as of December 31, 2008 was:**

Ordinary shares: 1,315,525,463

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

**of the Securities Act.**

YES  NO

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

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

YES  NO

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

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

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

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

U.S. GAAP

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

Other

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

Item 17

Item 18

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

YES  NO

**Table of Contents**

**PRESENTATION OF FINANCIAL AND OTHER INFORMATION**

The consolidated financial statements contained in this annual report on Form 20-F have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and with IFRS as adopted by the European Union, as of December 31, 2008.

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

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

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

trademarks used or that may be or have been used under license by sanofi-aventis and /or its affiliates, such as Actonel<sup>®</sup>, Actonelcombi<sup>®</sup>, Optinate<sup>®</sup> and Acrel<sup>®</sup>, trademarks of Procter & Gamble Pharmaceuticals, Copaxone<sup>®</sup>, a trademark of Teva Pharmaceutical Industries, Exubera<sup>®</sup>, a trademark of Pfizer Products Inc., Mutagrip<sup>®</sup>, a trademark of Institut Pasteur, TroVax<sup>®</sup>, a trademark of Oxford BioMedica, Gardasil<sup>®</sup> and Rotateq<sup>®</sup>, trademarks of Merck & Co., Inc., Herceptin<sup>®</sup>, a trademark of Genentech, NanoCrystal<sup>®</sup>, a trademark of Elan Pharmaceuticals, Xyzal<sup>®</sup>, a trademark of UCB;

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

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

The data relative to market shares and ranking information presented in Item 4. Information on the Company B. Business Overview Markets Marketing and distribution is based on sales data from IMS Health MIDAS (IMS), retail and hospital, for calendar year 2008, in constant euros (unless otherwise indicated).

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

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

- (i) sales as published by IMS excluding sales generated by the vaccines business, equating to the scope of our pharmaceutical operations;
- (ii) adjustments to data for Germany, to reflect the significant impact of parallel imports;
- (iii) IMS sales of products sold under alliance or license agreements which we recognize in our consolidated net sales but which are not attributed to us in the reports published by IMS; and
- (iv) adjustments related to the exclusion of IMS sales for products which we do not recognize in our consolidated net sales but which are attributed to us by IMS.

## **Table of Contents**

Data relative to market shares and ranking information presented herein for our vaccines business is based on internal estimates unless stated otherwise.

Product indications described in this annual report are composite summaries of the major indications approved in the product's principal markets. Not all indications are necessarily available in each of the markets in which the products are approved. The summaries presented herein for the purpose of financial reporting do not substitute for careful consideration of the full labeling approved in each market.

### **CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS**

This annual report contains forward-looking statements. We may also make written or oral forward-looking statements in our periodic reports to the Securities and Exchange Commission on Form 6-K, in our annual report to shareholders, in our proxy statements, in our offering circulars and prospectuses, in press releases and other written materials and in oral statements made by our officers, directors or employees to third parties. Examples of such forward-looking statements include:

projections of operating revenues, net income, adjusted net income, earnings per share, adjusted earnings per share, capital expenditures, positive or negative synergies, dividends, capital structure or other financial items or ratios;

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

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

statements of assumptions underlying such statements.

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

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

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

our ability to renew our product portfolio;

the increasingly challenging regulatory environment for the pharmaceutical industry;

uncertainties over the pricing and reimbursement of pharmaceutical products;

fluctuations in currency exchange rates; and

slowdown of global economic growth.

We caution you that the foregoing list of factors is not exclusive and that other risks and uncertainties may cause actual results to differ materially from those in forward-looking statements.

Forward-looking statements speak only as of the date they are made. Other than required by law, we do not undertake any obligation to update them in light of new information or future developments.

**Table of Contents****TABLE OF CONTENTS**

<u>Part I</u>		
Item 1.	<u>Identity of Directors, Senior Management and Advisers</u>	1
Item 2.	<u>Offer Statistics and Expected Timetable</u>	1
Item 3.	<u>Key Information</u>	1
	<u>A. Selected Financial Data</u>	1
	<u>B. Capitalization and Indebtedness</u>	3
	<u>C. Reasons for Offer and Use of Proceeds</u>	3
	<u>D. Risk Factors</u>	3
Item 4.	<u>Information on the Company</u>	13
	<u>A. History and Development of the Company</u>	14
	<u>B. Business Overview</u>	15
	<u>C. Organizational Structure</u>	66
	<u>D. Property, Plant and Equipment</u>	66
Item 4A.	<u>Unresolved Staff Comments</u>	68
Item 5.	<u>Operating and Financial Review and Prospects</u>	68
Item 6.	<u>Directors, Senior Management and Employees</u>	105
	<u>A. Directors and Senior Management</u>	105
	<u>B. Compensation</u>	116
	<u>C. Board Practices</u>	124
	<u>D. Employees</u>	128
	<u>E. Share Ownership</u>	130
Item 7.	<u>Major Shareholders and Related Party Transactions</u>	134
	<u>A. Major Shareholders</u>	134
	<u>B. Related Party Transactions</u>	135
	<u>C. Interests of Experts and Counsel</u>	135
Item 8.	<u>Financial Information</u>	136
	<u>A. Consolidated Financial Statements and Other Financial Information</u>	136
	<u>B. Significant Changes</u>	137
Item 9.	<u>The Offer and Listing</u>	137
	<u>A. Offer and Listing Details</u>	137
	<u>B. Plan of Distribution</u>	138
	<u>C. Markets</u>	138
	<u>D. Selling Shareholders</u>	140
	<u>E. Dilution</u>	140
	<u>F. Expenses of the Issue</u>	140
Item 10.	<u>Additional Information</u>	141
	<u>A. Share Capital</u>	141
	<u>B. Memorandum and Articles of Association</u>	141
	<u>C. Material Contracts</u>	155
	<u>D. Exchange Controls</u>	155
	<u>E. Taxation</u>	155
	<u>F. Dividends and Paying Agents</u>	161
	<u>G. Statement by Experts</u>	161
	<u>H. Documents on Display</u>	162
	<u>I. Subsidiary Information</u>	162
Item 11.	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	162
Item 12.	<u>Description of Securities other than Equity Securities</u>	166
<u>Part II</u>		
Item 13.	<u>Defaults, Dividend Arrearages and Delinquencies</u>	167
Item 14.	<u>Material Modifications to the Rights of Security Holders</u>	167
Item 15.	<u>Controls and Procedures</u>	167
Item 16.	<u>[Reserved]</u>	167
Item 16A.	<u>Audit Committee Financial Expert</u>	167
Item 16B.	<u>Code of Ethics</u>	168



## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Item 16C.	<u>Principal Accountants Fees and Services</u>	168
Item 16D.	<u>Exemptions from the Listing Standards for Audit Committees</u>	168
Item 16E.	<u>Purchases of Equity Securities by the Issuer and Affiliated Purchasers</u>	168
Item 16F.	<u>Change in Registrant's Certifying Accountant</u>	168
Item 16G.	<u>Corporate Governance</u>	168
<u>Part III</u>		
Item 17.	<u>Financial Statements</u>	170
Item 18.	<u>Financial Statements</u>	170
Item 19.	<u>Exhibits</u>	170

**Table of Contents**

**PART I**

**Item 1. Identity of Directors, Senior Management and Advisers**

N/A

**Item 2. Offer Statistics and Expected Timetable**

N/A

**Item 3. Key Information**

*A. Selected Financial Data*

**SUMMARY SELECTED FINANCIAL DATA**

The tables below set forth selected consolidated financial data for sanofi-aventis. These financial data are derived from the sanofi-aventis consolidated financial statements. The sanofi-aventis consolidated financial statements for the years ended December 31, 2008, 2007 and 2006 are included in Item 18 of this annual report.

The consolidated financial statements of sanofi-aventis for the years ended December 31, 2008, 2007 and 2006 have been prepared in compliance with IFRS issued by the International Accounting Standards Board (IASB) and with IFRS adopted by the European Union. The term IFRS refers collectively to international accounting and financial reporting standards (IAS and IFRS) and to interpretations of the interpretations committees (SIC and IFRIC). The opening balance sheet as of the IFRS transition date (January 1, 2004) and the comparative financial statements for the year ended December 31, 2004 have been prepared in accordance with the same principles.

Sanofi-aventis reports its financial results in euros.

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

<i>( million, except per share data)</i>	<b>As of and for the year ended December 31,</b>				
	<b>2008</b>	<b>2007</b>	<b>2006</b>	<b>2005</b>	<b>2004</b>
<b>IFRS Income statement data</b>					
Net sales	27,568	28,052	28,373	27,311	14,871
Gross profit	21,480	21,636	21,902	20,947	11,294
Operating income	4,394	5,911	4,828	2,888	2,426
Net income attributable to equity holders of the Company	3,851	5,263	4,006	2,258	1,986
Earnings per share: basic ( ) <sup>(a)</sup>	2.94	3.91	2.97	1.69	2.18
Earnings per share: diluted ( ) <sup>(b)</sup>	2.94	3.89	2.95	1.68	2.17
<b>IFRS Balance sheet data</b>					
Intangible assets and goodwill	43,423	46,381	52,210	60,463	61,567
Total assets	71,987	71,914	77,763	86,945	85,557
Outstanding share capital	2,611	2,657	2,701	2,686	2,668
Equity attributable to equity holders of the Company	44,866	44,542	45,600	46,128	40,810
Long term debt	4,173	3,734	4,499	4,750	8,654
Cash dividend paid per share ( ) <sup>(c)</sup>	2.20 <sup>(d)</sup>	2.07	1.75	1.52	1.20
Cash dividend paid per share (\$) <sup>(c) (e)</sup>	3.06 <sup>(d)</sup>	3.02	2.31	1.80	1.62

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

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

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

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

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

**Table of Contents****EXCHANGE RATE INFORMATION*****Exchange rate information***

The following table sets forth, for the periods and dates indicated, certain information concerning the exchange rates for the euro from 2004 through February 2009 expressed in U.S. dollar per euro. The information concerning the U.S. dollar exchange rate is based on the noon buying rate in New York City for cable transfers in foreign currencies as certified for customs purposes by the Federal Reserve Bank of New York (the Noon Buying Rate ). We provide the exchange rates below solely for your convenience. We do not represent that euros were, could have been, or could be, converted into U.S. dollars at these rates or at any other rate. For information regarding the effect of currency fluctuations on our results of operations, see Item 5. Operating and Financial Review and Prospects.

	<b>Period- end Rate</b>	<b>Average Rate <sup>(1)</sup></b>	<b>High</b>	<b>Low</b>
	<b>(U.S. dollar per euro)</b>			
2004	1.35	1.25	1.36	1.18
2005	1.18	1.24	1.35	1.17
2006	1.32	1.27	1.33	1.19
2007	1.46	1.38	1.49	1.29
2008	1.39	1.47	1.60	1.24
Last 6 months				
2008				
September	1.41	1.43	1.47	1.39
October	1.27	1.33	1.41	1.24
November	1.27	1.27	1.3	1.25
December	1.39	1.35	1.44	1.26
2009				
January	1.28	1.32	1.39	1.28
February	1.27	1.28	1.31	1.25

<sup>(1)</sup> The average of the Noon Buying Rates on the last business day of each month during the relevant period for year average, on each business day of the month for monthly average.

***B. Capitalization and Indebtedness***

N/A

***C. Reasons for Offer and Use of Proceeds***

N/A

***D. Risk Factors***

*Important factors that could cause actual financial, business, research or operating results to differ materially from expectations are disclosed in this annual report, including without limitation the following risk factors and the factors described under Cautionary Statement Regarding Forward-Looking Statements. In addition to the risks listed below, we may be subject to other material risks that as of the date of this report are not currently known to us or that we deem immaterial at this time.*

## Table of Contents

### **Risks Relating to Legal Matters**

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

Competitors may file marketing authorization requests for generic versions of some of our products. Approval and market entry of a generic product would reduce the price that we receive for these products and/or the volume of the product that we would be able to sell, and could materially adversely affect our business, results of operations and financial condition. Our products could also be affected if a competitor's innovative drug were to become available as a generic. Additionally, a number of our products acquired through business combinations have substantial balance sheet carrying values, as disclosed at Note D.4. to our consolidated financial statements, which could be substantially impaired by the introduction of a generic competitor, with adverse effects on our financial condition and assets.

Through patent and other proprietary rights, we hold exclusivity rights for a number of our research-based products, and are involved in litigation worldwide to enforce these rights against generics and proposed generics. (See Item 8. Financial Information - A. Consolidated Financial Statements and Other Financial Information - Information on Legal or Arbitration Proceedings and Note D.22.b) to our consolidated financial statements included in this annual report at Item 18 for additional information.) However, these rights are limited in time and do not always provide effective protection for our products: competitors may successfully avoid our patents through design innovation, we may not hold sufficient evidence of infringement to bring suit, or our infringement claim may not result in a decision that our rights are valid, enforceable and infringed.

Moreover, even in cases where we do ultimately prevail in our infringement claim, legal remedies available for harm caused to us by infringing products may be inadequate to make us whole. A competitor may launch at risk before the initiation or completion of the court proceedings, and the court may decline to grant us a preliminary injunction to halt further at risk sales and remove the infringing product from the market. Additionally, while we would be entitled to obtain damages in such a case, the amount that we may ultimately be awarded and able to collect may be insufficient to compensate all harm caused to us.

Finally, our successful assertion of a given patent against one competing product is not necessarily predictive of our future success or failure in asserting the same patent or *a fortiori* the corresponding foreign patent against a second competing product because of such factors as possible differences in the formulations of the competing products, intervening developments in law or jurisprudence, local variations in the patents and differences in national patent law and legal systems.

A number of the Group's products are already subject to aggressive generic competition (in particular, in the United States where legislative initiatives to further facilitate the introduction of generic drugs or comparable biologic products through accelerated approval procedures may create further challenges) and additional products could become subject to generic competition in the future. A few particularly significant products that may face the risk of generic competition in a major market as early as 2009 are described below:

Lovenox® may face generic competition in the United States following a decision by a U.S. court (upheld on appeal in May 2008) to the effect that our patent is unenforceable. While we have petitioned the U.S. Supreme Court to hear this case, there can be no assurance that it will do so or that the U.S. Supreme Court's ruling would change the outcome of this case. While we are not aware of any Food and Drug Administration (FDA) decision to approve any of the related Abbreviated New Drug Applications (ANDAs) filed to date, there currently is no stay in effect against FDA approval.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

Ambien® CR may face generic competition in the United States following the expiration of data protection in March 2009. Several ANDAs have been filed in respect of different generic formulations of this product, but we have only filed patent infringement suits to oppose certain of these.

---

## **Table of Contents**

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

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

Product liability is a significant business risk for us, particularly in the United States where product liability claims can be particularly costly. Substantial damage awards have been made in certain jurisdictions against pharmaceutical companies based upon claims for injuries allegedly caused by the use of their products. Not all possible side effects of a drug can be anticipated based on preapproval clinical studies involving only several hundred to several thousand patients. Routine review and analysis of the continually growing body of post-marketing safety surveillance and clinical trials provide additional information—for example, potential evidence of rare, population-specific or long-term adverse reactions or of drug interactions that were not observed in preapproval clinical studies—and may cause product labeling to evolve, restriction of therapeutic indications and potentially even the suspension or withdrawal of a product. Several pharmaceutical companies have recalled or withdrawn products from the market because of actual or suspected adverse reactions to their products, and currently face significant product liability claims. We are currently defending a number of product liability claims (see Note D.22.a) to the consolidated financial statements included at Item 18 of this annual report and Item 8. Financial Information—A. Consolidated Financial Statements and Other Financial Information Information on Legal or Arbitration Proceedings), and there can be no assurance that the Group will not face additional claims in the future.

Although we continue to insure part of our product liability, product liability coverage is increasingly difficult and costly to obtain, and in the future it is possible that self-insurance may become the sole commercially reasonable means available for managing the product liability risk of our pharmaceutical and vaccines businesses. The availability of insurance capacity may also suffer from the possible effects of the global financial crisis on insurers that remain active in this market. Moreover, given the long time span required to evaluate risks that have actually materialized, the insolvency of a carrier could negatively affect our ability to achieve the practical recovery of the coverage for which we have already paid a premium.

Product liability claims, regardless of their merits or the ultimate success of the Group's defense, are costly, divert management attention and harm our reputation and demand for our products. Substantial product liability claims, if successful, could adversely affect our business, results of operations and financial condition.

### **Claims and investigations relating to marketing practices and competition law could adversely affect our business, results of operations and financial condition.**

The marketing of our products is heavily regulated, and alleged failures to comply fully with applicable regulations could subject us to substantial fines, penalties and injunctive or administrative remedies, potentially leading to the imposition of additional regulatory controls or exclusion from government reimbursement programs. Sanofi-aventis and certain of its subsidiaries are under investigation by various government entities and are defending a number of lawsuits relating to antitrust and/or pricing and marketing practices, including, for example, class action lawsuits and whistle blower litigation. See Item 8. Financial Information—A. Consolidated Financial Statements and other Financial Information Information on Legal or Arbitration Proceedings and Note D.22.c) to our consolidated financial statements included at Item 18 of this annual report.

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



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

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

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

## **Table of Contents**

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

Unfavorable outcomes in pending litigation matters or in future litigation could preclude the commercialization of products, negatively affect the profitability of existing products and subject us to substantial fines, penalties and injunctive or administrative remedies, potentially leading to the imposition of additional regulatory controls or exclusion from government reimbursement programs. Any such result could materially and adversely affect our results of operations, financial condition, or business. See Item 8. Financial Information A. Consolidated Financial Statements and other Financial Information Information on Legal or Arbitration Proceedings and Notes D.22.c) and D.22.d) to our consolidated financial statements included at Item 18 of this annual report.

In addition, changes in tax laws or in their application with respect to matters such as tax rates, transfer pricing, dividends, controlled companies or a restriction in certain forms of tax relief, could affect our effective tax rate and our future results.

## **Risks Relating to Our Business**

### **We may fail to adequately renew our product portfolio whether through our own research and development or through the making of acquisitions or strategic alliances.**

To be successful in the highly competitive pharmaceutical industry, we must commit substantial resources each year to research and development in order to develop new products to take the place of products facing expiration of patent and regulatory data exclusivity. In 2008, we spent 4,575 million on research and development, amounting to approximately 16.6% of our net sales. See Item 4. Information on the Company B. Business Overview Pharmaceutical Research & Development and Vaccines Research and Development . There can be no assurance that any of these compounds will be proven safe or effective.

The research and development process typically takes from 10 to 15 years from discovery to commercial product launch. This process is conducted in various stages, and during each stage there is a substantial risk that we will not achieve our goals and will have to abandon a product in which we have invested substantial amounts including in late stage development (Phase III). Each regulatory authority may impose its own requirements in order to grant a license to market the product, including requiring local clinical studies, and may delay or refuse to grant approval, even though a product has already been approved in another country. In addition, obtaining regulatory marketing approval is not a guarantee that the product will achieve commercial success.

The patent protection that we are able to obtain for our products may also prove unsatisfactory (whether in terms of scope of coverage or expiration dates). Our ongoing investments in new product launches and research and development for future products could therefore result in increased costs without a proportionate increase in revenues.

As a complement to its portfolio of products in development, sanofi-aventis pursues a strategy of acquisitions, in-licensing and partnerships. The implementation of this strategy depends on our ability to identify business development opportunities at a reasonable cost and under acceptable conditions of financing. Because of the active competition among pharmaceutical groups for such business development opportunities, there can be no assurance of our success in completing these transactions when such opportunities are identified.

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

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

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

## **Table of Contents**

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

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

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

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

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

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

The commercial success of our products depends in part on the conditions under which our products are reimbursed. Pressure on pricing and reimbursement is strong due to:

price controls imposed by governments in many countries;

removal of a number of drugs from government reimbursement schemes;

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

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

In addition to the pricing pressures they exert, state and private third-party payers and purchasers of pharmaceutical products may reduce volumes of sales by restricting access to formularies or otherwise discouraging physician prescriptions of our products. Changes in the pricing

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

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

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

Over the past several years, growth of the global pharmaceutical market has become increasingly tied to global economic growth. In this context, a substantial and long lasting slowdown of the global economy or major national economies such as the United States could negatively affect growth in the global pharmaceutical market and, as a result, adversely affect our business. This effect may be expected to be particularly strong in markets having significant co-pays or lacking a developed third-party payer system, as individual patients may delay or

<sup>(1)</sup> Information in this section is complementary to Note B.8.8. to our consolidated financial statements included at Item 18 of this annual report, with regards to information required by IFRS 7, and is covered by our independent registered public accounting firms' report on the consolidated financial statements.

## **Table of Contents**

decrease out-of-pocket healthcare expenditures. Such a slowdown could also reduce the sources of funding for national social security systems, leading to heightened pressure on drug prices, increased substitution of generic drugs, and the exclusion of certain products from formularies.

Additionally, to the extent the slowing economic environment may lead to financial difficulties or even the failure of major players including wholesalers, the Group could experience disruptions in the distribution of its products as well as the adverse effects described below at We are subject to the risk of non-payment by our customers.

### **We rely on third parties for the marketing of some of our products.**

We market some of our products in collaboration with other pharmaceutical companies. For example, we currently have major collaborative arrangements with Bristol-Myers Squibb (BMS) for the marketing of Plavix<sup>®</sup> and Aprovel<sup>®</sup> in the United States and several other countries, with Procter & Gamble Pharmaceuticals for the osteoporosis treatment Actonel<sup>®</sup>, with Teva for Copaxone<sup>®</sup>, and with Merck & Co., Inc. for the distribution of vaccines in Europe. See Item 4. Information on the Company B. Business Overview Markets Alliances. When we market our products through collaboration arrangements, we are subject to the risk that certain decisions, such as the establishment of budgets and promotion strategies, are subject to the control of our collaboration partners, and that deadlocks may adversely affect the activities conducted through the collaboration arrangements. For example, our alliances with BMS are subject to the operational management of BMS in some countries, including the United States. We cannot be certain that our partners will perform their obligations as expected. Further, our partners might pursue their own existing or alternative technologies or product candidates in preference to those being developed or marketed in collaboration with us.

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

Many of our products are manufactured using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. Our vaccine products in particular are subject to the risk of manufacturing stoppages or the risk of loss of inventory because of the difficulties inherent to the sterile processing of biological materials and the potential for the unavailability of adequate amounts of raw materials meeting our standards. Additionally, specific conditions must be respected both by the Group and its customers for the storage and distribution of many of our products, *e.g.*, cold storage for certain vaccines and insulin-based products. The complexity of these processes, as well as strict company and government standards for the manufacture of our products, subject us to risks. The occurrence or suspected occurrence of out-of-specification production or storage can lead to lost inventories, and in some cases product recalls, with consequential reputational damage and the risk of product liability (See Risks Relating to Legal Matters Product liability claims could adversely affect our business, results of operations and financial condition, above). The investigation and remediation of any identified problems can cause production delays, substantial expense, lost sales and the delay of new product launches.

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

Third parties supply us with a substantial portion of our raw materials, active ingredients and medical devices, which exposes us to the risk of a supply interruption in the event that our suppliers experience financial difficulties or are unable to manufacture a sufficient supply of our products meeting Group quality standards. It also increases the risk of quality issues, even at the most scrupulously selected suppliers. For example, in 2008 we recalled a limited number of batches of Lovenox<sup>®</sup> and depreciated significant unused inventory following the discovery of quality issues at a Chinese supplier of raw materials. If disruptions or quality concerns were to arise in the third-party supply of raw materials,

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

active ingredients or medical devices, this could adversely affect our ability to sell our products in the quantities demanded by the market and could damage our reputation and relationships with our customers. See also The manufacture of our products is technically complex, and supply interruptions, product recalls or inventory losses caused by unforeseen events may reduce sales, delay the launch of new products and adversely affect our operating results and financial condition, above. Even though

## **Table of Contents**

we aim to have backup sources of supply whenever possible, including by manufacturing backup supplies of our principal active ingredients at a second or third facility when practicable, we cannot be certain they will be sufficient if our principal sources become unavailable. Switching sources and manufacturing facilities may require significant time. Some raw materials essential to the manufacture of our products are not widely available from sources we consider reliable; for example, we have approved only a limited number of suppliers of heparins for use in the manufacture of Lovenox®. See Item 4. Information on the Company B. Business Overview Production and Raw Materials for a description of these outsourcing arrangements. Any of these factors could adversely affect our business, operating results or financial condition.

### **Counterfeit products could harm our business.**

The prescription drug supply has been increasingly challenged by vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the internet. Counterfeit products are frequently unsafe or ineffective, and can be potentially life-threatening. To distributors and users, counterfeits may be visually indistinguishable from the authentic version. Reports of adverse reactions to counterfeit drugs or increased levels of counterfeiting could materially affect patient confidence in the authentic product, and could harm the business of companies such as sanofi-aventis. Additionally, it is possible that adverse events caused by unsafe counterfeit products will mistakenly be attributed to the authentic product, entailing substantial reputational and financial harm to the manufacturer of the authentic product.

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

In line with industry practice, we manufacture our vaccines and many of our prescription pharmaceutical products with ingredients derived from animal or plant tissue. Most of these products cannot be made economically, if at all, with synthetic ingredients. We subject our products incorporating these ingredients to extensive tests and believe them to be safe. There have been instances in the past where the use of biologically derived ingredients by sanofi-aventis or its competitors has been alleged to be an actual or theoretical source of harm, including infection or allergic reaction, or instances where production facilities have been subject to prolonged periods of closure because of possible contamination. Such allegations have on occasion led to damage claims and increased resistance on the part of patients to such ingredients. A substantial claim of harm caused by a product incorporating biologically derived ingredients or a contamination event could lead us to incur potentially substantial costs as a result of, among other things, litigation of claims, product recalls, adoption of additional safety measures, manufacturing delays, investment in patient education, and development of synthetic substitutes for ingredients of biological origin. Such claims could also generate patient resistance, with a corresponding adverse effect on sales and results of operations.

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

We run the risk of non-payment by our customers, which consist principally of wholesalers, distributors, pharmacies, hospitals, clinics and government agencies. While we seek to manage our exposure to client credit through such measures as the establishment of client credit profiles and credit limits, obtaining guarantees and insurance, and credit risk surveillance via tracking of payment times and late payments, it is not possible to eliminate this risk which is accentuated by the current worldwide financial crisis. The United States, which is our largest market in terms of sales, poses particular client credit risk issues, because of the concentrated distribution system in which approximately 87% of our consolidated U.S. pharmaceutical sales were accounted for by just three wholesalers. We are also exposed to large wholesalers in other markets, particularly in Europe. An inability of one or more of these wholesalers to honor their debts to us could adversely affect our financial condition.



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

Our future funding obligations for our main defined-benefit pension plans depend on changes in the future performance of assets held in trust for these plans, the interest rates used to determine funding levels, actuarial

<sup>(1)</sup> Information in this section is complementary to Note B.8.8. to our consolidated financial statements included at Item 18 of this annual report, with regards to information required by IFRS 7, and is covered by our independent registered public accounting firms' report on the consolidated financial statements.

**Table of Contents**

data and experience, inflation trends, the level of benefits provided for by the plans, as well as changes in laws and regulations. Adverse changes of those factors could increase our unfunded obligations under such plans, which would require more funds to be contributed and hence negatively affect our cash flow and results.

**Environmental Risks of Our Industrial Activities**

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

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

fires and/or explosions from inflammable substances;

storage tank leaks and ruptures; and

discharges or releases of toxic or hazardous substances.

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

the shutdown of affected facilities; and

the imposition of civil or criminal penalties.

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

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

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

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

that we currently own or operate;

that we formerly owned or operated; or

where waste from our operations was disposed.

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

Furthermore, we are or may become involved in claims, lawsuits and administrative proceedings relating to environmental matters. Some current and former sanofi-aventis subsidiaries have been named as potentially responsible parties or the equivalent under the U.S. Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended (also known as Superfund), and similar statutes in France, Germany, Italy, Brazil and elsewhere. As a matter of statutory or contractual obligation, we and/or our subsidiaries may retain responsibility for environmental liabilities at some of the sites our predecessor companies, or our

## **Table of Contents**

subsidiaries that we demerged, divested or may divest. We have disputes outstanding, for example, with Rhodia over environmental remediation at several sites no longer owned by the Group. An adverse outcome in such disputes might have a significant adverse effect on our operating results. See Note D.22.e) to the consolidated financial statements included at Item 18 of this annual report.

Finally, stricter environmental, safety and health laws and enforcement policies could result in substantial costs and liabilities to our Group and could subject our handling, manufacture, use, reuse or disposal of substances or pollutants to more rigorous scrutiny than is currently the case. Consequently, compliance with these laws could result in significant capital expenditures as well as other costs and liabilities, thereby adversely affecting our business, results of operations or financial condition.

## **Risks Related to Financial Markets<sup>(1)</sup>**

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

Because we sell our products in numerous countries, our results of operations and financial condition could be adversely affected by fluctuations in currency exchange rates. We are particularly sensitive to movements in exchange rates between the euro and the U.S. dollar, the British pound, the Japanese yen, and to currencies in emerging countries. In 2008, approximately 31% of our net sales were realized in the United States. While we incur expenses in those currencies, the impact of currency exchange rates on these expenses does not fully offset the impact of currency exchange rates on our revenues. As a result, currency exchange rate movements can have a considerable impact on our earnings. When deemed appropriate and when technically feasible, we enter into transactions to hedge our exposure to foreign exchange risks. These efforts, when undertaken, may fail to offset the effect of adverse currency exchange rate fluctuations on our results of operations or financial condition. For more information concerning our exchange rate exposure, see Item 11. Quantitative and Qualitative Disclosures about Market Risk.

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

As of December 31, 2008, the Group's net debt amounted to 1.8 billion. In addition to debt outstanding, the Group has contracted a number of credit lines and put into place commercial paper and medium term note programs with the aim of providing liquidity. See Item 11. Quantitative and Qualitative Disclosures about Market Risk. In the context of a market-wide liquidity crisis, the Group may be faced with reduced access to sources of financing, including under programs currently in place, or less favorable conditions. Were our sources of financing to be substantially reduced, we cannot guarantee that the Group would be in a position to refinance existing debt or incur new debt on terms that we would consider to be commercially reasonable if at all.

## **Risks Relating to an Investment in our Shares or ADSs**

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

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

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

- <sup>(1)</sup> Information in this section is complementary to Note B.8.8. to our consolidated financial statements included at Item 18 of this annual report with regard to information required by IFRS 7, and is covered by our independent registered public accounting firms' report on the consolidated financial statements.

**Table of Contents**

**Persons holding ADSs rather than shares may have difficulty exercising certain rights as a shareholder.**

Holders of ADSs may have more difficulty exercising their rights as a shareholder than if they directly held shares. For example, if we offer new shares and they have the right to subscribe for a portion of them, the depositary is allowed, at its own discretion, to sell for their benefit that right to subscribe for new shares instead of making it available to them. Also, to exercise their voting rights, as holders of ADSs, they must instruct the depositary how to vote their shares. Because of this extra procedural step involving the depositary, the process for exercising voting rights will take longer for holders of ADSs than for holders of shares. ADSs for which the depositary does not receive timely voting instructions will not be voted at any meeting.

**Our two largest shareholders own a significant percentage of the share capital and voting rights of sanofi-aventis.**

At December 31, 2008, Total and L. Oréal, our two largest shareholders, held approximately 11.29% and 8.99% of our issued share capital, respectively, accounting for approximately 18.27% and approximately 14.89%, respectively, of the voting rights (excluding treasury shares) of sanofi-aventis. See Item 7. Major Shareholders and Related Party Transactions A. Major Shareholders. Affiliates of each of these shareholders are currently serving on our Board of Directors. To the extent these shareholders continue to hold a large percentage of our share capital and voting rights, Total and L. Oréal will remain in a position to exert heightened influence in the election of the directors and officers of sanofi-aventis and in other corporate actions that require shareholders' approval.

**Sales of our shares may cause the market price of our shares or ADSs to decline.**

Neither Total nor L. Oréal is, to our knowledge, subject to any contractual restrictions on the sale of the shares each holds in our Company. Both of these shareholders have announced their intent to sell all or part of their stakes in our company, and have recently liquidated part of their respective holdings. Sales of a substantial number of our shares, or a perception that such sales may occur, could adversely affect the market price for our shares and ADSs.

## **Table of Contents**

### **Item 4. Information on the Company**

#### **Introduction**

We are a global pharmaceutical group engaged in the research, development, manufacture and marketing of healthcare products. In 2008, our net sales amounted to 27,568 million. Based on 2008 sales, we are the fourth largest pharmaceutical group in the world and the largest pharmaceutical group in Europe (source: IMS sales year end 2008; all available channels). Sanofi-aventis is the parent of a consolidated group of companies. A list of the principal subsidiaries included in this consolidation is shown at Note F. to our consolidated financial statements included at Item 18 of this annual report.

Our business includes two main activities: (i) pharmaceuticals and (ii) human vaccines through sanofi pasteur.

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

*Thrombosis:* Our thrombosis medicines include two leading drugs in their categories: Plavix<sup>®</sup>, an anti-platelet agent indicated for a number of atherothrombotic conditions, and Lovenox<sup>®</sup>, a low molecular weight heparin indicated for prophylaxis and treatment of deep vein thrombosis and for unstable angina and myocardial infarction;

*Cardiovascular:* Our cardiovascular medicines include two major hypertension treatments: Aprovel<sup>®</sup> and Tritace<sup>®</sup>;

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

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

*Central Nervous System (CNS):* Our major CNS medicines include Stilnox<sup>®</sup>/Ambien<sup>®</sup> CR, the world's leading insomnia prescription medication; Copaxone<sup>®</sup>, an immunomodulating agent indicated in multiple sclerosis; and Depakine<sup>®</sup>, a leading epilepsy treatment; and

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

The global portfolio of sanofi-aventis also comprises a wide range of other pharmaceutical products, including prescription drugs and products sold over the counter (OTC), making up our base business.

We are the world leader in the vaccines industry. Our net sales amounted to 2,861 million in 2008, with leading vaccines in five areas:

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

Influenza vaccines such as Fluzone<sup>®</sup> and Vaxigrip<sup>®</sup>, used for seasonal campaigns, the latter in both hemispheres. Additionally, we manufacture pre-pandemic avian influenza vaccines (including H5N1 vaccines) as part of the global pandemic preparedness efforts in both our French and U.S. facilities;



---

## **Table of Contents**

Adult and adolescent booster vaccines protecting against pertussis, tetanus, diphtheria and polio. Our main products include: Adacel<sup>®</sup> (the first trivalent booster against pertussis, tetanus and diphtheria for adolescents and adults, launched in the United States in 2005), Decavac<sup>®</sup>, Repevax<sup>®</sup> and Revaxis<sup>®</sup>;

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

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

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

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

In the description below, the following should be kept in mind:

A drug can be referred to either by its international non-proprietary name (INN), or by its brand name, which is normally exclusive to the company that markets it. In most cases, our brand names, which may vary from country to country, are protected by trademark registrations. In general, we have chosen in this annual report to refer to our products by the brand names that we use in France, except for Allegra<sup>®</sup> (sold in France as Telfast<sup>®</sup>), Tritace<sup>®</sup> (sold in France as Triatec<sup>®</sup>), and Amaryl<sup>®</sup> (sold in France as Amarel<sup>®</sup>) as well as Ambien<sup>®</sup> CR (an extended-release formulation of zolpidem tartrate, not sold in France);

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

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

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

### ***A. History and Development of the Company***

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

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

We are present in more than 100 countries on five continents with more than 98,000 employees worldwide at year end 2008. Our legacy companies, Sanofi-Synthélabo (formed by a merger between Sanofi and Synthélabo in 1999) and Aventis (formed by the combination of Rhône-Poulenc and Hoechst also in 1999), bring to the Group more than a century of experience in the pharmaceutical industry.

Sanofi was founded in 1973 by Elf Aquitaine, a French oil company, when it took control of the Labaz group, a pharmaceutical company. Its first significant venture into the United States market was the acquisition of the prescription pharmaceuticals business of Sterling Winthrop – an affiliate of Eastman Kodak – in 1994.

Synthélabo was founded in 1970 through the merger of two French pharmaceutical laboratories, Laboratoires Dausse (founded in 1834) and Laboratoires Robert & Carrière (founded in 1899). In 1973, the French cosmetics group L'Oréal acquired the majority of its share capital.

## **Table of Contents**

Hoechst traces its origins to the second half of the 19th century, with the German industrial revolution and the emergence of the chemical industry. Traditionally active in pharmaceuticals, Hoechst strengthened its position in that industry by taking a controlling interest in Roussel-Uclaf in 1974 and the U.S. pharmaceutical company Marion Merrell in 1995.

Rhône-Poulenc was formed in 1928 from the merger of two French companies: a chemical company created by the Poulenc brothers and the Société Chimique des Usines du Rhône, which was founded in 1895. The company's activities in the first half of the 20th century focused on producing chemicals, textiles and pharmaceuticals. Rhône-Poulenc began to focus its activities on life sciences in the 1990s, which led to the successive purchases of Rorer, a U.S. pharmaceutical company acquired in two stages in 1990 and 1997, Pasteur Mérieux Connaught in the area of vaccines in 1994 and the U.K.-based pharmaceuticals company Fisons in 1995.

Sanofi-Synthelabo took control of Aventis in August 2004 and changed its registered name to sanofi-aventis. On December 31, 2004, Aventis merged with and into sanofi-aventis, with sanofi-aventis as the surviving company.

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

### **Strategy**

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

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

### **Increasing innovation in Research & Development**

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

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

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

## **Table of Contents**

### **Exploring external growth opportunities**

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

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

### **Pharmaceutical Products**

#### **Main Pharmaceutical Products**

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

The following table sets forth the net sales of our best selling pharmaceutical products for the year ended December 31, 2008. These products are major contributors to public health. The sections that follow provide additional information on the indications and market position of these products in their principal markets. The Group's intellectual property relating to our products is material to our operations and is described at Patents, Intellectual Property and Other Rights Product Overview, below. As disclosed in Note D.22.b) to our consolidated financial statements included at Item 18 of this annual report, we are involved in significant litigation concerning the patent protection of a number of these products.

**Table of Contents**

<b>Therapeutic Area / Product Name</b>	<b>2008 Net Sales ( million)</b>	<b>Drug Category / Main Areas of Use</b>
<b>Thrombosis</b>		
Lovenox® (enoxaparin sodium)	2,738	Low molecular weight heparin Deep vein thrombosis
Plavix® (clopidogrel bisulfate)	2,616	Unstable angina / non-Q-Wave myocardial infarction Platelet adenosine disphosphate receptor antagonist Atherothrombosis
		Acute coronary syndrome with and without ST segment elevation
<b>Cardiovascular</b>		
Aprovel® (irbesartan)/CoAprovel®	1,202	Angiotensin II receptor antagonist Hypertension
Tritace® (ramipril)	513	Angiotensin Converting Enzyme Inhibitor Hypertension
		Congestive heart failure
		Nephropathy
<b>Metabolic disorders</b>		
Lantus® (insulin glargine)	2,450	Long-acting analog insulin Type 1 and 2 diabetes mellitus
Amaryl® (glimepiride)	387	Sulfonylurea Type 2 diabetes mellitus
<b>Oncology</b>		
Taxotere® (docetaxel)	2,033	Cytotoxic agent Breast cancer
		Non small cell lung cancer
		Prostate cancer
		Gastric cancer
		Head and Neck cancer
Eloxatine® (oxaliplatin)	1,348	Cytotoxic agent Colorectal cancer
<b>Central Nervous System</b>		
Stilnox®/Ambien®/Myslee® (zolpidem tartrate)	829	Hypnotic Sleep disorders
<i>includes Ambien® CR</i>	475	
Copaxone® (glatiramer acetate)	622	Non-interferon immunomodulating agent Multiple sclerosis
Depakine® (sodium valproate)	329	Anti-epileptic Epilepsy
<b>Internal Medicine</b>		
<i>Respiratory/Allergy</i>		
Allegra® (fexofenadine hydrochloride)	688	Antihistamine Allergic rhinitis
		Urticaria

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

***Thrombosis***

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

**Lovenox®/Clexane®**

Lovenox® (enoxaparin sodium) is the most widely studied and used low molecular weight heparin (LMWH) in the world. It has been used to treat an estimated 200 million patients in 100 countries since its launch and is



## **Table of Contents**

approved for more clinical indications than any other LMWH. A comprehensive dossier of clinical studies has demonstrated the benefits and safety of Lovenox® in the prophylaxis and treatment of deep vein thrombosis (DVT) and in acute coronary syndromes (ACS). It has become the product of reference in clinical trials for the development of new anticoagulants in both venous and arterial indications.

In the field of venous thromboembolism (VTE) prevention, Lovenox® use continues to grow especially for prevention of VTE in medical patients.

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

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

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

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

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

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

**Plavix® / Iscover®**

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Plavix® (clopidogrel bisulfate), a platelet adenosine diphosphate (ADP) receptor antagonist with a rapid onset of action that selectively inhibits platelet aggregation induced by ADP, is indicated for long-term prevention of atherothrombotic events in patients with a history of recent myocardial infarction, recent ischemic stroke or established peripheral arterial disease. Plavix® is currently the only drug indicated for the secondary prevention of atherothrombosis regardless of the location of the arteries initially affected (heart, brain, lower limbs). This indication is supported by the results of the landmark CAPRIE trial, including almost 20,000 patients. CAPRIE demonstrated the superior efficacy of Plavix® over acetylsalicylic acid (ASA, the active ingredient of Aspirin®), with a comparable safety profile.

Following the significant results of the CURE, CLARITY and COMMIT clinical trials, Plavix® is now also indicated for the treatment of acute coronary syndrome with and without ST segment elevation (ACS; Q-wave and non-Q-wave myocardial infarction and unstable angina) in combination with ASA. These indications are incorporated into the guidelines of the American Heart Association, the American College of Cardiology and the European Society of Cardiology.

## **Table of Contents**

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

The extensive clinical program for Plavix® including all completed, ongoing and planned studies, is one of the largest of its kind and has involved more than 100,000 patients overall. In addition, over 92 million patients worldwide are estimated to have been treated with Plavix® since its launch, providing significant evidence of real-life efficacy and safety experience with this product.

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

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

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

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

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

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

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

## ***Cardiovascular***

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Within the cardiovascular market, hypertension remains the most prevalent disease. Hypertension is defined as blood pressure above the normal level and is one of the main causes of severe heart, brain, blood vessel and eye complications. Our principal products for the treatment of cardiovascular diseases are:

### **Aprovel®/Avapro®/Karvea®**

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

## **Table of Contents**

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<sup>®</sup> and CoAprovel<sup>®</sup> tablets are available in various dosages, to fit the needs of patients with different levels of hypertension severity.

Aprovel<sup>®</sup> is indicated as a first-line treatment for hypertension and for the treatment of nephropathy in hypertensive patients with type 2 diabetes, in both Europe and the United States. CoAprovel<sup>®</sup> may be used in appropriate patients whose blood pressure is not adequately controlled on monotherapy, and as initial therapy in appropriate patients who are likely to need multiple drugs to achieve their blood pressure goals (in the United States only).

Several clinical trials have been undertaken in recent years in an effort to demonstrate the effects of Aprovel<sup>®</sup> beyond blood pressure control:

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

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

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

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

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

## **Tritace<sup>®</sup>/Triatec<sup>®</sup>/Delix<sup>®</sup>/Altace<sup>®</sup>**

Tritace<sup>®</sup> (ramipril) is an angiotensin converting enzyme (ACE) inhibitor indicated for the treatment of hypertension, congestive heart failure following or in the absence of acute myocardial infarction and nephropathy.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

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

## **Table of Contents**

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

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

## ***Metabolic Disorders***

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

## **Lantus®**

Lantus® (insulin glargine) is a long-acting basal insulin analog, offering improved pharmacokinetic and pharmacodynamic profiles compared to other basal insulins. Lantus® is indicated for once-daily subcutaneous administration in the treatment of adult patients with type 2 diabetes mellitus (T2DM), who require basal insulin for the control of hyperglycemia, and for adult and pediatric patients aged six years and above with type 1 diabetes mellitus (T1DM).

Lantus® can be administered subcutaneously thanks to syringes or specific pens including Lantus® SoloSTAR®. Lantus® SoloSTAR® is a pre-filled disposable pen available in over 50 countries worldwide. It is the only disposable pen that combines the following advantages; a low injection force, up to 80 units per injection and ease-of-use. In 2007, it was awarded a GOOD DESIGN Award by the Chicago Athenaeum Museum of Architecture and Design.

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

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

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

In 2008, the American Diabetes Association (ADA) and European Association for the Study of Diabetes (EASD) released the updated treatment recommendations for type 2 diabetes. Designed by a team of diabetes experts, the updated recommendations provide healthcare professionals with a consensus algorithm that further establishes basal insulins such as Lantus<sup>®</sup>, or a sulfonylurea such as Amaryl<sup>®</sup>, as two preferred second-line treatment options for people with diabetes who are unable to achieve glycemic control targets with lifestyle intervention and metformin alone. These new treatment recommendations reinforce the timely use of basal insulin as a Core Therapy for type 2 Diabetes.



---

**Table of Contents**

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

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

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

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

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

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

The GINGER study demonstrated the superiority of a basal bolus regimen with Lantus® and Apidra® to a premixed insulin regimen in terms of blood glucose control with no excess in hypoglycaemia rate in a population of advanced type 2 diabetes patients.

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

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

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

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

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

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

Lantus® is available in over 70 countries worldwide.

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

**Amaryl®/Amarel®/Solosa®**

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

## **Table of Contents**

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

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

The combination of metformin (which reduces hepatic glucose production and improves insulin resistance) with a sulfonylurea (which stimulates insulin secretion) is the rational combination for counteracting the two defects seen in type 2 diabetes. It is the most prescribed combination of diabetes drugs worldwide. Amaryl M<sup>®</sup>, a fixed-dose combination of glimepiride plus metformin in a single presentation was launched in 2007. The fixed dose treatment is more efficacious than either agent alone in patients with type 2 diabetes and has equal efficacy and better compliance than the free combination of glimepiride and metformin. In 2008, Amaryl M<sup>®</sup> was launched in India, Mexico and Brazil among other countries.

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

## **Acomplia<sup>®</sup>**

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

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

## ***Oncology***

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

## **Taxotere<sup>®</sup>**

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

Taxotere® is available in more than 100 countries as an injectable solution. It has gained approval for use in eleven indications in five different tumor types—breast, prostate, gastric, lung and head and neck. Taxotere® is indicated for early stage and metastatic breast cancer, first-line and second-line metastatic non-small cell lung cancer (NSCLC), androgen-independent (hormone-refractory) metastatic prostate cancer, advanced gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction and for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck.

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

## **Table of Contents**

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

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

The GEICAM 9805 trial, including 1,100 patients with node negative early stage breast cancer, demonstrated a significant survival benefit in favor of the Taxotere® regimen compared to a fluorouracil-based regimen. Efficacy results were presented during the 44th annual meeting of the American Society of Clinical Oncology (ASCO). Those new data will be part of the EMEA and FDA dossier planned to be filed in the first quarter of 2009 for a new indication of Taxotere® in association with doxorubicin and cyclophosphamide for the treatment of patients with node negative early stage breast cancer.

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

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

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

## **Eloxatine®**

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

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

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

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

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

## **Table of Contents**

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

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

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

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

### ***Central Nervous System***

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

#### **Stilnox®/Ambien®/Myslee®**

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

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

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

Stilnox® is marketed in over 100 countries. It was launched in Japan under the brand name Myslee® in December 2000 and became the leading hypnotic on the market within three years of its launch. Myslee® has been copromoted jointly with Astellas since 2006. We launched Ambien® CR in the United States in September 2005.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

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

### **Copaxone®**

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

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



## **Table of Contents**

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

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

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

## **Depakine<sup>®</sup>**

Depakine<sup>®</sup> (sodium valproate) is a broad-spectrum anti-epileptic that has been prescribed for more than 40 years. Numerous clinical trials, as well as long years of experience have shown that it is effective for all types of epileptic seizures and epileptic syndromes, and is generally well tolerated. Consequently, Depakine<sup>®</sup> remains a reference treatment for epilepsy worldwide.

Depakine<sup>®</sup> is also a mood stabilizer, registered in the treatment of manic episodes associated with bipolar disorder and in numerous countries in the prevention of mood episodes. Valproate is recommended as a first-line treatment in these indications by international guidelines such as the guidelines of the American Psychiatric Association, the Canadian Network for Mood and Anxiety Treatments and the U.K. NICE Guidance.

We provide a wide range of formulations of Depakine<sup>®</sup> which permits its adaptation to most types of patients: syrup, oral solution, injection, enteric-coated tablets, Chrono<sup>®</sup> (a sustained release formulation in tablets) and Chronosphere<sup>®</sup> (sustained release formulation of Depakine<sup>®</sup> packaged in stick packs, facilitating its use by children, the elderly and adults with difficulties swallowing).

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

The top three markets for Depakine<sup>®</sup> are the United Kingdom, France and Italy (based on 2008 net sales).

## ***Internal Medicine***

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

### **Respiratory/Allergy**

#### **Allegra®/Telfast®**

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

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

## **Table of Contents**

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

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

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

## **Nasacort®**

Nasacort®AQ Spray (NAQ) (triamcinolone acetonide) is an unscented, water-based metered-dose pump spray formulation unit containing a microcrystalline suspension of triamcinolone acetonide in an aqueous medium. First launched in 1996, NAQ is an intranasal corticosteroid, which is recommended in treatment guidelines as first-line treatment for moderate to severe allergic rhinitis patients. NAQ offers significant relief from nasal allergy symptoms to patients, with no scent, alcohol or taste.

Previously indicated for the treatment of the nasal symptoms of seasonal and perennial allergic rhinitis in adults and children six years of age and older, Nasacort®AQ received an additional approval for the seasonal and annual treatment of pediatric patients between the ages of 2 and 5 years from the FDA in September 2008.

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

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

## **Urology**

### **Xatral®/Uroxatral®**

Xatral® (alfuzosin) belongs to the class of alpha1-blockers. Capable of acting selectively on the lower urinary tract, it was the first alpha1-blocker indicated and marketed exclusively for the treatment of symptoms of benign prostatic hyperplasia (BPH). It is also the unique alpha1-blocker indicated as an adjunctive therapy with catheterization for acute urinary retention (AUR), a painful and distressing complication of BPH. Since 2003, Xatral® has obtained authorizations of this extension of the indication in 56 countries worldwide including 16 European countries.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Xatral® OD (extended release formulation) is active from the first dose, provides a rapid and lasting symptom relief and improves patient quality of life.

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

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

Lastly, Xatral® is the only alpha1-blocker showing no deleterious effect on ejaculation, as shown by the final results of the international ALF-LIFE trial.

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

## **Table of Contents**

The once-daily formulation of Xatral<sup>®</sup> (branded Uroxatral<sup>®</sup> in the United States) has been registered in over 90 countries and is marketed worldwide, with the exception of Australia and Japan.

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

## **Osteoporosis**

### **Actonel<sup>®</sup>/Optinate<sup>®</sup>/Acrel<sup>®</sup>**

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

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

Actonel<sup>®</sup> is available in various formulations (tablets and sachets) and dosages to better fit patients' needs:

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

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

Actonel<sup>®</sup> 30 mg is approved for the treatment of Paget's disease, a rare bone disorder.

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

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

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

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

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

### Other Pharmaceutical Products

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

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

**Table of Contents**

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

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

**Vaccines Products**

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

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

In Europe, our vaccine products are marketed by Sanofi Pasteur MSD, a joint venture held equally by sanofi pasteur and Merck & Co., which serves 19 countries. Sanofi Pasteur MSD is the market leader in Europe overall and in particular in France. In 2008, net sales of Sanofi Pasteur MSD, which are accounted for using the equity method, amounted to 1,272 million.

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

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

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

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Travel and Endemic Vaccines	309
Other Vaccines	177
<b>Total Human Vaccines</b>	<b>2,861</b>

—  
\* Seasonal and pandemic influenza vaccines.

### **Pediatric Combination and Poliomyelitis (polio) Vaccines**

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

Daptacel<sup>®</sup>, a trivalent vaccine against pertussis, diphtheria and tetanus, was launched in the United States in 2002 and has become a strong sales contributor due to its adaptation to immunization schedules. In 2008, the



## **Table of Contents**

FDA licensed Daptacel<sup>®</sup> vaccine for the fifth consecutive dose in the pediatric DTaP immunization series. Daptacel<sup>®</sup> is now licensed in the United States for the entire immunization series to protect against diphtheria, tetanus, and pertussis, enabling health care professionals to administer the same brand of DTaP vaccines.

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

Pentacel<sup>®</sup>, which is a vaccine protecting against five diseases (pertussis, diphtheria, tetanus, polio and *Haemophilus influenzae* type b), launched in the United States in 2008, is approved in ten countries and has been the standard for preventive care in Canada since its launch in 1997.

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

Sanofi Pasteur is one of the world's leading developers and manufacturers of polio vaccines, both in oral (OPV) and enhanced injectable (eIPV). We expect the use of eIPV to gradually increase given that the global eradication of polio is within reach, with only four countries in the world remaining polio-endemic. As a result, sanofi pasteur is expanding its production capacity to meet this growing demand. The worldwide polio eradication initiative of the World Health Organization (WHO) and UNICEF has positioned sanofi pasteur as a global preferred partner with both OPV and eIPV vaccines. In 2005, sanofi pasteur developed the first new polio vaccine in nearly 30 years for use in eradication, Oral Monovalent Polio Vaccine-type 1. This product is still being used as part of the WHO strategy to end polio transmission in endemic countries. In 2007, Pentaxim<sup>®</sup>, an acellular-based pentavalent vaccine containing eIPV, was launched in the international region, including Mexico and Turkey. Mexico is the first Latin American country to integrate eIPV in its pediatric immunization schedule. In 2008, eIPV was launched in Russia following the decision by the Russian authorities to choose the inactivated polio vaccine from sanofi pasteur for primary immunization of all infants. eIPV is the vaccine of choice for post-eradication polio immunization programs in the Russian federation.

## **Influenza vaccines**

Sanofi Pasteur is the world leader in the production and marketing of influenza vaccines. Sales of the influenza vaccines Fluzone<sup>®</sup> and Vaxigrip<sup>®</sup>/Mutagrip<sup>®</sup> have more than tripled since 1995 and annual production reached more than 170 million doses in 2008 to better meet increasing demand. We expect the global demand for influenza vaccines to continue to grow within the next decade, due to an increased disease awareness and wider government immunization recommendations. Given the awareness of a potential influenza pandemic amongst health authorities, medical professionals and the public at large, the demand for influenza vaccines has increased in general.

In recent years, influenza vaccine demand has experienced strong growth in many other countries, particularly in China, South Korea and Mexico. This trend is expected to continue over the coming years. Sanofi Pasteur will remain focused on maintaining its leadership in the influenza market and on meeting the increased demand. In November 2007, sanofi pasteur signed an agreement with the Chinese authorities for a project to build an influenza vaccine facility in Shenzhen (Guangdong Province) with the goal of producing influenza vaccines for the Chinese market by 2012. The foundation stone of this new facility was laid in October 2008. In November 2008, sanofi pasteur signed an agreement with Birmex and the Mexican Health Authorities for a project to build a new influenza vaccine facility in Ocoyoacac. The building of the plant is planned to start in 2009.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

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

## **Table of Contents**

On February 26, 2009 the European Commission granted marketing authorization for sanofi pasteur's INTANZA®/IDflu®, the first intradermal (ID) microinjection influenza vaccine. The advantages of this vaccine, in particular the convenience and the ease of administration, should help improve the coverage rate in Europe. This new vaccine for seasonal influenza will be marketed as Intanza® or IDflu®. Intanza®/IDflu® vaccine is now approved in the European Union territory for the prevention of seasonal influenza in both the adult (aged 18 and over) and elderly (aged 60 and over) populations.

### **Adult and Adolescent Boosters**

The incidence of pertussis (whooping cough) is on the rise globally, affecting children, adolescents and adults. Its resurgence, combined with an increased awareness of the dangers of vaccine-preventable diseases in general, has led to higher sales of this product group in recent years. Adacel®, the first trivalent adolescent and adult booster against diphtheria, tetanus and pertussis, was licensed and launched in the United States in 2005. Adacel® has been the standard of care in Canada since 2004, where most provinces provide routine adolescent immunization. This product plays an important role in efforts to better control pertussis, not only by preventing the disease in adolescents and adults but also by breaking the cycle of transmission to infants too young to be immunized or only partially vaccinated.

### **Meningitis and pneumonia vaccines**

Sanofi Pasteur is at the forefront of developing vaccines to prevent meningitis and introduced the first conjugate quadrivalent vaccine against meningococcal meningitis, arguably the deadliest form of meningitis in the world. In 2008, sales of Menactra® continued to grow in the United States following the implementation of the recommendations of the Advisory Committee on Immunization Practices (ACIP) for routine vaccination of pre-adolescents (11-12 years old), adolescents at high school entry (15 years old) and college freshmen living in dormitories. In October 2007, FDA granted sanofi pasteur licensure to expand the indication of Menactra® to children 2 years through 10 years of age. Menactra® is now indicated for people aged 2-55 years in the United States as well as in Canada. Additional submissions are expected during the coming years in various parts of the world. Use of meningococcal meningitis vaccines is expected to grow significantly through anticipated future use in multiple segments of the population.

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

### **Travel and Endemic Vaccines**

Sanofi Pasteur's Travel/Endemic vaccines provide the widest range of traveler vaccines in the industry, and include hepatitis A, typhoid, rabies, yellow fever, cholera, measles, mumps, rubella (MMR) and antivenoms. These vaccines are used in endemic settings in the developing world and are the basis for important partnerships with governments and organizations such as UNICEF. These vaccines are also used by military and travelers to endemic areas. As the global market leader in the majority of these vaccine markets, sanofi pasteur's Travel/Endemic activity has exhibited stable growth.

### **Other vaccines**

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

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

### **Pharmaceutical Research & Development**

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

## **Table of Contents**

### ***Global and focused organizations: Discovery and Development***

#### **Discovery Research**

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

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

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

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

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

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

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

#### **Opening our organization to the outside world**

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

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

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

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

### **New operating models**

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

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

## **Table of Contents**

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

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

## **Development**

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

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

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

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

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

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

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

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

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

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



**Table of Contents****Portfolio**

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

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

**R&D portfolio**

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

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

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

Sanofi-aventis is gearing up to:

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

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

## Table of Contents

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

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

### **Sanofi-Aventis Research and Development Achievements in 2008**

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

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

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

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

Two NDAs for new chemical entities were submitted in the United States and in Europe: Multaq® (dronedarone), an antiarrhythmic drug in atrial fibrillation, and Ciltyri® (eplivanserin), a 5-HT<sub>2A</sub> antagonist in insomnia.

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

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

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

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

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

The following programs were halted in 2008:

Cardiovascular: **Ilepatril** (AVE7688, vasopeptidase inhibitor, uncontrolled or resistant hypertension, chronic kidney disease stage 3; Phase IIB). Development was stopped based on an unfavorable expected benefit/risk ratio as compared to current and potential future therapies. **SL65.0472** (5-HT<sub>1B</sub>/5-HT<sub>2A</sub> antagonist, peripheral artery disease; Phase IIB). Development was stopped following results of the MASCOT Phase IIB study which showed no significant difference of the investigational drug compared to placebo and cilostazol.

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

**Table of Contents**

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

CNS: **Amibegron** (SR58611, beta-3 agonist; Phase III) in Major Depressive Disorders (MDD) in monotherapy and in combination with SSRI and **SSR149415** (V1b antagonist; Phase IIB) in MDD and General Anxiety Disorders (GAD) were discontinued due to an unfavorable product profile. **Surinabant** (SR147778, CB-1 receptor antagonist) was discontinued after a Phase IIB study in smoking cessation did not achieve statistically significant results. **Volinanserin** (M100907, 5-HT<sub>2A</sub> antagonist, insomnia Phase III) developed in sleep maintenance insomnia, was stopped after the results of the Phase III study for insufficient efficacy.

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

*Project Highlights*

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

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

**Thrombosis**

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

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

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

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

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

**Table of Contents**

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

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

**Cardiovascular**

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

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

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

**XRP0038** (NV1FGF, non-viral fibroblast growth factor 1, critical limb ischemia; Phase III). XRP0038 is an injectable non-viral DNA plasmid and gene therapy-based approach for the promotion of angiogenesis in patients with peripheral arterial disease that statistically significantly prolonged time to amputation as compared to placebo in a Phase IIb study in patients with critical limb ischemia. A Phase III program (TAMARIS study) is currently ongoing. The primary objective is to demonstrate the safety and effectiveness of XRP0038 in the prevention of major amputations in critical limb ischemia patients. Submission is planned for end of 2010.

**Metabolic Disorders**

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

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



**Table of Contents**

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

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

**Oncology**

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

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

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

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

**Alvocidib** (flavopiridol, HMR1275, cyclin-dependent kinase inhibitor, chronic lymphocytic leukaemia (CLL); Phase III). Alvocidib is being developed in collaboration with Ohio State University and the U.S. National Cancer Institute. A pivotal clinical Phase II/III program to support accelerated/conditional approval in refractory CLL patients is on going in Europe and the United States. Additional studies will be exploring the potential benefit of alvocidib in various other hematological malignancies.

**Aflibercept** (VEGF Trap, AVE0005, anti-angiogenesis agent; solid tumors; Phase III). VEGF (Vascular Endothelial Growth Factor) Trap is being developed under an alliance with Regeneron Pharmaceuticals. VEGF Trap is a novel anti-angiogenesis agent that acts as a decoy receptor or Trap for circulating VEGF. Four Phase III studies in combination with chemotherapy in patients with several solid tumors are ongoing in the following indications: in first line advanced prostate cancer (with Taxotere<sup>®</sup>/prednisone), in second line non-small cell lung cancer (with Taxotere<sup>®</sup>), in second line metastatic colorectal cancer (with FOLFIRI) and in first line metastatic pancreas cancer (with gemcitabine). Additional exploratory studies in earlier stage disease or other indications are being conducted either by sanofi-aventis and Regeneron or in collaboration with the U.S. National Cancer Institute. Registration in refractory ovarian cancer as single agent was cancelled as the results, although demonstrating biological activity, are unlikely to meet regulatory requirements.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

---

**Table of Contents**

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

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

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

**Central Nervous System**

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

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

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

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

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

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



## **Table of Contents**

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

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

## **Internal Medicine**

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

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

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

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

## ***Principal Partnerships***

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

## **Discovery Research**

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

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

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

- **Critical Path Institute** (Tucson, Arizona, United States): sanofi-aventis is a member of the Predictive Safety Testing Consortium (PSTC), which aims at identifying and developing methods for testing drug safety.
- **Dyax Corp.** (Cambridge, Massachusetts, United States): see sanofi-aventis Research and Development Achievements in 2008 above.
- **dScreen Consortium**: founded with the assistance of the Alsace Biovalley cluster (France), sanofi-aventis launched in September 2008 a research initiative conducted with Raindance Technologies (Lexington, Massachusetts, United States) and Louis Pasteur University (Strasbourg, France) to develop the new generation of High-Throughput Screening (HTS) for drug discovery applications.

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

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

## Table of Contents

- **Regeneron Pharmaceuticals, Inc.** (Tarrytown, New York, United States): very active, global, strategic collaboration agreement (signed in 2007) to discover, develop, and commercialize fully-human therapeutic antibodies. In 2008, two antibodies entered into preclinical development (see also *Discovery Research* ).
- **Institute of Hematology and Blood Diseases Hospital, Chinese Academy of Medical Sciences** (Tianjin, China): the purpose of the agreement is the isolation of acute myeloid leukemia stem cells and the generation of monoclonal antibodies against these cells with the aim to capitalize on the increasing evidence of the role of cancer-stem cells. Such antibodies would serve as valuable vectors to study these rare cells and may become the basis for new therapeutic strategies.
- **Coley** (Wellesley, Massachusetts, United States): global license and collaboration agreement on research into CpG (Cytosine phosphodiester Guanine) oligonucleotides, which act as immunomodulators, for the treatment of certain respiratory disorders.
- **Mitsubishi Pharmaceutical Corp.** (Tokyo, Japan): identifying and developing new protective agents for the treatment of neurodegenerative diseases.
- **Genfit** (Lille, France): collaboration covering several projects, particularly pharmacological characterization and selection of the best drug candidates of sanofi-aventis to act on an innovative target involved in metabolic and inflammatory mechanisms and launch of a new program based on a new target involved in inflammatory diseases.
- **INSERM/Innogenetics** (through affiliate INSERM Transfert, Paris, France and Gent, Belgium): collaboration that will make it possible to study the role of specific forms of the key Alzheimer protein amyloid beta, and to discover new therapeutic avenues for Alzheimer's disease.
- **Global Alliance for TB drug Development**: collaboration agreement to accelerate the discovery, development and clinical use of drugs against tuberculosis.

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

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

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

### **License and development agreements**

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

clinical development.

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

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

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



**Table of Contents**

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

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

**Partnerships for access to medicines**

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

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

**Vaccines Research and Development**

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

**Sanofi Pasteur R&D Pipeline**

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

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

Edgar Filing: SANOFI-AVENTIS - Form 20-F

in infants	<b>Rabies</b>	<b>Dengue</b>	
(Monovalent)	mAb post exposure	Mild-to-severe	<b>Pediacel® EU</b>
	prophylaxis	dengue fever	DTP-Polio-Hib <sup>(1)</sup>
<b>Tuberculosis</b>			
Prevention of disease	<b>Melanoma</b>		<b>ADACEL®</b>
	Tumor antigen		DTP <sup>(1)</sup> 4-6 years
<b>Flu Pandemia</b>	administered		
Low dose	through viral vector		<b>Menactra®</b>
	Treatment of		Menactra Infant/Toddler
<b>ACAM-Flu-A</b>	stage III & IV		9-12 months
Broad protection against			
influenza A strains			<b>Flu<sup>(1)</sup> Micro-injection</b>
			New method of delivery U.S.
			<b>IMOJEV</b>
			Japanese encephalitis
			Prevention of infection
			<b>HIV (Thailand)</b>
			Prevention of
			infection
			Proof of concept
			<b>Flu</b>
			New formulation U.S.

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

---

**Table of Contents****Project highlights****Influenza**

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

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

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

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

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

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

**Pediatric Combination & Adolescent/Adult Booster Vaccines**

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

**Pentacel**<sup>®</sup> The FDA granted a license in June 2008 and the product was launched later that year.

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

## Table of Contents

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

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

**Adacel®** a trivalent vaccine to boost immunity in adolescents and adults against diphtheria, tetanus, and pertussis is currently marketed in Canada, Germany and the United States. In 2008, efforts remained focused on expanding its area of licensure and on extending its indications primarily the pre-school booster indication in countries where the product is already marketed.

## **Meningitis Program**

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

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

**Meninge A, C, Y, W conj. Second Generation** this project targets the infant primary/booster series schedule for introduction of a second generation meningococcal vaccine that uses an alternative conjugation technology.

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

## **Pneumococcal Vaccine Program**

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

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

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

**Rabies Vaccine**

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

---

## Table of Contents

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

## **New Vaccine Targets**

**Dengue** Dengue fever is of growing epidemiological importance due to global socio-climatic changes, and is a major medical and economic burden in the endemic areas of Asia, Pacific, Latin America and Africa; it is also one of the leading causes of fever among travelers. Multiple approaches were tested to develop a vaccine covering the four viral serotypes of dengue fever in order to prevent this disease and its severe complications (hemorrhagic fever). Results of a Phase II clinical trial of adults in the United States demonstrated proof of concept of the lead vaccine candidate that is based on the ChimeriVax technology. Administration of the quadrivalent candidate vaccine against dengue fever promoted neutralizing antibodies against the four serotypes responsible for dengue fever. Expanded Phase II studies are ongoing in endemic areas in adults as well as children. Sanofi Pasteur has maintained its relationship with the WHO and the Pediatric Dengue Vaccine Initiative, a program of the International Vaccine Institute funded by the Gates Foundation to make dengue a vaccine preventable disease and to accelerate vaccine introduction in the pediatric endemic population through disease burden evaluation, vaccine advocacy and vaccine access. In February 2009, the sanofi pasteur dengue vaccine entered into a pediatric clinical study in Thailand.

**IMOJEV** The ChimeriVax technology was further leveraged to develop a vaccine for protection against infection with Japanese encephalitis virus (JEV). Japanese encephalitis is endemic in Southeast Asia; replacement of the currently available vaccines with the single dose product is anticipated to provide a strong competitive advantage. Positive Phase III results were obtained in adults. Extension of clinical testing (Phase IIb) in children and toddlers (12-24 months) occurred in 2008. In addition, recruitment for the Phase III bridging trial for the Thai licensing was completed.

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

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

**Chlamydia trachomatis** *Chlamydia trachomatis* is the most commonly reported sexually transmitted bacterial pathogen and produces serious morbidity and long-term sequelae, 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 sequelae. The *Chlamydia trachomatis* project goal is to develop a recombinant protein vaccine for prophylactic vaccination against the *Chlamydia trachomatis* sexually transmitted infection. The target population is pre-sexually active women who are between 11 and 14 years of age. The project continued in the preclinical stage in 2008 as the composition of the candidate prototype vaccine for further clinical development was identified.

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

**Tuberculosis** Statens Serum Institute of Denmark (SSI) granted sanofi pasteur a license to its technology with regard to the use of certain fusion proteins in the development of a tuberculosis vaccine. The license from SSI includes access to the Intercell IC31<sup>®</sup> adjuvant. The candidate vaccine is made up of recombinant protein units currently in a clinical Phase I trial. A previous study in adults indicated the candidate SSI sub-unit vaccine to be safe and immunogenic. Multiple Phase I clinical trials are currently ongoing

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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



---

## Table of Contents

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

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

**ACAM-Cdiff** Phase II started in February 2009. *Clostridium difficile* is the leading cause of infectious diarrhea in hospitals, in the adult and particularly elderly population. The epidemiology of the *C. difficile* associated disease (CDAD) has been increasing at an alarming rate since 2003, driven primarily by the emergence of a treatment resistant, highly virulent strain CD027. The disease burden cost is estimated to be over \$3 billion in both the United States and the European Union. ACAM-Cdiff is a toxoid-based vaccine for the primary prevention of *C.difficile* associated with diarrhea. *C.difficile* is a major public health concern in North America and Europe. There is currently no vaccine available.

## **Animal Health: Merial**

Merial, a joint venture in which we and Merck & Co. Inc. each hold 50%, is one of the world's leading animal healthcare companies dedicated to the research, development, manufacture and delivery of innovative pharmaceuticals and vaccines used by veterinarians, farmers and pet owners. Its net sales for 2008 amounted to \$2,643 million.

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

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

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

Merial operates through a network of 16 production sites, with major sites located in France, the United States, Brazil and China. The major R&D sites are located in France and in the United States. Merial employs approximately 5,800 employees worldwide.

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

**Patents, Intellectual Property and Other Rights**

**Patent Protection**

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

active ingredients;

pharmaceutical formulations;

---

**Table of Contents**

product manufacturing processes;

intermediate chemical compounds;

therapeutic indications/methods of use;

delivery systems; and

enabling technologies, such as assays.

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

The protection a patent affords the related product depends upon the type of patent and its scope of coverage, and may also vary from country to country. In Europe for instance, applications for new patents may be submitted to the European Patent Office (EPO), an intergovernmental organization which centralizes filing and prosecution. As of January 2008, an EPO patent application may cover the 34 EP Convention member states including all 27 member states of the European Union. The granted European patent establishes corresponding national patents with uniform patent claims among the member states. However, some older patents were not approved through this centralized process, resulting in patents having claim terms for the same invention that differ by country. Additionally, a number of patents prosecuted through the EPO may pre-date the EP Convention accession of some current EP Convention member states, resulting in different treatment in those countries.

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

The expiration or loss of a product patent may result in significant competition from generic products and can result in a dramatic reduction in sales of the original branded product. In some cases, it is possible to continue to obtain commercial benefits from product manufacturing trade secrets or other types of patents, such as patents on processes, intermediates, product, structure, formulations, methods of treatment, indications or delivery systems. Certain categories of products, such as traditional vaccines and insulins, have been historically relatively less reliant on patent protection and may in many cases have no patent coverage, although it is increasingly frequent for novel vaccines and insulins to be patent protected. See Focus on Biologics below.

One of the main limitations on our operations in some countries outside the United States and Europe is the lack of effective intellectual property protection or enforcement for our products. The World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIP) has required developing countries to amend their intellectual property laws to provide patent protection for pharmaceutical products since January 1, 2005 although it provides a limited number of developing countries an extension to 2016. While the situation has gradually improved, the lack of protection for intellectual property rights or the lack of robust enforcement of intellectual property rights poses difficulties in certain countries. Additionally, in recent years a number of countries faced with health crises have waived or threatened to waive intellectual property protection for specific products, for example through compulsory licensing.

**Regulatory Exclusivity**

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

## **Table of Contents**

In the United States, the FDA will not grant final marketing approval to a generic competitor for a New Chemical Entity ( NCE ) until the expiration of the regulatory exclusivity period (generally five years) that commences upon the first marketing authorization of the reference product. It will accept the filing of an Abbreviated New Drug Application (ANDA) containing a patent challenge a year before the end of this regulatory exclusivity period (see the descriptions of ANDAs, below). In addition to this exclusivity granted to new drug products, significant line extensions of existing NCEs may qualify for an additional 3-year regulatory exclusivity. Also, under certain limited conditions, it is possible to extend any unexpired U.S. regulatory and patent-related exclusivities by a pediatric extension. See Pediatric Extension , below).

In the European Union, generic drug applications will not be accepted for review until eight years after the first marketing authorization (data exclusivity) or approved for marketing until ten years after the first marketing authorization of the reference product (marketing exclusivity). These exclusivities may be extended in some cases. While this exclusivity is intended to be applicable throughout the European Union, in a decentralized system, national authorities may act in ways that are inconsistent with EU data exclusivity. For example, although European marketing exclusivity for clopidogrel expired in July 2008, in May 2008 the German Health authority BfArM had already registered a competitor's clopidogrel product based on a contested interpretation of the law and in 2006 the Polish and Bulgarian authorities registered generics of clopidogrel bisulfate based on these countries' contested position that EU marketing exclusivities need not be applied by individual countries where generics had been approved prior to their accession date.

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

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

## **Pediatric Extension**

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

In the United States, the FDA may ask for pediatric studies if it has determined that information related to the use of the drugs in the pediatric population may produce health benefits. The FDA has invited us by written request to provide additional pediatric data on several of our top 15 products. Under the Hatch-Waxman Act, timely provision of data meeting the FDA's requirements may result in the FDA treating the product as if its regulatory exclusivity and patent life had been extended by six months, to the extent these protections have not already expired (the so-called pediatric exclusivity ). The Top 15 products having received past FDA grants of pediatric exclusivity are Aprovel<sup>®</sup>, Lantus<sup>®</sup>, Amaryl<sup>®</sup>, Allegra<sup>®</sup>, Eloxatine<sup>®</sup>, and Ambien<sup>®</sup>/Ambien<sup>®</sup> CR. Written requests have also been issued to us with respect to Plavix<sup>®</sup>, Taxotere<sup>®</sup> and Lovenox<sup>®</sup>.

In Europe, a new regulation on pediatric medicines entered into force on January 26, 2007. This regulation provides for the progressive implementation through 2009 of pediatric research obligations with associated possible rewards including an extension of patent protection (for patented medicinal products) and regulatory exclusivity for pediatric marketing authorization (for off-patent medicinal products). For additional

details, see Regulation below.

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

## Table of Contents

### Product Overview

We summarize below the intellectual property coverage in our major markets of the products described above at Principal Pharmaceutical Products. In the discussion of patents below, we focus on compound patents and any secondary patents listed in the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book) or on their foreign equivalents, because these patents tend to be the most relevant in the event of an application by a competitor to produce a generic version of one of our products or the equivalent of these patents in other countries (see Challenges to Patented Products, below). In some cases, products may also benefit from pending patent applications and from patents not eligible for Orange Book listing (e.g., patents claiming industrial processes). In each case below, we specify whether the active ingredient is claimed by an unexpired patent. Where patent terms have been extended to compensate for regulatory delay, the extended dates are presented below. U.S. patent expirations presented below reflect U.S. Patent and Trademark Office dates, and therefore do not reflect six-month pediatric extensions to the FDA's Orange Book dates for the products concerned (Aprovel®, Lantus®, Amaryl®, Eloxatine®, Stilnox®/Ambien® CR and Allegra®). We do not provide secondary patent information relating to formulations already available as an unlicensed generic. References below to patent protection in Europe indicate the existence of relevant patents in most major markets in the European Union. Specific situations may vary country by country, most notably with respect to older patents and to countries having only recently joined the European Union. See Patents, Intellectual Property and other Rights above.

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

#### *Lovenox® (enoxaparin sodium)*

**U.S.**  
Compound: Declared unenforceable by a February 2007 U.S. District Court decision

**E.U.**  
Compound: June 2011 in most of EU; exceptions: June 2010 in France, no compound patent in force in Spain, Portugal, Finland, Norway, Greece and much of Eastern Europe

**Japan**  
Compound: expired  
  
Regulatory exclusivity until 2016

#### *Plavix® (clopidogrel bisulfate)*

**U.S.**  
Compound: November 2011

**E.U.**  
Compound: 2013 in most of EU; no compound patent in force in Spain, Portugal, Finland, Norway and much of Eastern Europe.

**Japan**  
Compound: 2013  
  
Secondary: crystalline form 2 (2020)

Secondary: two patents covering the crystalline form 2 each expiring in 2019

Secondary: crystalline form 2 (2019)

Regulatory exclusivity until 2014

#### *Aprovel® (irbesartan)*

**U.S.**  
Compound: September 2011

**E.U.**  
Compound: August 2012 in most of EU; exceptions: expires March 2011 in the Czech Republic, Hungary, Romania, Slovakia and 2013 in Lithuania and Latvia. No compound patent in force in Spain, Portugal, Finland, Norway and much of Eastern Europe

**Japan**  
Compound: 2016  
  
Secondary: Formulation (2021)

Secondary: Formulation (2015)

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



**Table of Contents**

	<i>Lantus® (insulin glargine)</i>	
<b>U.S.</b> Compound: 2014	<b>E.U.</b> Compound: 2014 in most of EU; no compound patent in force in much of Eastern Europe	<b>Japan</b> Compound: 2014
		Regulatory exclusivity until October 2011
	Regulatory exclusivity until June 2010	
	<i>Taxotere® (docetaxel)</i>	
<b>U.S.</b> Compound: May 2010	<b>E.U.</b> Compound: November 2010 in most of EU; no compound patent in force in Spain, Portugal, Finland, Norway and much of Eastern Europe	<b>Japan</b> Compound: June 2012
Secondary: formulation (2012 to 2013)		Secondary: formulation (2012 to 2013)
	Secondary: additional patent coverage ranging through 2013	
	<i>Eloxatine® (oxaliplatin)<sup>1</sup></i>	
<b>U.S.</b> Compound: expired	<b>E.U.</b> Compound: expired	<b>Japan</b> N/A
Secondary: coverage ranging through 2016	Genericized	
Regulatory exclusivity: expired February 2008		
	<i>Copaxone® (glatiramer acetate)<sup>2</sup></i>	
<b>U.S.</b> Compound: 2014	<b>E.U.</b> Compound: 2015	<b>Japan</b> N/A
	<i>Actonel® (risedronate sodium)<sup>3</sup></i>	
<b>U.S.</b> Compound: December 2013	<b>E.U.</b> December 2010 in Austria, Belgium, France, Germany, the Netherlands, the United Kingdom, Sweden, Switzerland and Italy; 2013 in Spain; expired elsewhere	<b>Japan</b> N/A
Secondary: coverage ranging through 2018		
	Secondary: coverage ranging through 2018	
	<i>Stilnox® (zolpidem tartrate)</i>	
<b>U.S.</b> Compound patent: expired	<b>E.U.</b> Compound patent: expired	<b>Japan</b> Compound patent: expired

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Secondary: Ambien® CR formulation (2019)

Genericized

Secondary: Ambien® CR formulation  
(2019)

Regulatory exclusivity until March 2009 for  
Ambien® CR (regulatory exclusivity on active  
ingredient has expired)

Regulatory exclusivity until 2010 on all  
formulations

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

**Table of Contents**

<i>Allegra® (fexofenadine hydrochloride)</i>		
<b>U.S.</b> Compound: expired	<b>E.U.</b> Compound: expired	<b>Japan</b> Compound: expired
Secondary: coverage ranging through 2017	Genericized	Secondary: coverage ranging through 2016
Single entity form genericized, licensed generic D®-12 Hour form in November 2009 <sup>1</sup>		
<i>Depakine® (sodium valproate)</i>		
<b>U.S.</b> N/A	<b>E.U.</b> Compound: expired	<b>Japan</b> Compound: expired
	Secondary: Depakine® Chronosphere® formulation (2017)	Secondary: Depakine® Chronosphere® formulation (2017)
<i>Nasacort® (triamcinolone acetonide)</i>		
<b>U.S.</b> Compound: expired	<b>E.U.</b> Compound: expired	<b>Japan</b> Compound: expired
Secondary: formulation and method of use 2016	Secondary: formulation 2017	Secondary: formulation 2017 (application pending)
Generic licensed as early as 2011 <sup>1</sup>		
<i>Xatral® (alfuzosin hydrochloride)</i>		
<b>U.S.</b> Compound: expired	<b>E.U.</b> Compound: expired	<b>Japan</b> Compound: expired
Secondary: formulation 2017	Secondary: formulation 2017	Secondary: formulation 2017
Regulatory exclusivity: expired June 2008		
<i>Tritace® (ramipril)</i>		
<b>U.S.</b> N/A	<b>E.U.</b> Compound: expired	<b>Japan</b> Compound: expired
	Genericized	

Edgar Filing: SANOFI-AVENTIS - Form 20-F

*Amaryl® (glimepiride)*

**U.S.**  
Compound: expired

**E.U.**  
Compound: expired

**Japan**  
Compound: expired

Genericized

Genericized

Regulatory exclusivity until March 2009

<sup>1</sup> License granted to Barr in settlement of patent litigation.

Patents held or licensed by the Group do not in all cases provide effective protection against a competitor's generic version of our products. For example, notwithstanding the patents listed above competitors have launched generic versions of Eloxatine® in Europe, Allegra® in the United States and Plavix® in Germany.

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

---

## **Table of Contents**

We caution the reader that there can be no assurance that we will prevail when we assert a patent in litigation and that there may be instances in which the Group determines that it does not have a sufficient basis to assert one or more of the patents mentioned in this report, for example in cases where a competitor proposes a formulation not appearing to fall within the claims of our formulation patent, a salt or crystalline form not claimed by our composition of matter patent, or an indication not covered by our method of use patent.

### **Challenges to Patented Products**

In the United States, companies have filed Abbreviated New Drug Applications (ANDAs), containing challenges to patents related to a number of our products. An ANDA is an application by a drug manufacturer to receive authority to market a generic version of another company's approved product, by demonstrating that the purportedly generic version has the same properties as the original approved product. ANDAs may not be filed with respect to drugs licensed as a biological. See [Focus on Biologics](#) below. An ANDA relies on the safety and other technical data of the original approved product, and does not generally require the generic manufacturer to conduct clinical trials (thus the name abbreviated new drug application), presenting a significant benefit in terms of time and cost. As a result of regulatory protection of our safety and other technical data, the ANDA may generally be filed only five years following the initial U.S. marketing authorization of the original product. This period is reduced to four years if the ANDA includes a challenge to a patent listed in the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the [Orange Book](#), and owned by or licensed to the manufacturer of the original version. However, in such a case if the patent holder or licensee brings suit in response to the patent challenge within the statutory window, then the FDA is barred from granting a final approval to an ANDA during the 30 months following the patent challenge (this bar being referred to in our industry as a 30 month stay), unless, before the end of the 30 months, a court decision or settlement has determined either that the ANDA does not infringe the listed patent or that the listed patent is invalid and/or unenforceable. FDA approval of an ANDA after this 30-month period does not resolve outstanding patent disputes, but it does remove the regulatory impediments to a product launch by a generic manufacturer willing to take the risk of later being ordered to pay damages to the patent holder. Procedures comparable to the ANDA exist in other major markets.

In Canada, an Abbreviated New Drug Submission may be filed with respect to a generic version of an existing drug only after data exclusivity has expired, and a stay on regulatory approval of a generic for up to 24 months may be obtained if a listed patent is asserted.

In the European Union, a generic drug manufacturer may reference the data of the regulatory file for the original approved product after data exclusivity has expired. However, there is no patent listing system in Europe comparable to the [Orange Book](#), which would allow the patent holder to bar the competent authorities from granting the marketing approval by bringing patent infringement litigation prior to approval. As a result, generic products may be approved for marketing following the expiration of marketing exclusivity without regard to the patent holder's rights.

Nevertheless, in most of these jurisdictions once the product is launched and in some jurisdictions already before (once launch is imminent), the patent holder can seek an injunction against this marketing if its patents are infringed. See [Item 8. Financial Information](#) [A. Consolidated Financial Statements and Other Information](#) [Information on Legal or Arbitral Proceedings](#) and [Note D.22.b](#) to our consolidated financial statements included at [Item 18](#) of this annual report.

The accelerated ANDA-type procedures are potentially applicable to most, but not all, of the products we manufacture. See [Focus on Biologics](#) and [Regulation](#) below. We seek to defend our patent rights vigorously in these cases. Success or failure in the assertion of a given patent against one competing product is not necessarily predictive of the future success or failure in the assertion of the same patent or *a fortiori* the corresponding foreign patent against a second competing product because of such factors as possible differences in the formulations of the competing products, intervening developments in law or jurisprudence, local variations in the patents and differences in national patent law and legal systems.



## **Table of Contents**

### **Trademarks**

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

The degree of trademark protection varies country by country, as each state implements its own laws applicable to trademarks used in its territory. In most countries, trademark rights may only be obtained by registration. In some countries, trademark protection is primarily based on use. Registrations are granted for a fixed term (in most cases ten years) and are renewable indefinitely, but in some instances may be subject to the continued use of the trademark. When trademark protection is based on use, it covers the products and services for which the trademark is used. When trademark protection is based on registration, it covers only the products and services designated in the registration. Additionally, in certain cases, we may enter into a coexistence agreement with a third-party that owns potentially conflicting rights in order to better protect and defend our trademarks.

### **Production and Raw Materials**

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

We generally develop and manufacture the active ingredients that we use in our products. We have a general policy of producing the active ingredients for our principal products at our own plants in order to minimize our dependence on external manufacturers and control the product throughout the production cycle. In some cases however, we have outsourced certain production elements, especially as part of supply agreements entered into within the framework of plant divestitures. Thus we outsource a part of the production of the active ingredients used in Stilnox<sup>®</sup> or Xatral<sup>®</sup>, a part of the chemical activity linked with Lovenox<sup>®</sup> and certain formulations of various pharmaceutical products. Our main subcontractors are Patheon, Famar, Catalent, GSK-NDB, Haupt and Sofarimex. These subcontractors are required to follow our guidelines in terms of quality, logistics and other criteria.

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

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

We purchase the raw materials used to produce Lovenox<sup>®</sup> from a number of sources. In 2008, we recalled a limited number of batches of Lovenox<sup>®</sup> and depreciated substantial unused stocks following the discovery of impurities in raw materials purchased from a Chinese supplier.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Our main European pharmaceutical production facilities are located in France, Germany, Italy, Spain, the United Kingdom and Hungary. In North America, we run two facilities in the United States (Kansas City and Saint Louis) and one in Canada (Laval). We have one plant in Japan (Kawagoe) and additional facilities located in many other parts of the world. To carry out the production of vaccines, sanofi pasteur uses a wide industrial operations network, with sites located in North America, France, China, Thailand and Argentina.

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



**Table of Contents**

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

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

The manufacturing and research operations of sanofi-aventis are subject to increasingly stringent health, safety and environmental laws and regulations. These laws and regulations are complex and rapidly changing, and sanofi-aventis invests the necessary sums for compliance with them. This investment, which aims to respect health, safety and the environment, varies from year to year and totaled approximately 120 million in 2008.

The applicable environmental laws and regulations may require sanofi-aventis to eradicate or reduce the effects of chemical substance usage and release at its various sites. The sites in question may belong to the company, be currently operational, or they may have been owned or operational in the past. Under some of these laws and regulations, a current or previous owner or operator of a property may be held liable for the costs of removal or remediation of hazardous substances on, under or in its property, or transported from its property to third party sites, without regard to whether the owner or operator knew of, or under certain circumstances caused the presence of the contaminants, or at the time site operations occurred, the discharge of those substances was authorized.

Moreover, as for a number of companies involved in the pharmaceutical, chemical and agrochemical industries, soil and groundwater contamination has occurred at some company sites in the past, and may still occur or be discovered at others. In the Group's case, such sites are mainly located in the United States, Germany, France, Hungary, Brazil, Italy and the United Kingdom. As part of a program of environmental audits conducted over the last few years, detailed assessments of the risk of soil and subsoil contamination have been carried out at current and former company sites. In cooperation with national and local authorities, the Group constantly assesses the rehabilitation work required and this work has been implemented when appropriate. Long-term rehabilitation work has been completed or is in progress in Rochester, Cincinnati, Mount-Pleasant, East Palo Alto, Ambler and Portland in the United States; Frankfurt in Germany; Beaucaire, Valernes, Limay, Rousset and Vitry in France; Dagenham in the United Kingdom; Brindisi and Garessio in Italy; and on a number of sites divested to third parties and covered by contractual environmental guarantees granted by sanofi-aventis. Sanofi-aventis may also have potential liability for investigation and cleanup at several other sites. Provisions have been established for the sites already identified and to cover contractual guarantees for environmental liabilities for sites that have been divested. For example, in 2007 the State of New Jersey initiated a claim against Bayer CropScience seeking compensation for damages caused to natural resources (NRD) at a former Rhône-Poulenc site in the United States, resulting in indemnification claims by Bayer CropScience against the Group under contractual environmental guarantees granted at the time of Bayer's acquisition of the CropScience business. Rehabilitation studies and an NRD assessment are underway in a similar project in Portland, Oregon. Potential environmental contingencies arising from certain business divestitures are described in Note D.22.e) to the consolidated financial statements included at Item 18 of this annual report. In 2008, sanofi-aventis spent more than 48 million on rehabilitating sites previously contaminated by ground pollution. As of December 2008, the most comprehensive review possible had been carried out of the legacy of environmental pollution. In light of data collected during this review, the Group adjusted the provisions to approximately 589 million as at December 31, 2008.

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

To our knowledge, the Group is not currently subject to liabilities for non-compliance with current HSE laws and regulations that could be expected to significantly jeopardize its activities, financial situation or operating income. We also believe that we are in substantial compliance

with current HSE laws and regulations

## **Table of Contents**

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

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

### ***Health***

From the development of compounds to the commercial launch of new drugs, sanofi-aventis research scientists continuously assess the effect of products on human health. This expertise is made available to employees through two committees responsible for chemical and biological risk assessment. The COVALIS committee classifies all chemical and pharmaceutical products handled within the Group and establishes workplace exposure limits for each of them. The TRIBIO Committee is responsible for classifying all biological agents according to their degree of pathogenicity, and applies rules for their containment and the preventive measures to be respected throughout the Group.

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

### ***Safety***

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

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

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

Our laboratories that specialize in process safety testing, which are fully integrated into our chemical development activities, apply methods to obtain the physico-chemical parameters of manufactured chemical substances (intermediate chemical compounds and active ingredients) and apply models to measure the effect of

## **Table of Contents**

potentially leachable substances in the event of a major accident. In these laboratories the parameters for qualifying hazardous reactions are also determined to define scale-up process conditions while transferring from development stage to industrial scale. All these data ensure the relevance of the risk assessments.

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

## ***Environment***

The main objectives of the environmental policy of sanofi-aventis are to implement clean manufacturing techniques, minimize the use of natural resources and reduce the environmental impact of its activities. In order to optimize and improve our environmental performance, sanofi-aventis is committed to progressively obtaining ISO 14001 certification. 34 manufacturing sites and three Research & Development sites are currently certified. This commitment is part of a strategy of continuous improvement practiced at all Group sites through the annual implementation of HSE progress plans. We believe that this strategy clearly expresses the commitment of both management and individuals to health, safety and the environment. As of January 1, 2008, six of the Group's European sites were included in the scope of the European CQ Emissions Credit Trading Scheme aimed at helping to reach the targets set by the Kyoto protocol.

The recent efforts of the Group in terms of environmental protection have mainly targeted reductions in energy consumption, greenhouse gas emissions control, improvements in the performance of water treatment installations, reduction of volatile organic compound emissions, raw material savings and recycling, and reductions in waste materials or increases in the percentage being recycled. Since 2005 we have reduced carbon dioxide emissions caused by our sales representation car fleet by 11% and our direct and indirect carbon dioxide emissions in relation to our activity levels per unit produced by 10%.

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

## **Markets**

A breakdown of revenues by activity and by geographic market for 2006, 2007 and 2008 can be found at Note D.35. to our consolidated financial statements included at Item 18 of this annual report.

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

**Marketing and Distribution**

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

the United States, also the world's largest pharmaceutical market

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

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

## Table of Contents

### Europe

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

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

### Japan

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

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

We are also enhancing our presence in certain developing markets with significant growth prospects, especially Brazil, Russia, India, China, and Mexico. A breakdown of our sales by geographic market is presented in Item 5. Operating and Financial Review and Prospects - Results of Operations - Year Ended December 31, 2008 Compared with Year Ended December 31, 2007.

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

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

Our medical sales representatives, who work closely with healthcare professionals, use their expertise to promote and provide information on our drugs. They represent our values on a day-to-day basis and are required to adhere to a code of ethics. Throughout 2008 we carried on our worldwide project initiated in 2007 aimed at increasing our sales forces' competitiveness and productivity. It resulted in the deployment of new management tools and the building of a more customer-focused selling model, that more comprehensively takes into consideration all

stakeholders in access to medicine decisions.

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

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

As most pharmaceutical companies do, we market and promote our products through a variety of advertising, public relations and promotional tools. We regularly advertise in medical journals and exhibit at major medical congresses. In some countries, products are also marketed directly to patients by way of television, radio, newspapers and magazines, and we sometimes use specific media channels to market our products. National education and prevention campaigns are used to improve patients' coverage on conditions such as deep vein thrombosis, osteoporosis, uncontrolled diabetes, influenza and arterial diseases in markets such as Germany, France and the United States.

Although we market most of our products with our own sales forces, we have entered into and continue to form partnerships to co-promote/co-market certain products in specific geographic areas. Our major alliances are detailed below under Alliances .



## **Table of Contents**

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

### **Alliances**

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

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

### ***Bristol-Myers Squibb (BMS)***

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

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

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

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

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

Under the alliance arrangements, there are two territories, one under our operational management and the other under the operational management of BMS. The territory under our operational management consists of Europe and most of Africa and Asia, while the territory under the operational management of BMS consists of the rest of the world excluding Japan. In Japan, Aprovel<sup>®</sup> has been marketed jointly by Shionogi Pharmaceuticals and Dainippon Sumitomo Pharma Co. Ltd since June 2008 through license and sub-license agreements signed with BMS. The BMS alliance does not cover rights to Plavix<sup>®</sup> in Japan.

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

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

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

we have the exclusive right to market Aprovel® and Plavix® in Eastern Europe, Africa and the Middle East, and we have the exclusive right to market Aprovel® in Asia (excluding Japan). Since September 2006, we have had the exclusive right to market Aprovel® in Scandinavia and Ireland.

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

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

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

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

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

## **Table of Contents**

### ***Procter & Gamble Pharmaceuticals (P&G)***

We in-license Actonel<sup>®</sup> from P&G. An alliance with P&G was concluded in April 1997 for the co-development and marketing of Actonel<sup>®</sup>. The 1997 agreements were amended following the acquisition of Aventis by sanofi-aventis, and later with respect to the marketing rights for Actonel<sup>®</sup> in certain countries in Europe.

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

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

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

*secondary co-promotion territory*: the product is jointly marketed through the alliance arrangements under the brand name Actonel<sup>®</sup> with sales booked by sanofi-aventis. The secondary co-promotion territory includes Ireland, Sweden, Finland, Greece, Switzerland, Austria, Portugal and Australia. The United Kingdom was also included until December 31, 2008. P&G may also at a later date exercise an option to co-promote the product in Denmark, Norway, Mexico and/or Brazil;

*co-marketing territory*: each company markets the products independently under its own brand name. This territory currently includes Italy. In Italy the product is sold under the brand name Actonel<sup>®</sup> by P&G and under the brand name Optinate<sup>®</sup> by sanofi-aventis. Each company also markets the product independently under its own brand name in Spain, although Spain is not included in the co-marketing territory; the product is marketed in Spain under the brand name Acrel<sup>®</sup> by P&G and under the brand name Actonel<sup>®</sup> by sanofi-aventis;

*P&G only territory*: the product has been marketed by P&G independently under the brand name Actonel<sup>®</sup> in Germany, Belgium and Luxembourg since January 1, 2008, in the Netherlands since April 1, 2008 and in the United Kingdom since January 1, 2009;

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

### ***Teva Pharmaceutical Industries (Teva)***

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

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

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

*exclusive marketing*: we have the exclusive right to market the product. This system is used in a number of European countries (Portugal, Italy, Greece, Finland, Denmark, Sweden, Norway, Iceland, Ireland, Luxembourg, Poland, Lichtenstein, Switzerland), as well as in Australia and New Zealand; and

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

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

## **Table of Contents**

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

## **Competition**

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

There are four types of competition in the pharmaceutical market:

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

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

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

competition between generic or biosimilar products.

We compete with other pharmaceutical companies in all major markets to develop innovative new products. We may develop new technologies and new patented products wholly in-house, but we also enter into collaborative R&D agreements in order to access new technologies.

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

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

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

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Competition from producers of generics has increased sharply in response to healthcare cost containment measures and to the increased number of products going off patent.

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

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

## **Table of Contents**

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

## **Regulation**

The global production and distribution of pharmaceuticals is highly regulated. National and supranational regulatory authorities administer a vast array of laws, directives and regulations that dictate the pre-approval testing, and the quality standards, in order to ensure safety and efficacy of a new drug. These authorities also regulate product labeling, manufacturing, importation/exportation and marketing as well as post-approval commitments which the product manufacturer is required to honor.

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

Europe, the United States, Japan and other Health Authorities all have high standards for pharmaceutical technical appraisal. Product approval usually takes one to two years, but depending on the country it can vary from six months to, in some cases, several years from the date of application. Factors such as the quality of data submitted, the degree of control exercised by the regulatory authority, the review procedures, the nature of the product and the condition to be treated, play a major role in the length of time a product is under review.

In recent years, intensive efforts have been made among the United States, the European Union, Japan and also other regions to harmonize product development and regulatory submission requirements. An example of this is that many pharmaceutical companies are now able to prepare and submit a common technical document (CTD) that can be used in different regions for a particular product with only local or regional adaptation.

However, the requirement of many countries (including Japan and several Member States of the European Union) to negotiate selling prices or reimbursement rates for pharmaceutical products with government regulators can substantially extend the time for market entry to long after initial marketing approval is granted. While marketing authorizations for new pharmaceutical products in the European Union have been substantially centralized with the European Medicines Agency (EMA), pricing and reimbursement remain a matter of national competence. See Pricing & Reimbursement below.

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

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

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

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

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



## Table of Contents

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

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

A new regulation in pediatric development came into force in January 2007 with implementation ongoing until 2009. It is aimed at promoting the development of drugs well adapted to children and ensuring safe use in the pediatric population. Incentives are proposed such as extension of SPC (Supplementary Protection Certificate) or data protection for PUMA (Pediatric Use Marketing Authorization).

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

In the United States, applications for drug approval are submitted for review by the U.S. Food and Drug Administration (FDA). The FDA has broad regulatory powers over all pharmaceutical products that are intended for sale and marketing in the United States. To commercialize a product in the United States, a New Drug Application (NDA) or Biological License Application (BLA) is filed with the FDA with data that sufficiently demonstrate the drug's quality, safety and efficacy. Specifically, the FDA must decide whether the drug is safe and effective for its proposed use, if the benefits of the drug's use outweigh its risks, whether the drug's labeling is adequate, and if the manufacturing of the drug and the controls used for maintaining quality are adequate to preserve the drug's identity, strength, quality and purity. Based upon this review, the FDA can require post-approval commitments. Approval for a new indication of a previously registered drug requires the submission of a supplemental NDA (sNDA).

Pharmaceutical manufacturers have committed to publishing protocols and results of clinical studies performed with their compounds in publicly accessible registries (Clinical Trials Registry and Clinical Trial Results Registry).

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

In the United States, generic drug manufacturers may file an Abbreviated NDA (ANDA). These applications are abbreviated because they are generally not required to include preclinical data, such as animal studies and human clinical data to establish safety and effectiveness. Instead, generic manufacturers need to demonstrate that their product is bioequivalent, *i.e.*, that it performs in humans in the same manner as the

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

innovator's product. Consequently, the length of time and cost required for development of such product can be considerably less than for the innovator's drug. See Patents, Intellectual Property and Other Rights, above, for additional information. The ANDA procedures in the United States can be used exclusively for pharmaceutical products approved under an NDA. See Focus on Biologics below.

In Japan, the regulatory authorities can require local development studies; they can also request bridging studies to verify that foreign clinical data are applicable to Japanese patients and also require data to determine

## **Table of Contents**

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

### **Focus on Biologics**

Products are usually referred to as biologics when they are derived from plant or animal tissues (e.g., blood products) or manufactured within living cells (e.g., antibodies, insulins, vaccines). Most biologics are complex molecules or mixture of molecules which are difficult if not impossible to fully characterize. For the characterisation and determination of these products quality a combination of physico-chemical-biological testing, together with their production process and its control, is needed.

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

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

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

In the United States, the regulations do not currently establish procedures for biosimilar versions of a reference drug registered as a biological under the Public Health Service Act. Inclusion of an abbreviated pathway for these products would require the law to be revised.

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

The FDCA provides for another abbreviated registration pathway for some biosimilar products; the so-called 505(b)(2) route. This pathway may be used notably for recombinant proteins. The registration file may partially refer to the existing data for the reference product but must be

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

completed with data specific to the biosimilar version, notably with preclinical and clinical data. However the FDA indicated that this pathway should remain limited to relatively simple cases and that taking into consideration the current state of scientific knowledge, it is unlikely that it could be applied to more complex products either from a structural or pharmacological point of view.

## **Table of Contents**

### **Pricing & Reimbursement**

Rising overall health care costs are leading to efforts to curb drug expenditures in most markets in which sanofi-aventis operates. Increasingly these efforts result in pricing and market access controls for pharmaceuticals. The nature and impact of these controls vary from country to country, but some common themes are reference pricing, systematic price reductions, formularies, volume limitations, patient co-pay requirements, and generic substitution. In addition, governments and third-party payers are increasingly utilizing emerging healthcare information technologies such as electronic prescribing and health records to enforce transparency and tight compliance with these regulations and controls. As a result, the environment in which pharmaceutical companies must operate in order to make their products available to patients and providers who need them continues to grow more complex each year.

In the United States, the government does not currently control pharmaceutical costs directly except in the case of prescriptions purchased or reimbursed by government entities such as Medicaid, Veterans Affairs, and the Department of Defense. These entities provide health insurance coverage to approximately 16.9% of the U.S. population. Third-party payers administer private plans that cover part of the U.S. population, as well as the Medicare prescription benefit for the elderly, which the federal government funds but does not manage. While they cannot directly control prices, third-party payers seek to decrease drug costs through reimbursement restrictions such as patient co-pays, step therapy protocols (protocols under which a brand product may be prescribed and reimbursed only if therapy has already failed using at least one low-cost generic drug, also known as fail first ), and prior authorization (requirements that a prescriber obtain third-party payer authorization prior to prescribing certain medications), in addition to rebate contracting with manufacturers. However, the new Democratic leadership in both the presidency and Congress has announced an intention to seek reform that could increase direct government involvement throughout the healthcare system in issues involving cost, equality and coverage.

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

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

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

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

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

### **Insurance and Risk Coverage**

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

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

## **Table of Contents**

Our captive, which participates in the first three of these programs, is run as an insurance company under the supervision of the Irish regulatory authorities, and has sufficient resources to meet the risks that it covers. It sets premiums for Group entities at market rates. Claims are assessed using the traditional models applied by insurance and reinsurance companies, and the company's reserves are regularly checked and confirmed by independent actuaries.

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

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

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

The principal risk exposure for our pharmaceutical products is covered with low deductibles at country level, the greatest level of risk being retained by our captive insurance company. The level of risk self-insured by the Group including our captive reinsurance company enables us to retain control over the management and prevention of risk. Our negotiations with third-party insurers and reinsurers are tailored to our specific risks. In particular, they allow for differential treatment of products in the development phase, for the discrepancies in risk exposure between European countries and the United States, and for specific issues arising in certain jurisdictions.

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

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

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





**Table of Contents****C. Organizational Structure**

Sanofi-aventis is the holding company of a consolidated group of subsidiaries. The table below sets forth our significant subsidiaries and affiliates as of December 31, 2008. For a complete list of our main consolidated subsidiaries, see Note F. to our consolidated financial statements, included in this annual report at Item 18.

Significant Subsidiary or Affiliate	Country	Ownership Interest
Aventis Inc.	United States	100%
Aventis Pharma S.A.	France	100%
Hoechst GmbH	Germany	100%
Sanofi-aventis Amerique du Nord S.N.C.	France	100%
Sanofi-aventis Deutschland GmbH	Germany	100%
Sanofi-aventis Europe S.A.S.	France	100%
Sanofi-aventis France S.A.	France	100%
Sanofi-aventis Participation S.A.S.	France	100%
Sanofi-aventis US LLC	United States	100%
Sanofi-aventis US Inc.	United States	100%
Sanofi Pasteur Inc.	United States	100%
Sanofi Pasteur S.A.	France	100%
Sanofi Winthrop Industrie S.A.	France	100%

Sanofi-aventis and its subsidiaries form a Group, organized around two business segments: pharmaceutical products and human vaccines.

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

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

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

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

*D. Property, Plant and Equipment*

Our worldwide headquarters and principal executive offices are located in Paris, France. Our U.S. headquarters are located in Bridgewater, New Jersey.

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

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

**Table of Contents****Breakdown of sites by nature**

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

**Research and Development Sites for the Pharmaceutical Activity**

Research and Development activities are housed at 29 sites:

13 sites in France, the largest in terms of surface area being in Vitry/Alfortville (approximately 96,000 sq.m), Montpellier (78,000 sq.m), Chilly/Longjumeau (77,000 sq.m) and Toulouse (38,000 sq.m);

7 sites in other European countries (Germany, United Kingdom, Hungary and Italy), the largest being in Frankfurt, Germany (84,000 sq.m). In Italy, a Research center located in Milan was inaugurated in May 2008;

5 sites in the United States, the largest being in Bridgewater, New Jersey (111,000 sq.m);

2 sites in Japan, in Tokyo and Kawagoe;

2 sites in China: the main Research and Development operations are located in Shanghai, with a Clinical Research Unit in Beijing.

**Industrial sites for the Pharmaceutical Activity**

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

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

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

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

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

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

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

United States: Kansas City (Allegra<sup>®</sup>, Amaryl<sup>®</sup>).

### Sanofi Pasteur Sites

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

### Breakdown of sites between owned and leased

Leased	72%
Owned	28%

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

\* Sites acquired in 2008 with Acambis.

## **Table of Contents**

We believe that our production plants and research facilities are in full compliance with regulatory requirements, well maintained, and generally adequate to meet our needs for the foreseeable future. However, we review our production facilities on a regular basis with regard to environmental, health, safety and security issues, quality compliance, and capacity utilization. For more information about our property, plant and equipment, see Note D.3. to our consolidated financial statements included at Item 18 of this annual report.

## **Capital Expenditures and Divestitures**

The book value of our property, plant and equipment at December 31, 2008 was 6,961 million. During 2008, we invested 1,359 million (see Note D.3. to the consolidated financial statements) in increasing capacity and improving productivity at our various production and R&D sites.

The Group's principal capital expenditures and divestitures for the years 2008, 2007 and 2006 are set out in this annual report at Item 5. Operating and Financial Review and Prospects Divestments, Acquisitions and Liquidity and Capital Resources and in the notes to the consolidated financial statements (Note D.1. Significant Acquisitions, Note D.2. Significant Divestments and Note D.4. Intangible assets and Goodwill).

Our principal investments in progress are related to:

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

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

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

## **Item 4A. Unresolved Staff Comments**

N/A

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

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

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

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

### **2008 Overview**

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

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

**Table of Contents**

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

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

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

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

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

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

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

Our operations generate significant cash flow. We recorded 8,523 million of net cash provided by operating activities in 2008 against 7,106 million in 2007. In 2004, we incurred significant debt to finance the acquisition of Aventis. As of year end 2008, we have reimbursed substantially all of this debt. In terms of financial position, we ended 2008 with our debt, net of cash and cash equivalents (meaning the sum of short-term debt and long-term debt less cash and cash equivalents) reduced to 1.8 billion (2007: 4.2 billion) despite share repurchases of 1.2 billion and a dividend payout of 2.7 billion in 2008. Debt, net of cash and cash equivalents, is a financial indicator that is used by management and investors to measure the Company's overall net indebtedness and to assess the Company's financing risk as measured by its gearing ratio (debt, net of cash and cash equivalents, to total equity). The gearing ratio improved from 9.5% at the end of 2007 to 3.9% at the end of 2008. See Liquidity and Capital Resources Consolidated Balance Sheet and Debt, below.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

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



**Table of Contents**

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

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

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

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

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

Adjusted net income breaks down as follows:

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

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

- (1) Impact of the acquisition of Symbion Consumer (see Note D.1. to our consolidated financial statements included at Item 18 of this annual report).
- (2) Includes 1,485 million of impairment losses ( 972 million net of tax) on Aventis intangible assets. (see Note D.5. to our consolidated financial statements included at Item 18 of this annual report).
- (3) Includes a gain of 566 million due to the effect of cuts in tax rates (primarily in Germany) on deferred tax liabilities recognized in 2004 on the remeasurement of acquired intangible assets of Aventis.
- (4) Includes the impact of the Zentiva acquisition: 3 million in 2008, and 108 million in 2007 (including 102 million of impairment losses on the investment in Zentiva).
- (5) Includes the impact of the Zentiva acquisition ( 11 million); amortization and impairment (net of tax) associated with the acquisition of Aventis ( 97 million); and reversal of a deferred tax liability relating to the investment in Merial ( 95 million).
- (6) Based on 1,309.3 million shares for 2008, 1,346.9 million shares for 2007 and 1,346.8 million shares for 2006, representing the weighted average number of shares outstanding.

---

**Table of Contents****Sources of Revenues and Expenses**

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

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

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

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

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

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

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

the charges related to the impairment of the goodwill; and

the charges related to the amortization and impairment of intangible assets, net of tax and minority interests.

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

---

## **Table of Contents**

We believe (subject to the material limitations discussed below) that disclosing non-GAAP adjusted net income also enhances the comparability of our ongoing operating performance. The elimination of the non-recurring items, such as the increase in cost of sales arising from the workdown of inventories remeasured at fair value, improves comparability between one period and the next. Lastly, we believe that the elimination of charges related to the amortization of definite-lived intangible assets also enhances the comparability of our ongoing operating performance relative to our peers in the pharmaceutical industry that carry these intangible assets (principally patents and trademarks) at low book values either because they are the result of in-house research and development that has already been expensed in prior periods or because they were acquired through business combinations that were accounted for as poolings-of-interest.

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

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

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

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

There are material limitations associated with the use of non-GAAP adjusted net income as compared to the use of IFRS net income in evaluating our performance, as described below:

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

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

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

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

## **Table of Contents**

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

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

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

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

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

## **Presentation of Net Sales**

In the discussion below, we present our consolidated net sales for 2008, 2007 and 2006. We break down our net sales among various categories, such as by business segment, product and geographic region. We refer to our consolidated net sales as `reported` sales.

In addition to reported sales, we also present and discuss comparable sales, another unaudited non-GAAP indicator that we believe is a useful measurement tool to explain changes in our reported net sales.

When we refer to the change in our net sales on a `comparable` basis, we mean that we exclude the impact of exchange rate fluctuations and changes in our group structure (due to acquisitions and divestitures of entities and rights to products, and changes in the consolidation percentage for consolidated entities). For any two periods, we exclude the impact of exchange rates by recalculating net sales for the earlier period on the basis of exchange rates used in the later period. We exclude the impact of acquisitions by including sales for a portion of the prior period equal to the portion of the current period during which we owned the entity or product rights based on sales information we receive from the party from whom we make the acquisition. Similarly, we exclude sales in the relevant portion of the prior period when we have sold an entity or rights to a product. If there is a change in the consolidation percentage of a consolidated entity, the prior period is recalculated on the basis of the consolidation method used for the current period.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

A reconciliation of our reported net sales to our comparable net sales is provided at Results of Operations Year Ended December 31, 2008 compared with Year Ended December 31, 2007 Net Sales and Results of Operations Year Ended December 31, 2007 compared with Year Ended December 31, 2006 Net Sales below.

### **Financial Presentation of Alliances**

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



## **Table of Contents**

### ***Bristol-Myers Squibb (BMS) Alliance***

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

There are three principal marketing arrangements that are used:

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

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

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

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

*Discovery Royalty.* As inventor of the two molecules, we earn a discovery royalty on all sales of Aprovel® and Plavix® regardless of the marketing system. The discovery royalty is reflected in our consolidated income statement in other revenues.

*Development Royalty.* In addition to the discovery royalty, we and BMS are each entitled to a development royalty related to certain know-how and other intellectual property in connection with sales of Aprovel® and Plavix®. Each legal entity that markets products pays a development royalty. We record development royalties paid to BMS in our consolidated income statement as an increase to our cost of sales in countries where we consolidate sales of the products. We record development royalties that we receive as other revenues in countries where BMS consolidates sales of the products.

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

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

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

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

we have the exclusive right to market Aprovel<sup>®</sup> and Plavix<sup>®</sup> in Eastern Europe, Africa and the Middle East, and we have the exclusive right to market Aprovel<sup>®</sup> in Asia (excluding Japan). Since September 2006, we have had the exclusive right to market Aprovel<sup>®</sup> in Scandinavia and in Ireland.

**Table of Contents**

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

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

we use the co-marketing system in Brazil, Mexico, Argentina and Australia for Plavix<sup>®</sup> and Aprovel<sup>®</sup> and in Colombia for Plavix<sup>®</sup>;

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

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

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

***Procter & Gamble Pharmaceuticals (P&G) Alliance***

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

*Co-promotion*, whereby sales resources are pooled but only one of the two partners invoices product sales. Co-promotion is carried out under contractual agreements and is not based on any specific legal entity. P&G sells the product and incurs all the related costs for the following countries: United States, Canada and France. This co-promotion scheme also included Germany, Belgium and Luxembourg until December 31, 2007 and the Netherlands until March 31, 2008. We recognize our share of income under the agreement in the income statement as a component of operating income on the line Other operating income. In the secondary co-promotion territories (the United Kingdom until December 31, 2008, Ireland, Sweden, Finland, Greece, Switzerland, Austria, Portugal and Australia), we sell the product and recognize all the revenues from sales of the product along with the corresponding expenses in our consolidated income statement;

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

*P&G only territories:* the product has been marketed by P&G independently under the brand name Actonel<sup>®</sup> in Germany, Belgium and Luxembourg since January 1, 2008, in the Netherlands since April 1, 2008 and in the United Kingdom since January 1, 2009; and

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

### **Impact of Exchange Rates**

We report our consolidated financial statements in euros. Because we earn a significant portion of our revenues in countries where the euro is not the local currency, our results of operations can be significantly affected by exchange rate movements between the euro and other currencies, primarily the U.S. dollar and, to a lesser extent, the British pound, the Japanese yen, and currencies in emerging countries. We experience these effects even though certain of these countries do not account for a large portion of our net sales. In 2008, we earned 31.2% of our net sales in the United States. A decrease in the value of the U.S. dollar against the euro has a negative impact on our revenues, which is not offset by an equal reduction in our costs and therefore negatively affects our operating income. A decrease in the value of the U.S. dollar has a particularly significant impact on our operating income, which is higher in the United States than elsewhere, and on the contribution to net income

## **Table of Contents**

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

For a description of positions entered into to manage operational exchange rate risks as well as our hedging policy, see Item 11. Quantitative and Qualitative Disclosures about Market Risk.

## **Divestments**

There were no significant divestments during 2008 and 2007.

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

## **Acquisitions**

The principal acquisitions during 2008 were as follows:

On September 25, 2008, sanofi-aventis completed the acquisition of Acambis plc for £285 million. Acambis plc became Sanofi Pasteur Holding Ltd, a wholly-owned subsidiary of Sanofi Pasteur Holding S.A. This company develops novel vaccines that address unmet medical needs or substantially improve current standards of care. Sanofi Pasteur and Acambis plc were already developing vaccines in a successful partnership of more than a decade: Acambis plc was conducting three of its major projects under exclusive collaboration agreements with sanofi pasteur, for vaccines against dengue, Japanese Encephalitis and West Nile virus. See Note D.4. to our consolidated financial statements included at item 18 of this annual report.

On September 1, 2008, sanofi-aventis completed the acquisition of the Australian company Symbion CP Holdings Pty Ltd (Symbion Consumer) for AUD560 million. Symbion Consumer manufactures, markets and distributes nutraceuticals (vitamins and mineral supplements) and over the counter brands throughout Australia and New Zealand. Symbion Consumer has a portfolio of brands including Natures Own, Cenovis, Bio-organics, Golden Glow and Microgenics. In 2007, Symbion Consumer sales amounted to around AUD190 million. Symbion Consumer is the market leader in Australia, with an estimated 21% market share. See Note D.4. to our consolidated financial statements included at item 18 of this annual report.

The principal acquisition during 2007 was as follows:

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

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

The principal acquisition during 2006 was as follows:

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

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

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

**Table of Contents****Results of Operations***Year Ended December 31, 2008 Compared with Year Ended December 31, 2007*

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

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

*Net Sales*

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

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

<i>( million)</i>	<b>2007</b>
<b>2007 Net Sales</b>	<b>28,052</b>
Impact of changes in Group structure	(393)
Impact of exchange rates	(1,083)
<b>2007 Comparable Net Sales</b>	<b>26,576</b>



**Table of Contents**

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

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

*Net Sales by Product Pharmaceuticals*

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

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

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

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

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

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

Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

**Table of Contents**

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

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

*Top 15 Products <sup>(1)</sup>*

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

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

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

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

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

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

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

**Table of Contents**

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

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

*Net Sales Human Vaccines (Vaccines)*

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

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

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

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

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

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

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

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

( million)

2008

Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

\* Seasonal and pandemic influenza vaccines.

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

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

\* Seasonal and pandemic influenza vaccines.

**Table of Contents**

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

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

*Net Sales by Geographic Region*

We divide our sales geographically into three regions: Europe, the United States and other countries. The following table breaks down our 2008 and 2007 net sales by region:

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

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

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

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

*Worldwide Presence of Plavix® and Aprovel®*

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Two of our leading products Plavix® and Aprove1® were discovered by sanofi-aventis and jointly developed with Bristol-Myers Squibb (BMS) under an alliance agreement. Worldwide, these products are sold by sanofi-aventis and/or BMS under the terms of this agreement which is described in Financial Presentation of Alliances BMS Alliance above, with the exception of Plavixapan which is outside the scope of the alliance.

The worldwide sales of these two products are an important indicator of the global market presence of sanofi-aventis products, and we believe this information facilitates a financial statement user's understanding and analysis of our consolidated income statement, particularly in terms of understanding our overall profitability in relation to consolidated revenues, and also facilitates a user's ability to understand and assess the effectiveness of our research and development efforts.

Also, disclosing sales made by BMS of these two products enables the investor to have a clearer understanding of trends in different lines of our income statement, in particular the lines Other revenues where royalties received on those sales are booked (see Other Revenues ); Share of profit/loss of associates (see Share of Profit/Loss of Associates ) where our share of profit/loss of entities included in the BMS Alliance and under BMS operational management is recorded; and Net income attributable to minority interests (see Net Income Attributable to Minority Interests ) where the BMS share of profit/loss of entities included in the BMS Alliance and under our operational management is recorded.



**Table of Contents**

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

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

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

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

(2) Net sales of Plavix® consolidated by sanofi-aventis, excluding sales to BMS ( 282 million in 2008 and 288 million in 2007).

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

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

(5) Net sales of Aprovel® consolidated by sanofi-aventis, excluding sales to BMS ( 94 million in 2008 and 87 million in 2007).

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

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

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

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

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

## **Table of Contents**

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

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

### *Other Revenues*

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

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

### *Gross Profit*

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

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

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

### *Research and Development Expenses*

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

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

### *Selling and General Expenses*

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

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

**Table of Contents***Other Operating Income and Expenses*

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

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

*Amortization of Intangibles*

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

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

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

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

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

<i>( million)</i>	<b>2008</b>	<b>2007</b>
Pharmaceuticals	5,864	5,509
Vaccines	593	597
<b>Total</b>	<b>6,457</b>	<b>6,106</b>

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

( million)	2008	2007
Europe	5,001	4,742
United States	4,718	4,952
Other countries	2,454	2,173
Unallocated costs <sup>(1)</sup>	(5,716)	(5,761)
<b>Total <sup>(2)</sup></b>	<b>6,457</b>	<b>6,106</b>

<sup>(1)</sup> Unallocated costs consist mainly of fundamental research and worldwide development of pharmaceutical molecules, and part of the cost of support functions.

<sup>(2)</sup> After charges for amortization of intangible assets of 3,483 million in 2008 and 3,654 million in 2007.

## **Table of Contents**

### *Restructuring Costs*

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

### *Impairment of Property, Plant & Equipment and Intangibles*

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

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

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

### *Gains and Losses on Disposals, and Litigation*

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

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

### *Operating Income*

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

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

### *Financial Income and Expenses*

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

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

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

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

### *Income before Tax and Associates*

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

### *Income Tax Expense*

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



## **Table of Contents**

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

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

### *Share of Profit/Loss of Associates*

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

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

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

### *Net Income*

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

### *Net Income Attributable to Minority Interests*

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

### *Net Income Attributable to Equity Holders of the Company*

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

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

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

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

**Table of Contents***Adjusted Net Income*

Adjusted net income breaks down as follows:

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

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

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

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

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

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

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

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

<i>( million)</i>	<b>2008</b>	<b>2007</b>
Pharmaceuticals	6,455	6,501
Vaccines	613	609
<b>Total adjusted net income</b>	<b>7,068</b>	<b>7,110</b>

*Adjusted Earnings Per Share*

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

**Table of Contents****Year Ended December 31, 2007 Compared with Year Ended December 31, 2006**

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

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

*Net Sales*

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

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

Edgar Filing: SANOFI-AVENTIS - Form 20-F

<i>( million)</i>	<b>2006</b>
<b>2006 Net Sales</b>	<b>28,373</b>
Impact of changes in Group structure	(15)
Impact of exchange rates	(1,069)
<b>2006 Comparable Net Sales</b>	<b>27,289</b>

**Table of Contents**

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

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

*Net Sales by Product Pharmaceuticals*

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

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

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

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

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

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

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Breast, lung, prostate,  
head and neck\*

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

\* From 2007.



**Table of Contents**

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

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

*Top 15 Products <sup>(1)</sup>*

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

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

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

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

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

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

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

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

Net sales of Acomplia<sup>®</sup> totaled 79 million in 2007.

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

**Table of Contents**

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

*Net Sales Human Vaccines (Vaccines)*

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

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

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

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

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

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

\* Seasonal and pandemic influenza vaccines.

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

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

( million) **Europe**

Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

\* Seasonal and pandemic influenza vaccines.

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

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

(1) Internal estimate

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

We divide our sales geographically into three regions: Europe, the United States and other countries. The following table breaks down our 2007 and 2006 net sales by region:

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

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

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

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

*Worldwide Presence of Plavix<sup>®</sup> and Aprovel<sup>®</sup>*

Two of our leading products Plavix<sup>®</sup> and Aprovel<sup>®</sup> were discovered by sanofi-aventis and jointly developed with Bristol-Myers Squibb (BMS) under an alliance agreement. Worldwide, these products are sold by sanofi-aventis and/or BMS under the terms of this agreement which is described in Financial Presentation of Alliances BMS Alliance .

The worldwide sales of these two products are an important indicator of the global market presence of sanofi-aventis products, and we believe this information facilitates a financial statement user's understanding and analysis of our consolidated income statement, in particular in terms of understanding our overall profitability in relation to consolidated revenues, and also facilitates a user's ability to understand and assess the effectiveness of our research and development efforts.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Also, disclosing sales made by BMS of these two products enables the investor to have a clearer understanding of trends in different lines of our income statement, in particular the lines "Other revenues" where royalties received on those sales are booked (see "Other Revenues"); "Share of profit/loss of associates" (see "Share of Profit/Loss of Associates") where our share of profit/loss of entities included in the BMS Alliance and under BMS operational management is recorded; and "Net income attributable to minority interests" (see "Minority Interests") where the BMS share of profit/loss of entities included in the BMS Alliance and under our operational management is recorded.

**Table of Contents**

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

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

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

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

(2) Net sales of Plavix® consolidated by sanofi-aventis, excluding sales to BMS ( 288 million in 2007 and 279 million in 2006).

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

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

(5) Net sales of Aprovel® consolidated by sanofi-aventis, excluding sales to BMS ( 87 million in 2007 and 104 million in 2006).

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

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

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

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

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

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



## **Table of Contents**

### *Other Revenues*

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

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

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

### *Gross Profit*

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

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

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

### *Research and Development Expenses*

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

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

*Selling and General Expenses*

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

*Other Operating Income and Expenses*

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

*Amortization of Intangibles*

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

**Table of Contents**

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

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

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

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

( million)	2007	2006
Pharmaceuticals	5,509	5,217
Vaccines	597	512
<b>Total</b>	<b>6,106</b>	<b>5,729</b>

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

( million)	2007	2006
Europe	4,742	4,603
United States	4,952	4,560
Other countries	2,173	2,082
Unallocated costs <sup>(1)</sup>	(5,761)	(5,516)
<b>Total <sup>(2)</sup></b>	<b>6,106</b>	<b>5,729</b>

<sup>(1)</sup> Unallocated costs consist mainly of fundamental research and worldwide development of pharmaceutical molecules, and part of the cost of support functions.

<sup>(2)</sup> After charges for amortization of intangible assets of 3,654 million in 2007 and 3,998 million in 2006.

*Restructuring Costs*

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

*Impairment of Property, Plant & Equipment and Intangibles*

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

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

*Gains and Losses on Disposals, and Litigation*

We made no major asset disposals during 2007.

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

## **Table of Contents**

### *Operating Income*

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

### *Financial Income and Expenses*

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

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

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

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

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

### *Income before Tax and Associates*

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

### *Income Tax Expense*

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

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

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

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

*Share of Profit/Loss of Associates*

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

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

*Net Income*

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

**Table of Contents***Net Income Attributable to Minority Interests*

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

*Net Income Attributable to Equity Holders of the Company*

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

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

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

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

*Adjusted Net Income*

Adjusted net income breaks down as follows:

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

<b>Adjusted earnings per share (in euro) <sup>(1)</sup></b>	<b>5.28</b>	<b>5.23</b>
---	-------------	-------------

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

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

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

<i>( million)</i>	<b>2007</b>	<b>2006</b>
Pharmaceuticals	6,501	6,479
Vaccines	609	561
<b>Total adjusted net income</b>	<b>7,110</b>	<b>7,040</b>



## **Table of Contents**

### *Adjusted Earnings Per Share*

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

### **Liquidity and Capital Resources**

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

### *Consolidated Statement of Cash Flows*

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

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

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

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

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

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

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

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

**Table of Contents****Consolidated Balance Sheet and Debt**

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

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

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

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

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

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

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

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

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

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

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

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

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

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

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

**Table of Contents**

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

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

***Liquidity***

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

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

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

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

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

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

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Irrevocable purchase commitments <sup>(2)</sup> :					
given	2,575	1,666	390	131	388
received	(278)	(126)	(64)	(27)	(61)
Other commercial commitments	2,624	128	424	323	1,749
Commitment related to Zentiva offer	1,226	1,226			
<b>Total contractual obligations and other commitments</b>	<b>13,823</b>	<b>5,133</b>	<b>3,279</b>	<b>2,629</b>	<b>2,782</b>
<b>Undrawn credit facilities<sup>(3)</sup></b>	<b>10,768</b>	<b>68</b>	<b>4,027</b>	<b>6,673</b>	

(1) A breakdown of debt is provided in Note D.17.g) to our consolidated financial statements included at Item 18 of this annual report, and a breakdown of obligations under finance leases is provided below.

(2) These comprise irrevocable commitments to suppliers of (i) property, plant and equipment, net of down payments (see Note D.3.) and (ii) goods and services.

(3) For details of confirmed credit facilities, see Note D.17.c).

## Table of Contents

We may have payments due to our current or former research and development partners under collaborative agreements. These agreements typically cover multiple products, and give us the option to participate in development on a product-by-product basis. When we exercise our option with respect to a product, we pay our collaboration partner a fee and receive intellectual property rights to the product in exchange. We also are generally required to fund some or all of the development costs for the products that we select, and to make payments to our partners when those products reach development milestones.

We have entered into collaboration agreements under which we have rights to acquire products or technology from third parties through the acquisition of shares, loans, license agreements, joint development, co-marketing and other contractual arrangements. In addition to upfront payments on signature of the agreement, our contracts frequently require us to make payments contingent upon the completion of development milestones by our alliance partner or upon the granting of approvals or licenses.

Because of the uncertain nature of development work, it is impossible to predict (i) whether sanofi-aventis will exercise further options for products, or (ii) whether the expected milestones will be achieved, or (iii) the number of compounds that will reach the relevant milestones. It is therefore impossible to estimate the maximum aggregate amount that sanofi-aventis will actually pay in the future under existing collaboration agreements.

Given the nature of its business, it is highly unlikely that sanofi-aventis will exercise all options for all products or that all milestones will be achieved.

The main collaborative agreements in the Pharmaceuticals segment are described below.

On December 22, 2008, sanofi-aventis announced the signature of a global licensing and collaboration agreement with Novozymes for the development and commercialization of a new antibiotic named plectasin NZ2114 that targets the treatment of severe infections such as pneumonia and septicemia. Under the terms of the agreement, sanofi-aventis was granted an exclusive worldwide license for the development, registration, and commercialization of the drug. The two companies will work jointly to develop and implement industrial-scale manufacturing of the plectasin NZ2114 drug substance, using a recombinant process that builds on Novozyme's proprietary expression technology. Future milestone payments under the agreement could reach up to \$64 million.

On February 12, 2008, sanofi-aventis and Dyax Corp. entered into agreements that granted sanofi-aventis an exclusive worldwide license for the development and commercialization of Dyax's fully human monoclonal antibody DX-2240, as well as a worldwide non-exclusive license to Dyax's proprietary Phage Display technology. Under the terms of the two agreements, Dyax could receive up to \$270 million in license fees and milestone payments, in the event of full commercial success in three indications for the DX-2240 project under development, and in one indication for the first antibody candidates developed by sanofi-aventis alone using the Phage Display technology.

On March 28, 2007, sanofi-aventis and Oxford BioMedica announced that they had entered into an exclusive global license agreement to develop and commercialize TroVax<sup>®</sup> for the treatment and prevention of cancers. Future milestone payments could reach up to 450 million. Oxford BioMedica will be entitled to escalating royalties on global sales of TroVax<sup>®</sup>, and to sales milestone payments if and when net sales of TroVax<sup>®</sup> reach certain levels.

In September 2003, sanofi-aventis signed a collaboration agreement with Regeneron in oncology to develop the Vascular Endothelial Growth Factor (VEGF) Trap program. Development milestone payments and royalties on VEGF Trap sales are payable under the contract. Total milestone payments could reach \$400 million if all indications specified in the contract obtain approval in the United

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

States, Europe and Japan. Sanofi-aventis will pay 100% of the development costs of the VEGF Trap. Once a VEGF Trap product starts to be marketed, Regeneron will repay 50% of the development costs (originally paid by sanofi-aventis) in accordance with a formula based on Regeneron's share of the profits, including royalties received in Japan. In 2005, the VEGF Trap program was extended to Japan, and the treatment of ocular pathologies was excluded from the scope of the collaboration agreement.

In November 2007, sanofi-aventis signed a further collaboration agreement with Regeneron to discover, develop and commercialize fully-human therapeutic antibodies.



---

**Table of Contents**

Under the terms of the research agreement, the Group will fund up to \$416 million of research over the next five years. Sanofi-aventis will have an option to extend the research agreement for an additional three years. Under the terms of the development agreement, sanofi-aventis will fund 100% of the development costs. Once a product begins to be marketed, Regeneron will repay out of its profits (provided they are sufficient) half of the development costs borne by sanofi-aventis.

In addition, Regeneron will be entitled to receive up to a total of \$250 million of sales milestone payments when the collaboration achieves certain aggregate annual excluding U.S. sales levels.

A collaboration agreement with IDM was signed in 2001. Under this agreement, IDM granted sanofi-aventis 20 development options on current and future research and development programs. For each option that leads to a commercially marketed product, IDM could receive between 17 million and 32 million depending on the potential of the market, plus reimbursement of the development costs. Contractually, sanofi-aventis may suspend the development program for each option exercised at any time and without penalty. In 2007, sanofi-aventis decided to suspend the development program for the treatment of melanoma, the only program for which it has exercised its option since the collaboration agreement with IDM was signed. At December 31, 2008, sanofi-aventis still had an option on 6 programs.

Under a collaboration agreement with Zealand Pharma signed in June 2003, sanofi-aventis obtained rights relating to the development and worldwide marketing of ZP10, an agent used in the treatment of type 2 diabetes. Under this agreement, sanofi-aventis is responsible for the development of this compound. Payments to Zealand Pharma could reach a total of \$85 million, contingent upon marketing approvals being obtained.

Under a co-promotion agreement with UCB, signed in September 2006, sanofi-aventis co-promotes Xyzal<sup>®</sup> in the United States jointly with UCB. Xyzal<sup>®</sup> is a prescription antihistamine. The agreement requires payments to be made on attainment of development and marketing milestones, based on regulatory approvals and sales targets. Total future payments under the agreement could reach \$130 million. The agreement also specifies how profits are split between sanofi-aventis and UCB.

Sanofi-aventis has entered into various other collaboration agreements with partners including Immunogen, Coley, Wayne State University, Innogenetics and Inserm, under which sanofi-aventis may be required to make total contingent payments of approximately 31 million over the next five years.

In 2008, sanofi-aventis returned its territory rights for the development and commercialization of the oral anti-cancer agent S-1 to Taiho Pharmaceutical Co., Ltd. As from the termination date, the milestone payments specified in this agreement no longer constitute commercial commitments. As of December 31, 2007, they represented a commitment of \$295 million.

The main collaborative agreements in the Vaccines segment are described below:

Following the acquisition of Acambis plc by sanofi pasteur during 2008, the agreements previously signed with Acambis (vaccines against Japanese encephalitis, West Nile virus and dengue fever) have been integrated into the Group's pipeline. These agreements represented future milestone payments of 57 million as of December 31, 2007.

In December 2007, sanofi pasteur signed an exclusive collaboration and commercialization agreement with Crucell N.V. for Crucell's rabies monoclonal antibodies. Under the terms of the agreement, Crucell will continue to develop and manufacture the product. The contract includes milestone payments that could reach \$53 million.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Sanofi Pasteur has entered into a number of other collaboration agreements with partners including Becton Dickinson, Crucell, Intercell, Vactech, Maxigen and SSI, under which sanofi pasteur may be required to make total contingent payments of around 52 million over the next five years.

### **Critical accounting and reporting policies**

Our consolidated financial statements are affected by the accounting and reporting policies that we use. Certain of our accounting and reporting policies are critical to an understanding of our results of operations and financial condition, and in some cases the application of these critical policies can be significantly affected by the

**Table of Contents**

estimates, judgments and assumptions made by management during the preparation of our consolidated financial statements. The accounting and reporting policies that we have identified as fundamental to a full understanding of our results of operations and financial condition are the following:

**Revenue recognition.** Our policies with respect to revenue recognition are discussed in Note B.14. to our consolidated financial statements included at Item 18 of this annual report. Revenue arising from the sale of goods is presented in the income statement under Net sales . Net sales comprise revenue from sales of pharmaceutical products, vaccines, and active ingredients, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities. Revenue is recognized when all of the following conditions have been met: the risks and rewards of ownership have been transferred to the customer; the Group no longer has effective control over the goods sold; the amount of revenue and costs associated with the transaction can be measured reliably; and it is probable that the economic benefits associated with the transaction will flow to the Group.

We offer various types of price reductions on our products. In particular, products sold in the United States are covered by various programs (such as Medicare and Medicaid) under which products are sold at a discount. Rebates are granted to healthcare authorities, and under contractual arrangements with certain customers. Some wholesalers are entitled to chargeback incentives based on the selling price to the end customer, under specific contractual arrangements. Cash discounts may also be granted for prompt payment. The discounts, incentives and rebates described above are estimated on the basis of specific contractual arrangements with our customers or of specific terms of the relevant regulations and/or agreements applicable for transactions with healthcare authorities, and of assumptions of the attainment of sales targets. They are recognized in the period in which the underlying sales are recognized, as a reduction of sales revenue. We also estimate the amount of product returns, on the basis of contractual sales terms and reliable historical data; the same recognition principles apply to sales returns. For additional details regarding the financial impact of discounts, rebates and sales returns see Note D.23. to our consolidated financial statements included at Item 18 of this annual report.

Non-product revenues, mainly comprising royalty income from license arrangements that constitute ongoing operations of the Group, are presented in Other revenues .

**Impairment Testing of Intangible Assets and Goodwill.** As discussed in Note B.6. (Impairment of property, plant and equipment, goodwill, intangible assets, and investments in associates) and in Note D.5. (Impairment of property, plant and equipment, goodwill and intangibles) to our consolidated financial statements included at Item 18 of this annual report, we test our intangible assets periodically for impairment. The most significant intangible assets that we test for impairment are those resulting from the business combination of Sanofi-Synthélabo and Aventis in 2004. We test for impairment on the basis of the same objective criteria that were used for the initial valuation. Our initial valuation and ongoing tests are based on the relationship of the value of our projected future cash flows associated with the asset to either the purchase price of the asset (for its initial valuation) or the carrying amount of the asset (for ongoing tests). The determination of the underlying assumptions related to the recoverability of intangible assets is subjective and requires the exercise of considerable judgment. Any changes in key assumptions about our business and prospects, or changes in market conditions, could result in an impairment charge.

**Pension and Retirement Benefits.** As described in Note B.23. (Employee Benefit Obligations) to our consolidated financial statements included at Item 18 of this annual report, we recognize our pension and retirement benefit commitments as liabilities on the basis of an actuarial estimate of the potential rights vested in employees and retirees as of the balance sheet date, net of the valuation of funds to meet these obligations. We prepare this estimate at least on an annual basis, taking into account actuarial assumptions, including life expectancy, staff turnover, salary growth, long-term return on plan assets, retirement and discounting of amounts payable. Depending on the assumptions and estimates used, the pension and post-retirement benefit expense could vary within a range of outcomes and have a material effect on reported earnings.

**Deferred Taxes.** As discussed in Note B.22. (Income tax expense) to our consolidated financial statements included at Item 18 of this annual report, we account for deferred taxes using the liability method, whereby deferred income taxes are recognized on tax loss

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

carry-forwards, and on the difference between the tax base and carrying amount of assets and liabilities. We calculate our deferred tax assets and liabilities using enacted tax rates applicable for the years during which we estimate that the

**Table of Contents**

temporary differences are expected to reverse. We do not record deferred tax assets when it is more likely than not that the deferred tax assets will not be realized. The estimates of recognized deferred tax assets are based on our assumptions regarding future profits and the timing of reversal of temporary differences. These assumptions are regularly reviewed; however, final deferred income tax could differ from those estimates.

**Provisions for risks.** Sanofi-aventis and its subsidiaries and affiliates may be involved in litigation, arbitration or other legal proceedings. These proceedings typically are related to product liability claims, intellectual property rights, compliance and trade practices, commercial claims, employment and wrongful discharge claims, tax assessment claims, waste disposal and pollution claims, and claims under warranties or indemnification arrangements relating to business divestitures. As discussed in Note B.12. (Provisions for risks) at Item 18 of this annual report, we record a provision where we have a present obligation, whether legal or constructive, as a result of a past event; when it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation; and when a reliable estimate can be made of the amount of the outflow of resources. For additional details regarding the financial impact of provisions for risks see Notes D.18.3. (Other provisions) and D.22. (Legal and Arbitral Proceedings) to our consolidated financial statements included at Item 18 of this annual report.

Provisions are estimated on the basis of events and circumstances related to present obligations at the balance sheet date, of past experience, and to the best of management's knowledge at the date of preparation of the financial statements. The assessment of provisions can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions. Given the inherent uncertainties related to these estimates and assumptions, the actual outflows resulting from the realization of those risks could differ from our estimates.

## **Table of Contents**

### **Item 6. Directors, Senior Management and Employees**

#### **A. Directors and Senior Management**

Since January 1, 2007, the office of Chairman has been separated from that of the Chief Executive Officer. The decision to separate the two offices was motivated by the need for effective succession planning at senior management level, in order to safeguard the dynamism and continuity of our corporate culture.

The Board of Directors, at its meeting of September 10, 2008, decided that the time was right for a change in strategic direction and hence for a change at senior management level. The Board therefore decided to appoint Christopher Viehbacher as Chief Executive Officer in place of Gérard Le Fur, effective December 1, 2008. The Board also set out three strategic imperatives for senior management:

the research and development of major innovative products, which remains one of the indispensable drivers of growth, must be better adapted to the new regulatory and economic constraints of the market;

the strong positions of the Group and its momentum in emerging markets must be significantly reinforced;

the development of other activities related to medicines and Healthcare must be actively continued.

The **Chairman** represents the Board of Directors. He organizes and directs the work of the Board, and is accountable for this to the Shareholders General Meeting. He is also responsible for ensuring that the corporate decision-making bodies chaired by him (Board of Directors and Shareholders General Meeting) operate properly.

If the offices of Chairman and Chief Executive Officer are separated, the Chairman may remain in office until the Ordinary General Meeting called to approve the financial statements and held during the calendar year in which he reaches the age of 70.

The **Chief Executive Officer** is responsible for the management of the Company, and represents it in dealings with third parties. He has the broadest powers to act in the name of the Company.

The Chief Executive Officer must be less than 65 years old.

Limits placed by the Board on the powers of the Chief Executive Officer.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

The Board of Directors has placed the following limits on the powers of the Chief Executive Officer to commit the Group in respect of investments and acquisitions:

a limit of 500 million for commitments made within a previously-approved strategy; and

a limit of 150 million for commitments made outside an approved strategy.

### ***Board of Directors***

Sanofi-aventis is administered by a Board of Directors with sixteen members.

The Shareholders' Annual General Meeting of May 14, 2008 appointed four new directors and reappointed nine existing directors. The terms of office of these directors were staggered, such that in each year from 2010 to 2012 one-third of the Board will be required to seek re-election each year.

The Board meeting of April 29, 2008 discussed the issue of director independence, subject to the decision on the appointment and reappointment of directors at the Shareholders' Annual General Meeting held on May 14, 2008. Out of the sixteen directors, eight were regarded as independent: Uwe Bicker, Jean-Marc Bruel, Lord Douro, Jean-René Fourtou, Claudie Haigneré, Klaus Pohle, Gunter Thielen and Gérard Van Kemmel.

A director is regarded as independent if he or she has no relationship of any kind with the Company, the Group or its management that is liable to impair his or her judgment. It is the responsibility of the Board, acting upon the recommendation of the Appointments and Governance Committee, to assess the independence of its members.

No more than one-third of the serving members of our Board of Directors may be aged more than 70.

**Table of Contents**

Subject to the authority expressly reserved by law to Shareholders' General Meetings and within the scope of the corporate objects, the Board of Directors deals with and takes decisions upon all issues relating to the proper management of the Company and other matters concerning the Board.

**Composition of the Board of Directors at December 31, 2008**

<b>Jean-François Dehecq</b>	Age	<i>69</i>
Chairman of the Board of Directors	Nationality	<i>French</i>
Director	First elected	<i>May 1999</i>
	Last reappointment	<i>May 2008</i>
	Term as director expires	<i>2011</i>
395,469 shares	Other directorships and appointments	
	Chairman of Policy Committee of the French Strategic Investment Fund	
	Director of Air France, Agence Nationale de la Recherche and Veolia Environnement	
	Member of IFPMA (International Federation of Pharmaceutical Manufacturers Associations)	
	Chairman of Association Nationale de la Recherche Technique	
	Chairman of the Board of Directors of ENSAM (Ecole Nationale Supérieure d'Arts et Métiers)	
	Member of Fondation Française pour la Recherche sur l'Epilepsie	
<b>Christopher Viehbacher</b>	Age	<i>48</i>
Chief Executive Officer	Nationalities	<i>German and Canadian</i>
Director	First elected	<i>December 2008</i>
	Term as director expires	<i>2010</i>
10,000 shares acquired in February 2009	Other directorships and appointments	
	Member of the Board of Directors of Health Leadership Council (United States), Research America (United States) and Burroughs Wellcome Fund (United States)	
	Member of Advisory Council of Center for Healthcare Transformation (United States)	
	Member of the Board of Visitors of Fuqua School of Business, Duke University (United States)	
<b>Uwe Bicker</b>	Age	<i>63</i>
Independent Director	Nationality	<i>German</i>



Edgar Filing: SANOFI-AVENTIS - Form 20-F

	First elected	<i>May 2008</i>
	Term expires	<i>2012</i>
300 shares	Other directorships and appointments	
	Chairman of the Supervisory Board of Dade Behring Holding GmbH (Germany)	
	Vice Chairman of the Supervisory Board of Epigenomics AG (Germany)	
	Member of the Supervisory Boards of Future Capital AG (Germany) and Definiens AG (Germany)	
	Director of Fondation Aventis (Foundation, Germany)	
	Chairman of the Board of Marburg University (Germany)	
	Member of the Board of Trustees of Bertelsmann Stiftung (Bertelsmann Foundation, Germany)	
<b>Jean-Marc Bruel</b>	Age	<i>73</i>
Independent Director	Nationality	<i>French</i>
	First elected	<i>August 2004</i>
	Last reappointment	<i>May 2008</i>
	Term expires	<i>2010</i>
7,958 shares	Other directorships and appointments	
	Director of Institut Curie and Villette Entreprise	

**Table of Contents**

<b>Robert Castaigne</b>	Age	62
Director	Nationality	<i>French</i>
	First elected	<i>February 2000</i>
	Last reappointment	<i>May 2008</i>
	Term expires	<i>2010</i>
500 shares	Other directorships and appointments	
	Director of Vinci, Société Générale since January 20, 2009 and Compagnie Nationale à Portefeuille (Belgium)	
	Chief Financial Officer of Total S.A. until May 31, 2008	
<b>Patrick de La Chevardière</b>	Age	52
Director	Nationality	<i>French</i>
	First elected	<i>May 2008</i>
	Term expires	<i>2012</i>
500 shares	Other directorships and appointments	
	Chief Financial Officer and member of the Executive Committee of Total S.A. since June 2008	
	Chairman and Chief Executive Officer of Total Chimie	
	Chairman of Total Nucléaire	
	Director of Elf Aquitaine, Total Gabon, Total Upstream UK Ltd, Omnium Insurance & Reinsurance Company Ltd (Bermuda), Total Oil Trading S.A. (Switzerland), Total International Ltd (Bermuda) and Socap International Ltd (Bermuda)	
<b>Thierry Desmarest</b>	Age	63
Director	Nationality	<i>French</i>
	First elected	<i>February 2000</i>
	Last reappointment	<i>May 2008</i>
	Term expires	<i>2011</i>
500 shares	Other directorships and appointments	
	Chairman of the Board of Directors and Chairman of the Appointment and Governance Committee of Total S.A.	
	Chairman of Fondation Total (Foundation)	
	Director and member of the Appointments Committee and the Compensation Committee of L Air Liquide	
	Director and member of the Compensation Committee of Renault SA	

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Director of Renault SAS, Bombardier Inc. (Toronto Canada) since January 21, 2009 and Musée du Louvre

Member of the Supervisory Board of Areva

Member of the Board of Directors of AFEP and Ecole Polytechnique

Chairman of Fondation de l' Ecole Polytechnique (Foundation)

<b>Lord Douro</b>	Age	<i>63</i>
Independent Director	Nationality	<i>British</i>
	First elected	<i>May 2002</i>
	Last reappointment	<i>May 2006</i>
	Term expires	<i>2010</i>

550 shares

Other directorships and appointments

Chairman of Richemont Holdings UK Ltd and Kings College London (United Kingdom)

Director of Pernod Ricard, Compagnie Financière Richemont AG (Switzerland), Abengoe Bioenergy (Spain) and GAM Worldwide (United Kingdom)

Senior Advisor of Calyon (United Kingdom)

Member of the Compensation Committee and the Appointments Committee of Pernod Ricard

Member of the Appointments Committee of Compagnie Financière Richemont AG (Switzerland)

**Table of Contents**

<b>Jean-René Fourtou</b>	Age	<i>69</i>
Independent Director	Nationality	<i>French</i>
	First elected	<i>August 2004</i>
	Last reappointment	<i>May 2008</i>
	Term expires	<i>2012</i>
2,891 shares	Other directorships and appointments	
	Chairman of the Supervisory Boards of Vivendi and Groupe Canal +	
	Member of the Supervisory Boards of Axa and Maroc Telecom	
	Director of Cap Gemini SA, Axa Millésimes SAS, Nestlé (Switzerland) and NBC Universal Inc. (United States),	
<b>Claudie Haigneré</b>	Age	<i>51</i>
Independent Director	Nationality	<i>French</i>
	First elected	<i>May 2008</i>
	Term expires	<i>2012</i>
500 shares	Other directorships and appointments	
	Vice President of the IAA (International Academy of Astronautics)	
	Advisor to the Director General of the ESA (European Space Agency)	
	Director of France Telecom, Cité des Sciences et de l' Industrie, Aéro-Club de France, and of Fondation de France, Fondation CGénial and Fondation d' Entreprise L' Oréal (Foundations)	
	Member of the Académie des Technologies, the Académie des Sports and the Académie Nationale de l' Air et de l' Espace	
<b>Igor Landau</b>	Age	<i>64</i>
Director	Nationality	<i>French</i>
	First elected	<i>August 2004</i>
	Last reappointment	<i>May 2008</i>
	Term expires	<i>2011</i>
11,693 shares	Other directorships and appointments	
	Director of HSBC France and INSEAD	
	Member of the Supervisory Boards of Allianz AG (Germany) and Adidas (Germany)	

Edgar Filing: SANOFI-AVENTIS - Form 20-F

**Christian Mulliez**

Age 48

Director

Nationality *French*

First elected *June 2004*

Last reappointment *May 2008*

Term expires *2010*

1,013 shares

Other directorships and appointments

Vice President, General Manager Administration and Finance of L Oréal

Chairman of the Board of Directors of Regefi

Director of DG 17 Invest, L Oréal USA Inc. and The Body Shop International (United Kingdom)

**Lindsay Owen-Jones**

Age 63

Director

Nationality *British*

First elected *May 1999*

Last reappointment *May 2008*

Term expires *2012*

15,000 shares

Other directorships and appointments

Chairman of the Board of Directors of L Oréal

Chairman of the Strategy Committee of L Oréal

Chairman of the Board of Directors of Fondation d Entreprise L Oréal (Foundation)

Chairman of Alba Plus, L Oréal UK Ltd and L Oréal USA Inc.

Vice Chairman of the Board of Directors of L Air Liquide

Director of Ferrari S.p.A. (Italia)

**Table of Contents**

<b>Klaus Pohle</b>	Age	71
Independent Director	Nationality	<i>German</i>
	First elected	<i>August 2004</i>
	Last reappointment	<i>May 2008</i>
	Term expires	<i>2012</i>
2,500 shares	Other directorships and appointments	
	Director of Labelux Group GmbH (Austria)	
	Director and Chairman of the Audit Committee of Coty Inc., New York	
	Member of the Supervisory Board and Chairman of the Audit Committee of DWS Investment GmbH, Frankfurt (Germany)	
<b>Gunter Thielen</b>	Age	66
Independent Director	Nationality	<i>German</i>
	First elected	<i>May 2008</i>
	Term expires	<i>2011</i>
500 shares	Other directorships and appointments	
	Chairman of the Supervisory Boards of Bertelsmann AG (Germany), Sixt AG (Germany) and Sixt Allgemeine Leasing GmbH (Germany)	
	Member of the Supervisory Boards of Leipziger Messe (Germany) and Groupe Bruxelles Lambert (Belgium)	
	Chairman of the Executive Board of Bertelsmann Stiftung AG (Foundation, Germany)	
<b>Gérard Van Kemmel</b>	Age	69
Independent Director	Nationality	<i>French</i>
	First elected	<i>May 2003</i>
	Last reappointment	<i>May 2007</i>
	Term expires	<i>2011</i>
500 shares	Other directorships and appointments	
	Director of Groupe Eurotunnel, Europacorp and Eurotunnel NRS Holders Company Limited (United Kingdom)	
	Member of the Audit Committee of Europacorp	

During 2008, the Board of Directors met eight times, with an overall attendance rate among Board members of 92%.

*Executive Committee*

The Executive Committee is chaired by the Chief Executive Officer.

The Committee meets twice a month, and has the following permanent members:

**Christopher Viehbacher**, Chief Executive Officer;

**Marc Cluzel**, Senior Vice President Research & Development;

**Laurence Debroux**, Senior Vice President Chief Strategic Officer, Senior Vice President Chief Financial Officer;

**Gilles Lhernould**, Senior Vice President Human Resources;

**Karen Linehan**, Senior Vice President Legal Affairs and General Counsel;

**Philippe Luscan**, Senior Vice President Industrial Affairs; and

**Hanspeter Spek**, Executive Vice President Pharmaceutical Operations.

## **Table of Contents**

### ***Management Committee***

The Management Committee is chaired by the Chief Executive Officer.

At the beginning of March 2009, the Management Committee comprised:

#### ***Christopher Viehbacher***

##### **Chief Executive Officer**

Chairman of the Management Committee

Chairman of the Executive Committee

since December 1, 2008

Age: 48

Christopher Viehbacher is both a graduate in Commerce of the Queens University (Ontario Canada) and a certified public accountant. After beginning his career at Price Waterhouse, he spent the major part of his professional life (1988-2008) in the GlaxoSmithKline (GSK) company where he acquired broad international experience in different positions across Europe, in the United States and Canada. In his last position, he was President Pharmaceutical Operations North America, Co-Chairman of the Portfolio Management Board and a member of the Board of Directors of GSK plc. He was appointed to his present position effective December 2008.

#### ***Hanspeter Spek***

Member of the Management Committee

##### **Executive Vice President Pharmaceutical Operations**

Member of the Executive Committee

Age: 59

Hanspeter Spek graduated from business school in Germany. In 1974, he completed a management training program at Pfizer International, and then joined Pfizer RFA as a junior product manager. He served in various positions at Pfizer RFA, including as manager of the marketing division. Mr. Spek joined Sanofi Pharma GmbH, a German subsidiary of Sanofi, in 1985 as Marketing Director, and served in various positions in Germany and then at Sanofi in France, before being named Senior Vice President Europe following the merger with Synthélabo in 1999. He served as Executive Vice President, International Operations from October 2000, until January 2003, when he was named in charge of worldwide operations of Sanofi-Synthélabo. He was appointed to his present position in August 2004.



***Pierre Chancel***

Member of the Management Committee

**Senior Vice President Global Marketing & Access**

Age: 52

Pierre Chancel, a pharmacist, is a graduate of the *Institut de Pharmacie Industrielle* in Paris. At Rhône-Poulenc, from 1994 to 1996, he was Marketing Director for Théraplix. From 1997 to 1999, Mr. Chancel served as Business Unit Manager in charge of products in the central nervous system, rheumatology and hormone replacement therapy fields. From 2003, he served as Managing Director of Aventis Operations in the United Kingdom and Ireland. Before being appointed to this position, he was in charge of global strategy development at Aventis, which led to the launch of the new diabetes treatment Lantus®. He was appointed to his present position in August 2004.

***Olivier Charmeil***

Member of the Management Committee

**Senior Vice President Pharmaceutical Operations, Asia / Pacific & Japan**

Age: 46

Olivier Charmeil is a graduate of HEC (*Ecole des Hautes Etudes Commerciales*) and of the *Institut d Etudes Politiques* in Paris. From 1989 to 1994, he worked in the Mergers & Acquisitions department of Banque de l Union européenne. He joined Sanofi Pharma in 1994 as head of Business Development. Subsequently, he held various posts within the Group, including Chief Financial Officer (Asia) for Sanofi-Synthélabo in 1999 and *Attaché* to the Chairman, Jean-François Dehecq, in 2000, before being appointed as Vice President, Development

## **Table of Contents**

within the Sanofi-Synthélabo International Operations Directorate, where he was responsible for China and support functions. In 2003, Olivier Charmeil was appointed Chairman and Chief Executive Officer of Sanofi-Synthélabo France, before taking the post of Senior Vice President, Business Management and Support within the Pharmaceutical Operations Directorate. In this role, he piloted the operational integration of Sanofi-Synthélabo and Aventis. He was appointed to his current position in February 2006. Since January 1, 2008, Operations Japan have reported to Olivier Charmeil.

### ***Marc Cluzel***

Member of the Management Committee

### **Senior Vice President Research & Development**

Member of the Executive Committee

Age: 53

Marc Cluzel is a Doctor of Medicine and a Doctor of Science. He began his career in hospital medicine before carrying out research at Johns Hopkins University (Baltimore) and Guy's Hospital (London). In 1991, he joined Sanofi Recherche as a clinical pharmacologist, and was then appointed successively as Senior Project Director in 1993, Vice President, Research Projects Management in 1996 (retaining this position after the 1999 merger with Synthélabo) and Vice President, International Development in 2001 (retaining this position after the 2004 merger with Aventis). Marc Cluzel was appointed to his current position in January 2007.

### ***Laurence Debroux***

Member of the Management Committee

**Senior Vice President Chief Strategic Officer** since February 11, 2009

### **Senior Vice President Chief Financial Officer**

Member of the Executive Committee since December 10, 2008

Age: 39

Laurence Debroux is a graduate of HEC (*Ecole des Hautes Etudes Commerciales*). She began her career with Merrill Lynch in London, and then worked in the Finance Department of the Elf Aquitaine Group from 1993 to 1996. She joined the Sanofi Group as Corporate Treasurer in 1996, and was appointed Head of Financing/Treasury in 1997. From 2000 to 2004, she served as Head of Strategic Planning, before becoming Deputy Chief Financial Officer, and then Chief Financial Officer in March 2007. She was appointed to her present position in February 2009. She remains in post as Chief Financial Officer until the appointment of her successor.

### ***Philippe Fauchet***

Member of the Management Committee

**Senior Vice President Business Development**

Since January 1, 2009

Age: 51

Philippe Fauchet is a graduate of HEC (*Ecole des Hautes Etudes Commerciales*), and also holds a law degree. After two years with a subsidiary of Renault, Philippe Fauchet joined Roussel Uclaf in 1984, and, held a number of posts in France, Japan and Korea, before becoming Vice President of the Asia-Pacific region for Hoechst Marion Roussel. He joined Sanofi in 1996, and headed up the Eastern Europe region from 1997, before becoming Vice President, Eastern Europe for Sanofi-Synthélabo in 1999. Philippe Fauchet took over as head of Sanofi-Synthélabo's Japanese operations in June 2001 and was appointed as Senior Vice President Pharmaceutical Operations, Japan in May 2005. He is also an advisor to the French Foreign Trade Commission. He was appointed to his current position in January 2009.

***Belén Garijo***

Member of the Management Committee

**Senior Vice President Pharmaceutical Operations, Europe and Canada** (excluding France)

Age: 48

Belén Garijo has a degree in medicine, majoring in clinical pharmacology. Her career in the pharmaceutical industry began at Abbott, where she was Medical Director of the Spanish subsidiary before being appointed Director of International Medical Affairs at Abbott's United States headquarters in Illinois. In 1996, she joined Rhône-Poulenc Rorer in Spain as Head of the Oncology Business Unit. She was subsequently responsible for Aventis' global marketing and medical strategy in Oncology, based in New Jersey, United States. She returned to

**Table of Contents**

Spain in 2003 as Managing Director of the Group's Spanish subsidiary. She was appointed to her current position in July 2006. The commercial operations of Germany have reported to Belén Garijo since January 1, 2008.

***Gregory Irace***

Member of the Management Committee

**Senior Vice President Pharmaceutical Operations, United States**

Age: 50

Gregory Irace holds a B.S. in accounting from Albany State University (New York). He began his career at Price Waterhouse in 1980 and received his CPA in 1982. He spent 11 years at Price Waterhouse becoming a Senior Audit Manager in 1988, and a Senior Manager in the Corporate Finance Department in 1989. In 1991 he joined Sterling Winthrop Inc. as Regional Controller and in 1993 he became Director of Financial Planning and Analysis for Sanofi Winthrop L.P. From October 1994 to January 2007, he was Chief Financial Officer of Sanofi's Pharmaceutical Operations in the United States, most recently serving as Senior Vice President, Finance and Administration and Chief Financial Officer of sanofi-aventis US. He was appointed to his present position in February 2007.

***Michel Labie***

Member of the Management Committee

**Senior Vice President Communications & Institutional and Professional Relations**

Age: 55

Michel Labie is a graduate of the Taipei *Ecole Normale de Langues* (Taiwan) and has a bachelor degree (*maîtrise*) in Chinese from the *Institut National des Langues et Civilisations Orientales* (INALCO) majoring in Chinese Traditional Pharmacopoeia. He began his career with Sanofi in 1981, opening the Company's Beijing bureau in China in 1982. In 1995, he moved to France as head of International Professional Relations, before becoming head of Institutional and Professional Relations in 2001. Michel Labie was appointed Vice President, Assistant Director of Communication in June 2006, and took up his current post in November 2006, retaining his responsibilities in the Institutional and Professional Relations Department.

***Marie-Hélène Laimay***

Member of the Management Committee

**Senior Vice President Audit and Internal Control Assessment**

Age: 50

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Marie-Hélène Laimay has a degree in business from a French business school (*Ecole Supérieure de Commerce et d Administration des Entreprises*) and a DECS (an accounting qualification). She spent three years as an auditor with Ernst & Young before joining Sanofi in 1985. Mrs. Laimay served in a variety of financial positions, including Financial Director of Sanofi's beauty division and Deputy Financial Director of Sanofi-Synthélabo following the merger with Synthélabo in 1999. From November 2000 to May 2002, she served as Vice President, Internal Audit, and from May 2002 to August 2004 as Senior Vice President, Chief Financial Officer, before being appointed to her present position.

### *Christian Lajoux*

Member of the Management Committee

### **Senior Vice President Pharmaceutical Operations, France**

Age: 61

Christian Lajoux has a degree (DEUG) in psychology, a bachelor degree (*maîtrise*) in philosophy and a post-graduate degree (DESS) in personnel management from the *Institut d Administration des Entreprises* (IAE Paris). He served in a variety of positions at Sandoz, including Division Director, before joining Sanofi Winthrop in 1993. He then served in various positions, including Director of Operations and Managing Director of Sanofi Winthrop France, before being appointed Senior Vice President France just prior to the merger with Synthélabo in 1999. He served in that position until being named as Senior Vice President Europe in January 2003, and then as Senior Vice President Pharmaceutical Operations France in August 2004. He was appointed as Chairman of Leem (*Les entreprises du médicament*) in July 2006 and Chairman of FEFIS (*Fédération Française des Industries de Santé*) in December 2008.

**Table of Contents**

***Jean-Pierre Lehner***

Member of the Management Committee

**Senior Vice President Chief Medical Officer**

Since February 11, 2009

Age: 61

Jean-Pierre Lehner holds a Medical degree from the School of Medicine, University of Paris, France. After spending four years as *Chef de Clinique*, Paris Hospitals, Department of Cardiology (Prof. Tricot), Bichat Hospital, Paris, France, Jean-Pierre Lehner joined Roussel Laboratories in 1981 as Medical Director (1981-1986), and was then appointed Medical Director of Roussel-Uclaf (1986-1992). He served successively as Senior Director of Clinical Investigations of Sanofi Recherche (1992-1996), as Scientific Senior Director of Sanofi Winthrop (1996-2002), as Vice President Medical Affairs Europe of sanofi-aventis (2003-2005), and as Senior Vice-President, Medical & Regulatory Affairs (2005-February 2009). He was appointed to his present position in February 2009.

***Gilles Lhernould***

Member of the Management Committee

**Senior Vice President Human Resources** since September 1, 2008

Member of the Executive Committee

Age: 53

Gilles Lhernould has a diploma in pharmacy and a master's degree (DEA) in industrial pharmacy. He began his career as a manufacturing supervisor at Laboratoires Bruneau, and in 1983 joined one of Sanofi's subsidiaries where he managed production and later the factory. Mr. Lhernould then served in a variety of positions within the Sanofi Group, including Director of Human Resources - Pharmaceuticals for Sanofi Pharma and Director of Operational Human Resources for Sanofi. Following the merger with Synthélabo in 1999, he served as Vice President in charge of integration and then Vice President of Information Systems, before being named as Senior Vice President, Industrial Affairs and Senior Vice President Industrial Affairs of sanofi-aventis. He was appointed to his present position effective September 2008.

***Karen Linehan***

Member of the Management Committee

**Senior Vice President Legal Affairs and General Counsel**

Member of the Executive Committee since December 10, 2008

Age: 50

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Karen Linehan graduated from Georgetown University with bachelor of arts and *juris doctorate* degrees. Prior to practicing law, Ms. Linehan served on the congressional staff of the Speaker of the U.S. House of Representatives from September 1977 to August 1986. Until December 1990, she was an Associate in a mid-size law firm in New York, New York. In January 1991, she joined Sanofi as Assistant General Counsel of its U.S. subsidiary. In July 1996, Ms. Linehan moved to Paris to work on international matters within the Group and she has held a number of positions within the Legal Department, most recently as Vice President Deputy Head of Legal Operations. She was appointed to her current position in March 2007.

### *Philippe Luscan*

Member of the Management Committee

**Senior Vice President Industrial Affairs** since September 1, 2008

Member of the Executive Committee since September 1, 2008

Age: 46

Philippe Luscan is a graduate in Biotechnology of the *Ecole Polytechnique* and the *Ecole des Mines* in Paris. He began his career in 1987 as a Production Manager at Danone. In 1990, he joined the Group as Director of the Sanofi Chimie plant at Sisteron, France, and subsequently served as Industrial Director of Sanofi in the United States, as Vice President Supply Chain and as Vice President Chemistry. He was appointed to his present position effective September 2008.

**Table of Contents**

***Antoine Ortolì***

Member of the Management Committee

**Senior Vice President Pharmaceutical Operations, Intercontinental**

Age: 55

Antoine Ortolì is a graduate of the *Ecole Supérieure de Commerce* in Rouen, France, and of INSEAD. He also holds a law degree and an accountancy qualification. He began his career in 1980 as a financial and systems auditor with Arthur Young and Co. In December 1981, he joined the Sanofi Group, where he served in a variety of positions, including Finance Director of the Pharmaceuticals Division and Director of the Latin America region. Following the merger with Synthélabo in 1999, he was named as Vice President, Latin America, and then as Senior Vice President, Asia Middle East in June 2001. In June 2003, he took on the role of Vice President, Intercontinental region at Sanofi-Synthélabo. He was appointed to his present position in January 2005.

***Philippe Peyre***

Member of the Management Committee

**Senior Vice President Corporate Affairs**

Age: 58

Philippe Peyre is a graduate of the *Ecole Polytechnique*, and began his career in management consultancy with Bossard before being appointed as a member of the General Management Committee of Bossard Gemini Consulting. In 1998, he joined Rhône-Poulenc Rorer as Senior Vice President Special Projects, and then served as Head of Integration at Aventis Pharma, and as Company Secretary and Senior Vice President, Business Transformation of Aventis. He was appointed to his present position in August 2004.

***Wayne Pisano***

Member of the Management Committee

**Senior Vice President Vaccines**

Age: 54

Wayne Pisano holds a bachelor's degree in biology from St. John Fisher College, Rochester, New York, and an MBA from the University of Dayton, Ohio. Prior to sanofi pasteur he held various marketing and sales positions with Reed and Carnrick Pharmaceuticals and Sandoz/Novartis. He joined sanofi pasteur as Vice President, U.S. Marketing in May 1997 and then served as Senior Vice President of U.S. Marketing & Sales, Executive Vice President of sanofi pasteur North America and Senior Vice President, Global Commercial Operations. He was appointed to his present position in August 2007.



*Jean-Philippe Santoni*

Member of the Management Committee

**Senior Vice President International Development**

Age: 54

Jean-Philippe Santoni holds a doctorate in Medicine and a masters degree in Human Biology. He began his career as a clinician specializing in hospital medicine and biology at various Academic Hospitals from the *Assistance Publique Hôpitaux de Paris* (APHP group). From 1985, he held various posts with responsibility for international clinical development and medical/regulatory affairs, first with Servier and subsequently with American Cyanamid/Lederlé. In 1990, he joined Synthélabo as International Medical Director. Following the merger with Sanofi in 1999, he served successively as Associate Vice President Medical and Regulatory Affairs, Vice President International Clinical Operations and Vice President International Clinical Development, a position he retained after the merger with Aventis in 2004. He was appointed to his present position in January 2007.

As of December 31, 2008, none of the members of the Management Committee had any principal business activities outside of sanofi-aventis.

**Table of Contents**

**Composition of the Management Committee at the beginning of March 2009**

115

## **Table of Contents**

### **B. Compensation**

#### **Compensation and pension arrangements for corporate officers**

Jean-François Dehecq is the Chairman of the Board of Directors of sanofi-aventis and Christopher Viehbacher is the Chief Executive Officer, having succeeded Gérard Le Fur effective December 1, 2008.

Jean-François Dehecq has been Chairman of the Board of Directors since January 1, 2007. He also chairs the Strategy Committee and the Appointments and Governance Committee. In accordance with the Internal Rules of the Board and in close collaboration with the Senior Management, he represents the Company in high-level dealings with governmental bodies and with the Group's key partners, both nationally and internationally, as well as playing a role in defining major strategic choices, especially as regards mergers, acquisitions and alliances. He maintains regular contact with the Chief Executive Officer, so that each is kept fully informed of the other's actions. The Chairman of the Board receives compensation in the form of fixed compensation, benefits in kind, and variable compensation. In addition, he may be granted stock options and performance shares. The overall compensation package is determined by the Board of Directors on the recommendation of the Compensation Committee.

The compensation of the Chief Executive Officer is determined by reference to the compensation paid to the chief executive officers of the leading global pharmaceutical companies and of the leading companies in the CAC 40 index. The Chief Executive Officer receives compensation in the form of fixed compensation, benefits in kind, and variable compensation. In addition, he may be granted stock options and performance shares. The overall compensation package is determined by the Board of Directors on the recommendation of the Compensation Committee. With effect from 2009, stock options granted to the Chief Executive Officer will be subject to performance conditions.

The Board of Directors has nevertheless decided that no performance shares will be awarded to executive Directors, members of the Executive Committee or members of the Management Committee in 2009.

However, an exception was made in the case of Christopher Viehbacher, Chief Executive Officer, who was awarded 65,000 performance shares on March 2, 2009, in line with the undertakings made on September 10, 2008, on the announcement of his appointment as Chief Executive Officer of sanofi-aventis effective December 1, 2008; these undertakings were made as compensation for loss of the benefits to which he had been entitled from his previous employer. The shares awarded to Christopher Viehbacher are subject to a performance condition.

Executive directors do not receive attendance fees in connection with their role as directors of sanofi-aventis. Nor does Jean-François Dehecq receive attendance fees in his capacity as chairman of the sanofi-aventis Appointments and Governance Committee or chairman of the Strategy Committee. Christopher Viehbacher does not receive attendance fees in his capacity as a member of the Strategy Committee.

#### **Jean-François Dehecq**

#### **Compensation, options and shares awarded to Jean-François Dehecq**

Edgar Filing: SANOFI-AVENTIS - Form 20-F

(in euros)	2007	2008
Compensation payable for the year (details provided in the table below)	2,215,146	2,279,853
Value of stock subscription options awarded during the year <sup>(1)</sup>	1,490,000	0
Value of performance shares awarded during the year	0	0
<b>Total</b>	<b>3,705,146</b>	<b>2,279,853</b>

<sup>(1)</sup> Valued at date of grant using the Black & Scholes method.

**Table of Contents****Compensation payable and paid to Jean-François Dehecq**

(in euros)	2007		2008	
	Payable	Paid	Payable	Paid
Fixed compensation <sup>(1)</sup>	1,300,000	1,300,000	1,300,000	1,300,000
Variable compensation <sup>(2)</sup>	910,000	1,898,000	975,000	910,000
Exceptional compensation	0	0	0	0
Attendance fees	0	0	0	0
Benefits in kind	5,146	5,146	4,853	4,853
<b>Total</b>	<b>2,215,146</b>	<b>3,203,146</b>	<b>2,279,853</b>	<b>2,214,853</b>

The amounts reported are gross amounts before taxes.

(1) Fixed compensation payable in respect of a given year is paid during that year.

(2) Variable compensation in respect of a given year is determined and paid at the start of the following year.

The amount reported for benefits in kind relates to a company car.

The variable compensation of Jean-François Dehecq for 2008 was based 25% on a quantitative criterion and 75% on qualitative criteria.

The quantitative criterion used is linked to adjusted earnings per share excluding selected items (see Item 5. Operating and Financial Review and Prospects Sources of Revenues and Expenses Adjusted Net Income ).

The qualitative criteria are essentially based on the support provided to the Chief Executive Officer, leadership of the Board of Directors, input on the Group's global strategy, and representation of high-level interests of the Group.

The variable compensation may represent between 60% and 75% of his fixed compensation.

Taking into account the above mentioned criteria, the Board of Directors fixed the variable compensation of Jean-François Dehecq for 2008 at 975,000, i.e., 75% of the fixed portion of his compensation.

His variable compensation is paid in 2009.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

No stock options were granted in 2008. The basic characteristics of previously granted options are set out in the table under **Share Ownership Existing Option Plans as of December 31, 2008** below.

The fixed compensation of Jean-François Dehecq for 2009 was maintained at 1,300,000. The criteria for the variable compensation are unchanged.

### Stock options held by Jean-François Dehecq

Origin	Date of shareholder authorization	Date of Board grant	Number of options granted	Start date of exercise period	Expiration date	Exercise price (in )	Number of options exercised as of 12/31/2008	Number of options cancelled or lapsed	Number of options outstanding
Sanofi-Synthélabo	05/18/99	05/24/00	160,000	05/25/04	05/24/10	43.25	153,586	0	6,414
Sanofi-Synthélabo	05/18/99	05/10/01	145,000	05/11/05	05/10/11	64.50	0	0	145,000
Sanofi-Synthélabo	05/18/99	05/22/02	145,000	05/23/06	05/22/12	69.94	0	0	145,000
Sanofi-Synthélabo	05/18/99	12/10/03	150,000	12/11/07	12/10/13	55.74	0	0	150,000
Sanofi-aventis	05/31/05	05/31/05	250,000	06/01/09	05/31/15	70.38	0	0	250,000
Sanofi-aventis	05/31/05	12/14/06	250,000	12/15/10	12/14/16	66.91	0	0	250,000
Sanofi-aventis	05/31/07	12/13/07	125,000	12/14/11	12/13/17	62.33	0	0	125,000
<b>Total</b>			<b>1,225,000</b>						<b>1,071,414</b>

**Table of Contents**

As of December 31, 2008, the number of outstanding options held by Jean-François Dehecq represented 0.08% of the share capital. Jean-François Dehecq did not exercise any stock options in 2008.

Jean-François Dehecq is covered by the Sanofi-Synthélabo top-up defined-benefit pension plan established in 2002 (and amended January 1, 2008) offered to executives of sanofi-aventis and its French subsidiaries, who meet the eligibility criteria specified in the plan rules. Under this plan, the benefits offered supplement the annuities payable under compulsory industry schemes, but are contingent upon the plan member ending his career within the Group. The plan is reserved for executives with at least ten years' service whose annual base compensation has for ten years exceeded four times the French social security ceiling, and is wholly funded by the Company.

The top-up pension, which may not exceed 37.50% of final salary, is in the form of a life annuity, and is transferable as a survivor's pension. The annuity is based on the arithmetical average of the three highest years' average annual gross compensation (fixed plus variable) paid during the five years (not necessarily consecutive) preceding final cessation of employment. This reference compensation is capped at 60 times the French social security ceiling applicable in the year in which the rights vest. The annuity varies according to length of service and supplements the compulsory industry schemes, subject to a cap equal to 52% of final salary on the total pension from all sources.

**Gérard Le Fur**

The compensation arrangements for Gérard Le Fur reported below cover the period during which he served as Chief Executive Officer, i.e. from January 1, 2008 through November 30, 2008.

**Compensation, options and shares awarded to Gérard Le Fur as Chief Executive Officer**

(in euros)	2007	2008
Compensation payable for the year (details provided in the table below)	2,705,036	1,922,348
Value of stock subscription options awarded during the year <sup>(1)</sup>	2,384,000	0
Value of performance shares awarded during the year	0	0
<b>Total</b>	<b>5,089,036</b>	<b>1,922,348</b>

<sup>(1)</sup> Valued at date of grant using the Black & Scholes method.

**Compensation payable and paid to Gérard Le Fur as Chief Executive Officer**

(in euros)	2007		2008	
	Payable	Paid	Payable	Paid
Fixed compensation <sup>(1)</sup>	1,350,000	1,350,000	1,237,500	1,237,500
Variable compensation <sup>(2)</sup>	1,350,000	1,100,000	680,000	1,350,000
Exceptional compensation	0	0	0	0

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Attendance fees	0	0	0	0
Benefits in kind	5,036	0	4,848	4,848
<b>Total</b>	<b>2,705,036</b>	<b>2,450,000</b>	<b>1,922,348</b>	<b>2,592,348</b>

The amounts reported are gross amounts before taxes.

- (1) Fixed compensation payable in respect of a given year is paid during that year
- (2) Variable compensation in respect of a given year is determined and paid at the start of the following year

The amount reported for benefits in kind relates to a company car.

The variable compensation of Gérard Le Fur for 2008 was based half on quantitative criteria, and half on qualitative criteria.



## Table of Contents

The quantitative criteria include trends in net sales, operating income before restructuring, impairment of property, plant and equipment and intangibles, gains and losses on disposals, and litigation, and primarily trends in adjusted earnings per share excluding selected items (see Item 5. Operating and Financial Review and Prospects – Sources of Revenues and Expenses – Adjusted Net Income ). These criteria were assessed with reference to the performance of the top 12 global pharmaceutical companies.

The qualitative criteria are based on leadership and strategic choices, the adaptation of the Group's structures, the progression of our research pipeline and the quality of investor communications.

Taking into account fulfillment of the quantitative criteria which account for 50% in the fixing of the variable compensation, the Board of Directors fixed the variable compensation of Gérard Le Fur for 2008 at €680,000.

His variable compensation is paid in 2009.

The Board meeting of September 10, 2008 removed Gérard Le Fur from office as Chief Executive Officer effective November 30, 2008. The Board decisions described below therefore predate the AFEP-MEDEF recommendations on the compensation of executive directors, issued on October 6, 2008 and incorporated in the AFEP-MEDEF corporate governance code.

On the advice of the Compensation Committee, the Board meeting of September 10, 2008 noted that, based on the terms approved by the Shareholders' Annual General Meeting of May 14, 2008, the conditions for awarding Gérard Le Fur a benefit equivalent to 24 months of his final total compensation had been met.

However, given the limited period for which he had held office, only half of this benefit was paid to him (i.e. €2,705,000).

Pursuant to a decision taken by the Board meeting of September 10, 2008, the terms of which were reviewed at the Board meeting of October 30, 2008, a non-competition undertaking was agreed with Gérard Le Fur effective through September 30, 2011, in consideration for which he will receive total compensation amounting to €250,000 per quarter.

Gérard Le Fur also agreed to continue providing his scientific expertise exclusively to sanofi-aventis and to remain as an employee of sanofi-aventis, in which capacity he will receive gross monthly compensation of €50,000 through September 30, 2010.

Under the terms of these arrangements, no other termination benefit will be payable for any reason.

No stock options were granted in 2008. The basic characteristics of previously granted options are set out in the table under Share Ownership – Existing Option Plans as of December 31, 2008 – below.

Gérard Le Fur will retain the stock options granted to him under previous plans.

Gérard Le Fur is eligible for the same top-up defined-benefit pension plan as that described for Jean-François Dehecq above.

**Christopher Viehbacher**

Christopher Viehbacher took office as Chief Executive Officer on December 1, 2008.

**Compensation, options and shares awarded to Christopher Viehbacher**

<b>(in euros)</b>	<b>2008</b>
Compensation payable for the year (details provided in the table below)	100,000
Value of stock subscription options awarded during the year	0
Value of performance shares awarded during the year	0
<b>Total</b>	<b>100,000</b>

**Table of Contents****Compensation payable and paid to Christopher Viehbacher**

(in euros)	2008	
	Payable	Paid
Fixed compensation <sup>(1)</sup>	100,000	100,000
Variable compensation <sup>(2)</sup>	0	0
Exceptional compensation <sup>(3)</sup>	2,200,000	0
Attendance fees	0	0
Benefits in kind	6,016	6,016
<b>Total</b>	<b>2,306,016</b>	<b>106,016</b>

The amounts reported are gross amounts before taxes.

(1) Fixed compensation payable in respect of a given year is paid during that year.

(2) Variable compensation in respect of a given year is determined and paid at the start of the following year.

(3) Exceptional compensation comprises the 2,200,000 benefit described below.

The amount reported for benefits in kind relates to a company car, and primarily to the payment of Christopher Viehbacher's relocation expenses from the United States to France and the cost of healthcare cover for his family in the United States pending their relocation to France. The Company also agreed to meet the cost of advice from a firm of tax consultants to assist Christopher Viehbacher in preparing his tax returns.

The fixed compensation of Christopher Viehbacher for 2009 was maintained at 1,200,000.

The variable compensation of Christopher Viehbacher will be based half on quantitative criteria and half on qualitative criteria.

The quantitative criteria include trends in our net sales relative to the objectives set by us and by our competitors, trends in our current operating income (operating income before restructuring, impairment of property, plant and equipment and intangibles, gains/losses on disposals, and litigation) relative to the objectives set by us and by our competitors, and trends in our adjusted net income per share excluding selected items (See Item 5. Operating and Financial Review and Prospects Sources of Revenues and Expenses Adjusted Net Income). These criteria will be assessed by reference to the performances of the leading global pharmaceutical companies.

The qualitative criteria relate to leadership and strategic choices, adaptation of our structures to the industry's environment, reconfiguration of our research efforts, commitment in terms of organic and external growth, and the quality of investor communications.

The variable compensation of Christopher Viehbacher may represent between 0% and 200% of his fixed compensation. In case of exceptional performance, it may exceed 200% of the fixed compensation.

To compensate him for the benefits lost in leaving his former employer, Christopher Viehbacher was also awarded the following benefits:

A benefit of 2,200,000, which was paid in January 2009.

250,000 stock subscription options (representing 0.02% of the share capital as of December 31, 2008) were granted to him on March 2, 2009, i.e., 50,000 more than had been contemplated on the announcement of his appointment in September 2008. The stock subscription options awarded to Christopher Viehbacher are subject to a performance condition.

65,000 performance shares (representing 0.005% of the share capital as of December 31, 2008) were awarded to him on March 2, 2009. These 65,000 performance shares were awarded to Christopher Viehbacher in line with the undertakings made on September 10, 2008, on the announcement of his appointment as Chief Executive Officer of sanofi-aventis effective December 1, 2008. The shares awarded to Christopher Viehbacher are subject to a performance condition.

An award of ten years of deemed service for the purposes of the top-up defined-benefit pension plan.

**Table of Contents**

At its meeting of December 17, 2008, the Board of Directors decided to ask the Shareholders Annual General Meeting of April 17, 2009 to approve the termination benefit entitlement of Chris Viehbacher on the following terms:

In the event of his removal from office as Chief Executive Officer, Christopher Viehbacher would receive a termination benefit equivalent to 24 months of total compensation on the basis of his fixed compensation effective on the date he ceases to hold office and the last variable compensation received prior to that date, subject to the performance criteria described below.

In accordance with article L. 225-42-1 of the Commercial Code, payment of the termination benefit will be contingent upon fulfillment of two of the three performance criteria, assessed over the three financial years preceding his ceasing to hold office or, if he leaves office prior to the end of the 2011 financial year, the most recently ended financial years.

The three criteria are:

the average of the ratios of adjusted net earnings (excluding selected items) to net sales for each financial year must be at least 15% (see Item 5. Operating and Financial Review and Prospects Sources of Revenues and Expenses Adjusted Net Income );

the average of the ratios of operating cash flow before changes in working capital to net sales for each financial year must be at least 18%;

the average of the growth rates for the Group s activities, measured for each financial year in terms of net sales on a comparable basis, must be at least equal to the average of the growth rates of the Pharmaceutical and Vaccines activities of the top 12 global pharmaceutical companies, measured for each financial year in terms of net sales adjusted for the principal effects of exchange rates and changes in scope of consolidation.

Any activation of this termination benefit would be carried out in compliance with the AFEP-MEDEF corporate governance code.

At its meeting of December 17, 2008, the Board of Directors also authorized the admission of Christopher Viehbacher to the sanofi-aventis top-up defined benefit pension plan offered to executives of sanofi-aventis and its French subsidiaries, who meet the eligibility criteria specified in the plan rules. This plan was set up on October 1, 2008 as the final stage in the process of harmonizing the status of personnel across the French subsidiaries, and its principal features are identical to those of the Sanofi-Synthélabo plan described above for Jean-François Dehecq and Gérard Le Fur.

**Commitments in favor of executive directors in post as of December 31, 2008**

Executive director	Contract of employment	Top-up pension plan	Compensation or benefits payable or potentially payable on termination of office or change in control	Compensation payable under non-competition clause
--------------------	------------------------	---------------------	---	---

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Jean-François Dehecq	No	Yes	Yes	No
Christopher Viehbacher	No	Yes	Yes	No

Jean-François Dehecq's termination benefit has been approved by the Shareholders' Annual General Meeting, most recently on May 14, 2008. Payment of the termination benefit, which is equivalent to 20 months of his last total compensation (fixed plus variable), is contingent upon fulfillment of two out of three performance criteria.

The first criterion is that the sanofi-aventis share price has outperformed the CAC 40 index since he first took office as Chairman and Chief Executive Officer of the Company on February 15, 1988.

## **Table of Contents**

The two other criteria, the fulfillment of which will be assessed over the three financial years preceding his ceasing to hold office, are:

The average of the ratios of adjusted net earnings (excluding selected items) to net sales for each financial year must be at least 15% (see Item 5. Operating and Financial Review and Prospects Sources of Revenues and Expenses Adjusted Net Income ).

The average of the ratios of operating cash flow before changes in working capital to net sales for each financial year must be at least 18%.

The terms for the termination benefit entitlement of Christopher Viehbacher, which will be submitted for approval by the Shareholders Annual General Meeting of April 17, 2009, are described above.

### **Lock-up period for shares obtained on exercise of stock options by, or disposition of performance shares to, the Chairman of the Board of Directors and the Chief Executive Officer**

The Chairman and the Chief Executive Officer will be required to retain in the form of sanofi-aventis shares 50% of any capital gains (net of taxes and social contributions) obtained by the exercise of stock options awarded under the 2007 and later plans until they cease to hold office.

The Chief Executive Officer will be required to retain in the form of sanofi-aventis shares 50% of any capital gains (net of taxes and social contributions) upon the disposition of the performance shares awarded in 2009.

They must continue to hold these shares as registered shares until they cease to hold office.

### **Compensation and pension arrangements for directors other than the Chairman and the Chief Executive Officer**

#### **Attendance fees**

The table below shows amounts paid to each member of the sanofi-aventis Board of Directors in respect of 2007 and 2008, including those whose term of office ended during the year.

Attendance fees in respect of 2007, the amount of which was set by the Board meeting of February 11, 2008, were paid in 2008.

Attendance fees in respect of 2008, the amount of which was set by the Board meeting of February 10, 2009, were paid in 2009.

For 2008, the basic annual attendance fee was set at 15,000, apportioned on a time basis for directors who assumed or left office during the year.



**Table of Contents**

The variable portion of the fee is linked to actual attendance by directors:

directors resident in France receive 5,000 per Board or Committee meeting attended, except for Audit Committee meetings for which the fee is 7,500 per meeting;

directors resident outside France receive 7,000 per Board meeting attended, and 7,500 per Committee meeting attended;

the chairman of the Compensation Committee receives 7,500 per Committee meeting;

the chairman of the Audit Committee, who is resident outside France, receives 10,000 per Committee meeting.

(in euros) Name	2007				2008			
	Attendance fees in respect of 2007 to be paid in 2008		Pension paid in 2007	Total gross compensation	Attendance fees in respect of 2008 to be paid in 2009		Pension paid in 2008	Total gross compensation
	Fixed	Variable			Fixed	Variable		
René Barbier de La Serre <sup>(1)</sup>	15,000	105,000		120,000	6,250	47,500		53,750
Uwe Bicker <sup>(2)</sup>					10,000	42,000		52,000
Jean-Marc Bruel	15,000	75,000	366,560	456,560	15,000	72,500	373,700	461,200
Robert Castaigne	15,000	25,000		40,000	15,000	42,500		57,500
Patrick de La Chevadière <sup>(2)</sup>					10,000	25,000		35,000
Thierry Desmarest	15,000	45,000		60,000	15,000	80,000		95,000
Jürgen Dormann <sup>(1)</sup>	15,000	28,000	1,562,487	1,605,487	6,250	29,000	1,593,750	1,629,000
Lord Douro	15,000	42,000		57,000	15,000	56,000		71,000
Jean-René Fourtou	15,000	40,000	1,559,475	1,614,475	15,000	80,000	1,590,040	1,685,040
Claudie Haigneré <sup>(2)</sup>					10,000	30,000		40,000
Serge Kampf <sup>(3)</sup>	11,250	15,000		26,250				
Igor Landau	15,000	25,000	2,135,061	2,175,061	15,000	35,000	2,176,908	2,226,908
Hubert Markl <sup>(1)</sup>	15,000	42,000		57,000	6,250	14,000		20,250
Christian Mulliez	15,000	30,000		45,000	15,000	40,000		55,000
Lindsay Owen-Jones	15,000	30,000		45,000	15,000	65,000		80,000
Klaus Pohle	15,000	112,000		127,000	15,000	126,000		141,000
Gunter Thielen <sup>(2)</sup>					10,000	35,500		45,500
Gérard Van Kemmel	15,000	82,500		97,500	15,000	125,000		140,000
Bruno Weymuller <sup>(1)</sup>	15,000	30,000		45,000	6,250	10,000		16,250
<b>Total</b>	<b>221,250</b>	<b>726,500</b>	<b>5,623,583</b>	<b>6,571,333</b>	<b>215,000</b>	<b>955,000</b>	<b>5 734 398</b>	<b>6 904 398</b>
<b>Total attendance fees</b>	<b>947,750</b>				<b>1,170,000</b>			

<sup>(1)</sup> Left office May 14, 2008.

<sup>(2)</sup> Assumed office May 14, 2008.

<sup>(3)</sup> Resigned from office October 30, 2007.

**Pensions**

The total amount recognized in 2008 in respect of corporate pension plans for corporate officers with current or past executive responsibilities at sanofi-aventis (or companies whose obligations have been assumed by sanofi-aventis) was 6.7 million.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

As retirees, Jean-Marc Bruel, Jürgen Dormann, Jean-René Fourtou and Igor Landau are covered by the GRCD top-up pension plan instituted in 1977 for senior executives of Rhône-Poulenc. This plan was amended in 1994, 1996, 1999 and 2003, and currently applies to 31 active or retired executives. At its meeting of December 17, 2008, the Board of Directors decided to close this plan to new entrants.

This is a defined-benefit plan, which covers the differential between the benefits available to members under other schemes and the overall defined benefit level. It aims to provide a replacement income of 60%-65% of salary, depending on length of service and the age at which the benefit is claimed. The benefit takes the form of a life annuity, indexed to the average revaluation of the basic Social Security annuity and to trends in the INSEE retail price index.

## **Table of Contents**

### **Compensation of senior management**

In 2008, total gross compensation before social charges paid to or accrued for the members of our Management Committee in post in 2008, including the Chief Executive Officer, amounted to 17 million, including 7 million for the members of the Executive Committee. Fixed compensation represented 9 million, including 3 million for the members of the Executive Committee.

The compensation of the other Management Committee and Executive Committee members is based on an analysis of the practices of major global pharmaceutical companies and the opinion of the Compensation Committee.

In addition to fixed compensation, these key executives receive variable compensation, the amount of which is determined by the actual performance and growth of the business areas for which he or she is responsible. Variable compensation generally represents 50% to 110% of their fixed compensation.

These compensation packages may be supplemented by the granting of stock options and performance shares (see Item 6. Directors, Senior Management and Employees – E. Share Ownership ).

The total amount accrued and recognized in the income statement for the year ended December 31, 2008 in respect of corporate pension plans for (i) corporate officers with current or past executive responsibilities at sanofi-aventis or at companies whose obligations have been assumed by sanofi-aventis and (ii) members of the Executive Committee and Management Committee was 12.7 million.

This total amount accrued for the year ended December 31, 2008 included 7 million for members of the Management Committee collectively (including 3.7 million for members of the Executive Committee collectively).

No stock options were granted in 2008. In light of the financial crisis and the turmoil in the financial markets at the end of 2008, the Board of Directors decided at its meeting of December 17, 2008, on the recommendation of the Compensation Committee, to defer any award of stock options and/or shares until March 2009, after the 2008 financial statements have been published.

As of December 31, 2008, 3,182,968 options had been granted to the members of our Management Committee, including 1,238,500 options to the members of our Executive Committee. As of the same date, 2,902,903 options granted to the members of our Management Committee were outstanding, including 1,165,210 options to the members of our Executive Committee. The exercise date and other basic characteristics of such options are set out in the table Share Ownership Existing Options Plans as of December 31, 2008 below. These figures do not include the options granted to Gérard Le Fur who has not been a member of our Management Committee and our Executive Committee since December 1, 2008.

Under French law, directors may not receive options solely as compensation for service on our Board, and thus our Company may grant options only to those directors who are also our officers.

Because some of our non-executive directors were formerly officers or executive officers of our Company or its predecessor companies, some of our non-executive directors hold sanofi-aventis stock options.

We do not have separate profit-sharing plans for key executives. As employees, they are able to participate in our voluntary and statutory profit-sharing schemes on the same terms as our other employees. These plans are described below under Employees Profit-sharing schemes.

### **C. Board Practices**

Neither we nor our subsidiaries have entered into service contracts with members of our Board of Directors providing for benefits. With respect to Christopher Viehbacher, Gérard Le Fur and Jean-François Dehecq, see also Item 6. Directors, Senior Management and Employees B. Compensation Compensation and pension arrangements for Jean-François Dehecq ; Item 6. Directors, Senior Management and Employees B.

**Table of Contents**

Compensation Compensation and pension arrangements for Gérard Le Fur ; and Item 6. Directors, Senior Management and Employees B.  
Compensation Compensation and pension arrangements for Christopher Viehbacher above.

Sanofi-aventis applies the guidance contained in the AFEP-MEDEF corporate governance code of December 2008.

Since 1999, our Board of Directors has been assisted in its deliberations and decisions by specialist committees.

During 2008, the Board of Directors decided to establish a Strategy Committee and to split the Compensation, Appointments and Governance Committee into two separate committees: a Compensation Committee and an Appointments and Governance Committee.

Members of these committees are chosen by the Board from among its members, based on their experience.

**Audit Committee**

At December 31, 2008, the Audit Committee comprised:

**Klaus Pohle**, Chairman;

**Jean-Marc Bruel**;

**Robert Castaigne**; and

**Gérard Van Kemmel**.

The Audit Committee is composed of three independent Board members. Robert Castaigne is also independent within the terms of the Sarbanes-Oxley Act. All four members of this committee have financial or accounting expertise as a result of their training and work experience. Two members qualify as financial experts within the terms of the Sarbanes-Oxley Act. See Item 16A. Audit Committee Financial Expert.

The roles of the Audit Committee are to review:

the scope of consolidation;

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

the annual parent company financial statements, the annual, half-year and quarterly consolidated financial statements, the annual and half-year management reports, and the statutory auditors' report;

control procedures, the report of management on internal control, and the statutory auditors' report on this report;

internal audit work programs, and periodic summaries of internal audit reports;

the appropriateness of elective accounting treatments;

the Group's cash position;

material risks and off balance sheet commitments;

any issue liable to have a material financial or accounting impact;

the use of non-GAAP indicators in financial communication; and

major litigation, on an annual basis.

The Audit Committee may visit or interview persons responsible for operational entities in furtherance of its role, having previously informed the Chairman of the Board and the Chief Executive Officer.

In carrying out its role, the Audit Committee may seek, via the Chairman of the Board or the Chief Executive Officer, interviews with persons involved in the preparation of the financial statements (Chief Financial and Chief Accounting Officers, persons responsible for Internal Audit), with or without the Chairman of the Board and Chief Executive Officer being present, and may request that it be supplied with all necessary information. The Audit Committee may interview the statutory auditors with or without management being present, and may consult external experts.

**Table of Contents**

In addition, the Committee:

directs selection procedures for the statutory auditors when their mandates are due for renewal, monitors fees paid to the statutory auditors, ensures that signatory partners are rotated every five years, and monitors compliance with auditor independence rules;

approves in advance any request to the statutory auditors to provide services unrelated to the audit of the financial statements, in compliance with the relevant laws;

ensures that internal early warning procedures relating to accounting, internal accounting controls and audit are in place and properly applied; and

ensures that independent directors receive no compensation other than attendance fees.

During 2008, the Audit Committee met seven times.

**Compensation, Appointments and Governance Committee**

The Compensation, Appointments and Governance Committee was divided into two separate committees in 2008.

Until April 29, 2008, this Committee was composed of:

**René Barbier de La Serre**, Chairman;

**Thierry Desmarest**;

**Jürgen Dormann**;

**Jean-René Fourtou**; and

**Lindsay Owen-Jones**.

The Compensation, Appointments and Governance Committee was composed of five Board members, three of whom were independent.

The Compensation, Appointments and Governance Committee met twice in 2008.

**Compensation Committee**

At December 31, 2008, this Committee was composed of:

**G rard Van Kemmel**, Chairman;

**Thierry Desmarest**;

**Jean-Ren  Fourtou**;

**Lindsay Owen-Jones**; and

**Gunter Thielen**.

The Compensation Committee is composed of five Board members, three of whom are independent.

The roles of the Compensation Committee are:

to make recommendations and proposals to the Board concerning the compensation, pension and welfare plans, top-up pension plans, benefits in kind and other pecuniary benefits of executive officers, and the granting of stock options;

to establish rules for determining the variable component of executive directors' compensation, and to ensure that these rules are applied;

to formulate general policy on the granting of stock options, and to determine the frequency of grants for each category of grantee;

to review the system for allocating attendance fees between directors; and

to advise Senior Management on the compensation of key senior executives.



**Table of Contents**

The Compensation Committee met three times in 2008.

**Appointments and Governance Committee**

At December 31, 2008, this Committee was composed of:

**Jean-François Dehecq**, Chairman;

**Thierry Desmarest**;

**Lord Douro**;

**Jean-René Fourtou**;

**Claudie Haignéré**;

**Lindsay Owen-Jones**; and

**Gérard Van Kemmel**.

The Appointments and Governance Committee is composed of seven Board members, four of whom are independent.

The roles of the Appointments and Governance Committee are:

to recommend suitable candidates to the Board for appointment as directors or as corporate officers;

to establish corporate governance rules for the Company, and to check that those rules are applied;

to check that there is adequate succession planning for the Company's executive bodies;

to check compliance with ethical standards within the Company and in its dealings with third parties;

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

on an annual basis, to provide the Board of Directors with a list of directors who can be regarded as independent; and

to formulate procedures for evaluating Board practices, and to check that those procedures are applied.

The Appointments and Governance Committee met twice in 2008.

### **Strategy Committee**

At December 31, 2008 this Committee was composed of:

**Jean-François Dehecq**, Chairman;

**Christopher Viehbacher**;

**Uwe Bicker**;

**Thierry Desmarest**;

**Jean-René Fourtou**; and

**Lindsay Owen-Jones**.

The Strategy Committee is composed of six Board members, two of whom are independent.

The Strategy Committee is tasked with assessing major strategic options with a view to the development of the Company's business.

It briefs the Board of Directors on issues of major strategic interest, such as:

acquisition, merger and alliance opportunities;

the development priorities put forward by Senior Management;

financial and stock market strategies, and compliance with key financial ratios;

potential diversification opportunities; and

and more generally, any strategic option judged to be essential to the Company's future.

**Table of Contents**

The Strategy Committee met twice in 2008.

**Statement on Corporate Governance as Required by Rule 303A.11 of the New York Stock Exchange's Listed Company Manual**

As required by the NYSE's listing standards for foreign private issuers (Rule 303A.11), our corporate web site includes a statement of the significant ways in which our corporate governance practices differ from the corporate governance practices that the NYSE's listing standards require of U.S. companies listed on the NYSE. This statement may be consulted at: [www.sanofi-aventis.com](http://www.sanofi-aventis.com) (information on our website is not incorporated by reference in this annual report).

**D. Employees****Number of Employees**

As of December 31, 2008, sanofi-aventis employed 98,213 people worldwide. The tables below give a breakdown of employees by geographic area and function as of December 31, 2008. Central and Eastern European countries are included in Other Europe.

**Employees by geographic area**

	As of December 31,					
	2008	%	2007	%	2006	%
France	28,223	28.74%	28,592	28.7%	28,964	28.9%
Other Europe	25,292	25.75%	26,785	27.0%	27,522	27.5%
United States	15,228	15.50%	15,921	16.0%	16,196	16.1%
Japan	3,121	3.18%	2,989	3.0%	2,928	2.9%
Other countries	26,349	26.83%	25,208	25.3%	24,679	24.6%
<b>Total</b>	<b>98,213</b>	<b>100%</b>	<b>99,495</b>	<b>100%</b>	<b>100,289</b>	<b>100%</b>

**Employees by function**

	As of December 31,					
	2008	%	2007	%	2006	%
Sales	33,507	34.12%	35,115	35.3%	35,902	35.8%
Research and Development	18,976	19.32%	19,310	19.4%	18,981	18.9%
Production	31,903	32.48%	31,292	31.5%	31,735	31.7%
Marketing and Support Functions	13,827	14.08%	13,778	13.8%	13,671	13.6%

<b>Total</b>	<b>98,213</b>	<b>100%</b>	<b>99,495</b>	<b>100%</b>	<b>100,289</b>	<b>100%</b>
--------------	---------------	-------------	---------------	-------------	----------------	-------------

**Industrial Relations**

Industrial relations within sanofi-aventis are founded on respect and dialogue. In this spirit, employee representatives and management meet frequently to exchange views, and to negotiate and sign agreements.

In 2008, the forums for dialogue with our employees that exist in most of the countries where we operate were kept regularly informed about the Group's progress.

At European level, the sanofi-aventis European Works Council, a forum for dialogue and consultation bringing together 40 representatives from the 27 European Union countries and the European Economic Area countries, met in March and September 2008 under the chairmanship of our Chief Executive Officer. The Council dealt with issues relating to our strategy, results and future prospects, and was updated on our research and development efforts and our distribution activities. The five employee representatives elected by the European Works Council sat on the sanofi-aventis Board of Directors in a consultative capacity during 2008.

## **Table of Contents**

In France, the Group's French Works Council (comprising 25 members and 25 alternates, plus representatives and alternates appointed by the trade unions) met in June and December 2008 under the chairmanship of our Chief Executive Officer. At these meetings, the Council was informed about our activities, financial position and employment trends.

A summary of collective agreements negotiated during the year is provided below.

Following the harmonization of the status of our French employees, a number of agreements applicable to all of our French companies were either renewed or amended:

- Group voluntary profit-sharing agreement applicable to France for 2008, 2009 and 2010;
- agreement on the employer's contribution to the Group employee savings plan;
- amendment to the agreement on the Group employee savings plan;
- agreement on creating and maintaining employment opportunities for people with disabilities; and
- agreement on the CAVDI top-up retirement, death and disability insurance scheme.

Many other specific agreements were signed within Group companies (sanofi-aventis Recherche et Développement, Sanofi Winthrop Industrie, Sanofi Chimie, sanofi-aventis France, sanofi pasteur and sanofi-aventis Groupe), on issues such as career and skills planning, gender equality, flexible working, the *compte épargne temps* plan (which enables employees to work hours of paid leave in return for additional compensation or future paid leave entitlement), and part-time working.

During 2008, we conducted negotiations in Europe associated with the reorganization plans required in a number of countries, especially in our sales operations, in response to changes in government healthcare policies.

### ***Profit-sharing Schemes, Employee Savings Schemes and Employee Share Ownership***

#### **Profit-sharing Schemes**

All employees of our French companies belong to voluntary and statutory profit-sharing schemes.

#### **Voluntary Scheme (*Intéressement des salariés*)**

These are collective schemes which are optional for the employer and contingent upon performance. The aim is to give employees an interest in the growth of the business and improvements in its performance.

The amount distributed by our French companies during 2008 in respect of voluntary profit-sharing for the year ended December 31, 2007 represented 2.4% of total payroll.

In June 2005, sanofi-aventis signed a three-year Group-wide agreement, effective from the 2005 financial year, and applicable to all French companies more than 50% owned by sanofi-aventis (except for sanofi pasteur, which remained outside the agreement for 2005 and 2006). Under the agreement, payments under the Group voluntary profit-sharing scheme are linked to growth in our adjusted net income excluding selected items. For a definition of adjusted net income, see Item 5. Operating and Financial Review and Prospects Sources of Revenues and Expenses Adjusted Net Income .

**Statutory Scheme (*Participation des salariés aux résultats de l'entreprise*)**

The scheme is a French legal obligation for companies with more than 50 employees that made a profit in the previous financial year.

The amount distributed by our French companies during 2008 in respect of the statutory scheme for the year ended December 31, 2007 represented 9.0% of total payroll.

In November 2007, sanofi-aventis signed a new Group-wide agreement for an indefinite period, covering all the employees of our French companies.

## **Table of Contents**

### **Distribution Formula**

In order to favor lower-paid employees, the voluntary and statutory profit-sharing agreements entered into since 2005 split the benefit between those entitled as follows:

- 60% on the basis of attendance during the year; and
- 40% on the basis of annual salary, up to a limit of three times the Social Security ceiling.

### **Employee Savings Schemes and Collective Retirement Savings Plan**

The employee savings arrangements operated by sanofi-aventis are based on a Group savings scheme (*Plan Epargne Groupe*) and a collective retirement savings plan (*Plan Epargne pour la Retraite Collectif*). These schemes reinvest the sums derived from the statutory and voluntary profit-sharing schemes (compulsory investments), and voluntary contributions by employees.

Since June 1, 2008, all of these arrangements have been open to all the employees of our French companies.

In June 2008, 78% of the employees who benefited from the profit-sharing schemes opted to invest in the collective retirement savings plan.

In 2008, 126.7 million and 56.9 million were invested in the Group savings scheme and the collective retirement savings plan respectively through the voluntary and statutory schemes for 2007, and through top-up contributions.

### **Employee Share Ownership**

At December 31, 2008, shares held by employees of sanofi-aventis and of related companies and by former employees under Group employee savings schemes amounted to 1.32% of the share capital.

### **E. Share Ownership**

#### **Senior Management**



## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Members of the Management Committee hold shares of our Company amounting in the aggregate to less than 1% of the Company's share capital.

At December 31, 2008, a total of 2,902,903 unexercised options to subscribe for or to purchase sanofi-aventis shares were held by the members of the Management Committee of sanofi-aventis including the 1,165,210 unexercised options to subscribe for or to purchase sanofi-aventis shares held by members of the Executive Committee. The terms of these options are summarized in the tables below. No stock options were granted in 2008.

During 2008, the members of the Management Committee of sanofi-aventis exercised 18,297 options to purchase or to subscribe for shares (including those exercised by Gérard Le Fur when he was still a member of the Management Committee).

### **Existing Option Plans as of December 31, 2008**

As of December 31, 2008, a total of 85,304,950 options were outstanding, including 77,233,922 options to subscribe for and 8,071,028 options to purchase sanofi-aventis shares. Out of this total, 48,713,680 were immediately exercisable, including 40,642,652 options to subscribe for shares and 8,071,028 options to purchase shares.

Stock options (which may be stock subscription options or stock purchase options) are granted to employees and corporate officers by the Board of Directors on the basis of recommendations from the Compensation Committee.

Granting options is a way of recognizing the grantee's contribution to the Group's development, and also of securing his or her future commitment to the Group.

**Table of Contents**

For each plan, the Compensation Committee and the Board assess whether it should take the form of stock subscription options or stock purchase options, based on criteria that are primarily financial.

A list of grantees is submitted by the Senior Management to the Compensation Committee, which reviews the list and then submits it to the Board of Directors, which grants the options. The Board also sets the terms for the exercise of the options (including the exercise price) and the lock-up period. The exercise price never incorporates a discount, and must be at least equal to the average of the quoted market prices on the 20 trading days preceding the date of grant by the Board. Stock option plans generally specify a lock-up period of four years.

No stock options were granted in 2008. In light of the financial crisis and the turmoil in the financial markets at the end of 2008, the Board of Directors decided at its meeting of December 17, 2008, on the recommendation of the Compensation Committee, to defer any award of stock options and/or shares until March 2009, after the 2008 financial statements have been published.

In accordance with the AFEP-MEDEF corporate governance code, the grant of options to the Chief Executive Officer made on March 2, 2009 (the first to take place after the code came into effect) was subject to a performance condition. The performance condition which must be fulfilled each of the financial years between 2009 and 2012 is based on the ratio of adjusted net earnings (excluding selected items) to net sales. No stock options were granted to the Chairman of the Board.

Options granted to the Chief Executive Officer represented 0.8% of the maximum total grant approved at the Shareholders' Annual General Meeting of May 31, 2007 (2.5% of our share capital) and 3% of the total grant made to all of the beneficiaries on March 2, 2009.

**Share Purchase Option Plans**

Origin	Date of shareholder authorization	Date of Board grant	Number of options initially granted	- to the 10 employees granted the most		Start date of exercise period	Expiration date	Purchase price (in )	Number exercised by 12/31/2008	Number canceled in 2008	Number outstanding
				- to corporate officers <sup>(1)</sup>	options <sup>(2)</sup>						
Synthélabo	6/28/1990	12/15/1993	364,000	130,000	104,000	12/15/1998	12/15/2013	6.36	350,800	5,200	8,000
Synthélabo	6/28/1990	10/18/1994	330,200	0	200,200	10/18/1999	10/18/2014	6.01	313,100	0	17,100
Synthélabo	6/28/1990	1/12/1996	208,000	0	52,000	1/12/2001	1/12/2016	8.56	188,730	0	19,270
Synthélabo	6/28/1990	4/05/1996	228,800	0	67,600	4/05/2001	4/05/2016	10.85	191,380	0	37,420
Synthélabo	6/28/1990	10/14/1997	262,080	0	165,360	10/14/2002	10/14/2017	19.73	225,906	5,200	30,974
Synthélabo	6/28/1990	6/25/1998	296,400	148,200	117,000	6/26/2003	6/25/2018	28.38	265,880	0	30,520
Synthélabo	6/23/1998	3/30/1999	716,040	0	176,800	3/31/2004	3/30/2019	38.08	375,500	5,720	334,820
Sanofi-Synthélabo	5/18/1999	5/24/2000	4,292,000	310,000	325,000	5/25/2004	5/24/2010	43.25	2,369,792	115,300	1,806,908
Sanofi-Synthélabo	5/18/1999	5/10/2001	2,936,500	145,000	286,000	5/11/2005	5/10/2011	64.50	275,061	103,700	2,557,739
Sanofi-Synthélabo	5/18/1999	5/22/2002	3,111,850	145,000	268,000	5/23/2006	5/22/2012	69.94	61,000	138,700	2,912,150

<sup>(1)</sup> Comprises the Chairman and Chief Executive Officer, the Chief Executive Officer or the Senior Executive Vice President in office as of the date of grant.

<sup>(2)</sup> Employed as of the date of grant.

**Table of Contents****Hoechst GmbH Share Purchase Option Plans**

A total of 316,127 Hoechst GmbH options to purchase shares remained outstanding on December 31, 2008.

**Share Subscription Option Plans**

Origin	Date of shareholder authorization	Date of grant	Number of options initially granted	- to the 10 employees		Start date of exercise period	Expiration date	Subscription price (in )	Number exercised by 12/31/2008	Number canceled in 2008	Number outstanding
				- to corporate officers <sup>(1)</sup>	granted the most options <sup>(2)</sup>						
Aventis	4/23/1997	12/15/1998	6,372,000	704,348	664,215	1/06/2002	12/15/2008	34.14	5,427,028	944,972	0
Aventis	5/26/1999	12/15/1999	5,910,658	586,957	463,485	1/06/2003	12/15/2009	50.04	2,731,307	544,567	2,634,784
Aventis	5/26/1999	5/11/2000	877,766	0	86,430	5/11/2003	5/11/2010	49.65	531,872	91,773	254,121
Aventis	5/24/2000	11/14/2000	13,966,871	1,526,087	1,435,000	11/15/2003	11/14/2010	67.93	1,272,007	2,299,433	10,395,431
Aventis	5/24/2000	3/29/2001	612,196	0	206,000	3/30/2004	3/29/2011	68.94	28,476	36,964	546,756
Aventis	5/24/2000	11/07/2001	13,374,051	1,068,261	875,200	11/08/2004	11/07/2011	71.39	880,241	2,745,756	9,748,054
Aventis	5/24/2000	3/06/2002	1,173,913	1,173,913	0	3/07/2005	3/06/2012	69.82	0	7	1,173,906
Aventis	5/14/2002	11/12/2002	11,775,414	352,174	741,100	11/13/2005	11/12/2012	51.34	4,560,846	1,722,432	5,492,136
Aventis	5/14/2002	12/02/2003	12,012,414	352,174	715,000	12/03/2006	12/02/2013	40.48	3,897,148	1,595,522	6,519,744
Sanofi-Synthelabo	5/18/1999	12/10/2003	4,217,700	240,000	393,000	12/11/2007	12/10/2013	55.74	177,780	162,200	3,877,720
Sanofi-aventis	5/31/2005	5/31/2005	15,228,505	400,000	550,000	6/01/2009	5/31/2015	70.38	6,500	1,501,855	13,720,150
Sanofi-aventis	5/31/2005	12/14/2006	11,772,050	450,000	585,000	12/15/2010	12/14/2016	66.91	0	576,590	11,195,460
Sanofi-aventis	5/31/2007	12/13/2007	11,988,975	325,000	625,000	12/14/2011	12/13/2017	62.33	0	313,315	11,675,660

(1) Comprises the Chairman and Chief Executive Officer, the Chief Executive Officer, the Senior Executive Vice President or members of the Management Board in office as of the date of grant.

(2) Employed as of the date of grant.

The main characteristics of our stock options are also described in Note D.15.8 to our consolidated financial statements, included in Item 18 of this annual report.

**Awards of Shares**

In 2009, the Board of Directors for the first time awarded shares to certain employees in order to give them a direct stake in the Company's future and performances via trends in the share price, as a partial substitute for the granting of stock options.

No shares were awarded to executive Directors, members of the Executive Committee or members of the Management Committee in 2009.

However, an exception was made in the case of Christopher Viehbacher, Chief Executive Officer, who was awarded 65,000 performance shares on March 2, 2009, in line with the undertakings made on September 10, 2008, on the announcement of his appointment as Chief Executive Officer of sanofi-aventis effective December 1, 2008; these undertakings were made as compensation for loss of the benefits to which he had

been entitled from his previous employer. The shares awarded to Christopher Viehbacher are subject to a performance condition. The performance condition which must be fulfilled each of the financial years before the transfer of the shares (i.e., 2009 and 2010) is based on the ratio of adjusted net earnings (excluding selected items) to net sales (see Item 5. Operating and Financial Review and Prospects Sources of Revenues and Expenses Adjusted Net Income ).

Shares are awarded to employees on the basis of a list put forward to the Compensation Committee, which then submits the list to the Board of Directors, which awards the shares. The Board sets the vesting conditions for the award, and any lock-up conditions for the shares. No performance conditions are attached.

#### **Shares Owned by Members of the Board of Directors**

As of December 31, 2008, members of our Board of Directors held in the aggregate 440,374 shares, or under 1% of the share capital and of the voting rights, excluding the beneficial ownership of 148,559,513 shares held by Total as of such date which may be attributed to Thierry Desmarest (who disclaims beneficial ownership of such shares) and excluding the beneficial ownership of 118,227,307 shares held by L. Oréal as of such date which may be attributed to Lindsay Owen-Jones (who disclaims beneficial ownership of such shares).

**Table of Contents**

**Transactions in Shares by Members of the Board of Directors**

On March 12, 2008, Gérard Le Fur, Chief Executive Officer, exercised 15,000 options to buy 15,000 shares at a price of 43.25 per share (Sanofi-Synthélabo plan of May 24, 2000).

On March 26, 2008, Uwe Bicker, member of the Board of Directors, bought 300 shares at a price of 51.90 per share.

On July 1, 2008, Claudie Haignéré, member of the Board of Directors, bought 500 shares at a price of 42.24 per share.

On August 11, 2008, Gunther Thielen, member of the Board of Directors, bought 500 shares at a price of 48.03 per share.

On December 8, 2008, Christian Mulliez, member of the Board of Directors, bought 450 shares at a price of 45.34 per share.

On December 15, 2008, Jean-René Fourtou, member of the Board of Directors, sold 1,932 shares at a price of 43.45 per share.

**Table of Contents****Item 7. Major Shareholders and Related Party Transactions****A. Major Shareholders**

The table below shows the ownership of our shares as of January 31, 2009, indicating the beneficial owners of our shares. To the best of our knowledge and on the basis of the notifications received as disclosed below, except as described below no shareholder holds more than 5% of our share capital or voting rights.

	Outstanding Shares		Actual Voting Rights <sup>(2)</sup>		Published Voting Rights <sup>(3)</sup>	
	Number	%	Number	%	Number	%
<b>Total</b>	145,929,513	11.09	287,442,340	18.11	287,442,340	17.99
<b>L Oréal</b>	118,227,307	8.99	236,454,614	14.89	236,454,614	14.80
<b>Treasury shares</b>	10,014,471	0.76			10,014,471	0.63
- of which held directly by sanofi-aventis	9,647,801	0.73				
<b>Employees<sup>(1)</sup></b>	17,158,705	1.30	31,106,735	1.96	31,106,735	1.95
<b>Public</b>	1,024,196,708	77.86	1,032,539,407	65.04	1,032,539,407	64.63
<b>Total</b>	<b>1,315,526,704</b>	<b>100</b>	<b>1,587,543,096</b>	<b>100</b>	<b>1,597,557,567</b>	<b>100</b>

(1) Shares held via the sanofi-aventis Group Employee Savings Plan.

(2) Based on the total number of voting rights as of January 31, 2009.

(3) Based on the total number of voting rights as of January 31, 2009 as published in accordance with article 223-11 and seq. of the General Regulations of the *Autorité des Marchés Financiers* (i.e., calculated before suspension of the voting rights of treasury shares).

Our *statuts* (bylaws) provide for double voting rights for shares held in registered form for at least two years. For more information relating to our shares, see Item 10. Additional Information B. Memorandum and Articles of Association.

Total and L Oréal are the only two entities known to hold more than 5% of the outstanding sanofi-aventis ordinary shares. As described below, these entities reduced their holdings in 2007 and 2008 after no significant changes in 2006 and 2005.

In accordance with our *statuts*, shareholders are required to notify us once they have passed the threshold of 1% of our share capital or our voting rights and each time they cross an incremental 1% threshold (see Item 10. Additional Information B. Memorandum and Articles of Association Requirements for Holdings Exceeding Certain Percentages ).

For the year ended December 31, 2008, we were informed that the following share ownership declaration thresholds had been passed:

Natixis Asset Management disclosed that the *Fonds Communs de Placement d'Entreprise* Actions sanofi-aventis (mutual fund) that it manages had gone below and then exceeded the 1% threshold stipulated in our *statuts* and held an interest of 1.05% (notification dated

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

March 12, 2008);

Total disclosed that, following the modification of the total number of shares and voting rights, it had exceeded the 13% threshold stipulated in our *statuts* and held an interest of 13.09% of our share capital and 19.64% of our voting rights (notification dated May 30, 2008);

Crédit Agricole Asset Management disclosed that through its *Fonds Communs de Placement* mutual funds it had exceeded and then gone below the 2% voting rights threshold stipulated in our *statuts* and held an interest of 2.03% of our share capital (notification dated June 13, 2008);

Caisse des Dépôts et Consignations disclosed that, following the modification of the total number of shares and voting rights, it had exceeded the 2% threshold stipulated in our *statuts* and held an interest of 2.02% of our share capital and 1.61% of our voting rights (notification dated May 15, 2008);

Dodge & Cox disclosed that it had exceeded the 4% threshold stipulated in our *statuts* and held 4.014% of our share capital on behalf of its clients (notification dated June 24, 2008);

Total disclosed that, following several sales of shares, it had gone below the 13% and 12% ownership thresholds and 19% voting right threshold stipulated in our *statuts* and held 11.99% of our share capital and 18.73% of our voting rights (notification dated November 7, 2008); and

Franklin Resources, Inc. disclosed that it had gone below the 2% threshold stipulated in our *statuts* and held 2.40% of our share capital and 1.97% of our voting rights on behalf of its clients (notification dated November 4, 2008);

## **Table of Contents**

Since January 1, 2009 we have been informed that the following share ownership declaration thresholds have been passed:

Total disclosed that, following several sales of shares, it had gone below the 11% ownership threshold and 18% voting right threshold stipulated in our *statuts* and held 10.99% of our share capital and 17.91% of our voting rights (notification dated February 16, 2009); and

Crédit Agricole Asset Management disclosed that through its *Fonds Communs de Placement* (mutual funds) it had exceeded the 2% voting right threshold stipulated in our *statuts* and held an interest of 2.42% of our share capital (notification dated January 23, 2009).

We estimate that we have approximately one million individual shareholders (including employees of sanofi-aventis and its subsidiaries, as well as retired employees holding shares via the sanofi-aventis Group Employee Savings Plan), composed of primarily French (49%) and American (32%) shareholders, of which a majority holds American Depositary Shares (ADS). Individual shareholders hold approximately 8% of our share capital.

Institutional shareholders (excluding Total and L. Oréal) hold approximately 70% of our share capital. Such shareholders are primarily American (27.1%), French (19.6%) and British (9.4%). German institutions hold 3.3% of our share capital, Swiss institutions hold 1%, institutions from other European countries hold 5.1% and Canadian institutions hold 1.2% of our share capital.

Other international institutional investors (excluding those from Europe, the United States and Canada) hold approximately 3.6% of our share capital; Chinese investors began holding shares in 2008.

(source: a survey conducted by Euroclear France as of December 30, 2008, and internal information).

### ***Shareholders Agreement***

We are unaware of any shareholders agreement currently in force.

## **B. Related Party Transactions**

In the ordinary course of business, we purchase materials, supplies and services from numerous companies throughout the world. Members of our Board of Directors are affiliated with some of these companies. We conduct our transactions with such companies on an arm's-length basis and do not consider the amounts involved in such transactions to be material.

On September 19, 2008, our wholly-owned subsidiary Sanofi-Aventis Europe and our associate Zentiva N.V. in which we hold 24.88% interest signed an agreement on the unanimous recommendation by Zentiva of an intended improved all-cash public offer of CZK 1,150 per share



## Edgar Filing: SANOFI-AVENTIS - Form 20-F

(compared to CZK 1,050 initially proposed) including, *inter alia*, a non-solicitation clause, matching rights, provisions relating to the termination of the agreement in certain circumstances, and a break fee of 25 million in the event that Zentiva withdraws its recommendation of the improved offer. Other than this agreement, during 2008 and through the date of this annual report, we have not been involved in, and we do not currently anticipate becoming involved in, any transactions with related parties that are material to us or to any of our related parties and that are unusual in their nature or conditions. We have not made any outstanding loans to or for the benefit of:

enterprises that, directly or indirectly, control or are controlled by, or are under common control with us;

enterprises or associates in which we have significant influence or that have significant influence over us;

shareholders beneficially owning a 10.0% or greater interest in our voting power;

any member of our Management Committee or Board of Directors or close members of such individuals' families; or

enterprises in which persons described above own, directly or indirectly, a substantial interest in the voting power or over which persons described above are able to exert significant influence.

### **C. Interests of Experts and Counsel**

N/A

**Table of Contents****Item 8. Financial Information*****A. Consolidated Financial Statements and Other Financial Information***

Our consolidated financial statements as of and for the years ended December 31, 2008, 2007, and 2006 are included in this annual report at Item 18. Financial Statements.

**Dividends on Ordinary Shares**

We paid annual dividends for the years ended December 31, 2004, 2005, 2006 and 2007 and our shareholders will be asked to approve the payment of an annual dividend of 2.20 per share for the 2008 fiscal year at our next annual shareholders meeting. If approved, this dividend will be paid on April 28, 2009.

We expect that we will continue to pay regular dividends based on our financial condition and results of operations. The proposed 2008 dividend equates to a distribution of 40.7% of our adjusted earnings per share. For information on the non-GAAP financial measure, adjusted earnings per share, see Item 5. Operating and Financial Review and Prospects Sources of Revenues and Expenses Adjusted Net Income.

The following table sets forth information with respect to the dividends paid by our Company in respect of the 2004, 2005, 2006 and 2007 fiscal years and the dividend that will be proposed for approval by our shareholders in respect of the year ended in 2008 at our April 17, 2009 shareholders meeting.

	2008 <sup>(1)</sup>	2007	2006	2005	2004
Net Dividend per Share (in €)	2.20	2.07	1.75	1.52	1.20
Net Dividend per Share (in \$) <sup>(2)</sup>	3.06	3.02	2.31	1.80	1.62

<sup>(1)</sup> Proposal, subject to shareholder approval.

<sup>(2)</sup> Based on the relevant year-end exchange rate.

The declaration, amount and payment of any future dividends will be determined by majority vote of the holders of our shares at an ordinary general meeting, following the recommendation of our Board of Directors. Any declaration will depend on our results of operations, financial condition, cash requirements, future prospects and other factors deemed relevant by our shareholders. Accordingly, we cannot assure you that we will pay dividends in the future on a continuous and regular basis. Under French law, we are required to pay dividends approved by an ordinary general meeting of shareholders within nine months following the meeting at which they are approved.

**Annual Payments on Participating Share Series A ( PSSA )**

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

The table below sets forth, for the years indicated, the amount of dividends paid per PSSA; see Item 9. The Offer and Listing for further detail). In the United States, the PSSAs exist in the form of American Depositary Shares issued by The Bank of New York Mellon, formerly known as The Bank of New York, as depositary, each representing one-quarter of a PSSA ( PSSA-ADSs ). The PSSAs are generally entitled to receive an annual payment determined according to a specific formula and subject to certain conditions.

The annual payments on the PSSAs are equal to the sum of a fixed portion ( 1.14 per PSSA) and a variable portion equal to the greater of 70% of the dividend per ordinary share or 150% of an amount calculated pursuant to a formula which takes into account changes in consolidated sales and consolidated net income.

Such amounts have been translated in each case into dollars and adjusted for the one-to-four ratio of PSSAs to PSSA-ADSs. Annual payments paid to holders of PSSA-ADSs will generally be exempt from French withholding tax.

In 2008, the annual payment per PSSA in respect of 2007 was equal to 15.7234.

	2007	2006	2005	2004	2003
Annual payment per PSSA	15.7234	13.4695	12.9929	0	6.0634
Annual payment per PSSA-ADS	\$ 5.8550	\$ 4.5877	\$ 4.1438	\$ 0	\$ 1.8530

## **Table of Contents**

### **Information on Legal or Arbitration Proceedings**

Our principal legal proceedings are described in Note D.22 to the consolidated financial statements included at Item 18 of this annual report, which we incorporate herein by reference, and are further updated below to reflect material developments through the date of this document.

We are also involved from time to time in a number of legal proceedings incidental to the normal conduct of our business, including proceedings involving product liability claims, intellectual property rights (particularly claims by generic product manufacturers seeking to limit the patent protection of sanofi-aventis products), compliance and trade practices, commercial claims, employment and wrongful discharge claims, tax assessment claims, waste disposal and pollution claims and claims under warranties or indemnification arrangements relating to business divestitures.

#### *Sanofi Pasteur Inc. Thimerosal Litigation*

*(Update to the caption Sanofi Pasteur Inc. Thimerosal Litigation at Note D.22.a) to our consolidated financial statements included herein at Item 18.)*

On February 12, 2009, the U.S. Court of Federal Claims announced decisions in the first three test cases which were the subject of hearings completed in 2007. In each decision it was held that the petitioners failed to establish that their claimed injuries were caused in any way by thimerosal containing vaccines and the MMR vaccine, and no compensation was awarded to any of them under the National Vaccine Injury Compensation Program (VICP). The claimants have 30 days to seek review of the decisions by the Claims Court, and thereafter may seek appellate review in the U. S. Court of Appeals for the Federal Circuit.

#### *SoloSTAR® Patent Litigation*

*(Update to the caption SoloSTAR® Patent Litigation at Note D.22.b) to our consolidated financial statements included herein at Item 18.)*

On February 11, 2009 the German Patent and Trademark Office cancelled at the request of sanofi-aventis Novo Nordisk's German Utility Model DE 200 23 819. The same Utility Model was already at stake in the infringement suit filed by Novo Nordisk regarding the SoloSTAR® disposable insulin pen that had been dismissed on May 20, 2008 by the Court of Mannheim.

#### *Lovenox® Patent Litigation*

*(Update to the caption Lovenox® Patent Litigation at Note D.22.b) to our consolidated financial statements included herein at Item 18.)*

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

On February 17, 2009 the United States District Court for the Central District of California dismissed without prejudice Amphastar's antitrust counterclaims in the Lovenox® patent litigation.

### ***B. Significant Changes***

In addition to the information included elsewhere in this annual report, we bring to your attention the following developments since the end of 2008.

Sanofi-aventis announced on February 25, 2009 that all conditions to the offer made by its subsidiary sanofi-aventis Europe to acquire Zentiva had been successfully fulfilled. The settlement of the offer will occur on March 11, 2009. Following settlement, and including the shares already held by sanofi-aventis Europe prior to the offer, sanofi-aventis Europe expects to hold around 94% of the outstanding share capital and voting rights of Zentiva.

## **Item 9. The Offer and Listing**

### ***A. Offer and Listing Details***

We have one class of shares. Each American Depositary Share, or ADS, represents one-half of one share. The ADSs are evidenced by American Depositary Receipts, or ADRs, which are issued by JPMorgan Chase Bank.

Our shares trade on the Eurolist market of Euronext Paris (Compartment A) and our ADSs trade on the New York Stock Exchange. There can be no assurances as to the establishment or continuity of a public market for our shares or ADSs.

**Table of Contents****Trading History**

The table below sets forth, for the periods indicated, the reported high and low quoted prices of our shares on the Eurolist market of Euronext Paris and on the New York Stock Exchange (source: Bloomberg).

Calendar period	Euronext Paris		NYSE	
	High (price per share in )	Low	High (price per ADS in \$)	Low
<b>Monthly</b>				
February 2009 <sup>(1)</sup>	47.50	39.82	30.63	25.54
January 2009	49.93	43.37	32.80	27.87
December 2008	47.79	41.35	33.57	26.59
November 2008	50.98	38.43	32.38	23.95
October 2008	49.99	36.055	34.32	24.89
September 2008	51.25	43.695	35.96	31.14
<b>2008</b>				
First quarter	66.90	44.30	49.04	35.06
Second quarter	51.24	41.27	39.70	32.11
Third quarter	51.25	41.61	37.11	31.14
Fourth quarter	50.98	36.055	34.32	23.95
Full Year	66.90	36.055	49.04	23.95
<b>2007</b>				
First quarter	71.80	62.50	46.60	41.37
Second quarter	71.95	59.65	48.30	39.97
Third quarter	63.19	56.20	43.56	37.90
Fourth quarter	65.93	58.09	48.30	41.54
Full Year	71.95	56.20	48.30	37.90
<b>2006</b>				
First quarter	79.85	69.50	48.32	41.91
Second quarter	79.10	69.80	49.25	44.21
Third quarter	79.25	66.90	50.05	42.43
Fourth quarter	70.90	64.85	46.60	41.65
Full Year	79.85	64.85	50.05	41.65
<b>2005</b>				
Full Year	76.70	56.40	45.87	36.60
<b>2004</b>				
Full Year	63.25	49.42	40.48	29.22
<b>2003</b>				
Full Year	60.00	41.50	37.92	22.53
<b>2002</b>				
Full Year (NYSE beginning on July 1)	84.30	49.78	32.80	24.90

**B. Plan and Distribution**

N/A

**C. Markets**

**Shares and ADSs**

Our shares are listed on the Euronext Paris Market (Compartment A) under the symbol `SAN` and our ADSs are listed on the New York Stock Exchange, or NYSE, under the symbol `SNY`. At the date of this annual report, our shares are included in a large number of indices including the CAC 40 Index, the principal French index published by Euronext Paris. This index contains 40 stocks selected among the top 100 companies based on free-float capitalization and the most active stocks listed on the Euronext Paris Market. The CAC 40 Index indicates trends on the French stock market as a whole and is one of the most widely followed stock price indices in France. Our shares are also included in the S&P Global 100 Index, the Dow Jones EuroSTOXX 50 and the MSCI Pan-Euro Index.

---

## Table of Contents

### **The Euronext Paris Market**

In February 2005, Euronext Paris overhauled its listing structure by implementing the Eurolist Market, a new single regulated market, which replaced the regulated cash markets formerly operated by Euronext Paris, i.e., the Bourse de Paris (which comprised the Premier Marché and the Second Marché) and the Nouveau Marché. As part of this process, Euronext Paris transferred on February 21, 2005 all shares and bonds listed on the Premier Marché, Second Marché and Nouveau Marché to the Eurolist Market.

Since February 21, 2005, all securities approved for admission to trading on Euronext Paris have been traded on a single market: Eurolist by Euronext, which was renamed Euronext Paris Market on November 28, 2007. The Euronext Paris Market is a regulated market operated and managed by Euronext Paris, a market operator (*entreprise de marché*) responsible for the admission of securities and the supervision of trading in listed securities. Euronext Paris publishes a daily official price list that includes price information on listed securities. The Euronext Paris Market is divided into three capitalization compartments: A for capitalizations over 1 billion, B for capitalizations between 1 billion and 150 million, and C for capitalizations less than 150 million.

### **Trading on the Euronext Paris Market**

Securities admitted to trading on the Euronext Paris Market are officially traded through authorized financial institutions that are members of Euronext Paris. Euronext Paris places securities admitted to trading on the Euronext Paris Market in one of two categories (continuous ( *continu* ) or fixing), depending on whether they belong to certain indices or compartments and/or on their trading volume. Our shares trade in the category known as *continu*, which includes the most actively traded securities. Shares are traded on each trading day from 9:00 a.m. to 5:30 p.m. (Paris time), with a pre-opening session from 7:15 a.m. to 9:00 a.m. and a post-closing session from 5:30 p.m. to 5:35 p.m. (during which pre-opening and post-closing sessions trades are recorded but not executed until the opening auction at 9:00 a.m. and the closing auction at 5:35 p.m., respectively). In addition, from 5:35 p.m. to 5:40 p.m., trading can take place at the closing auction price. Trading in a share belonging to the *continu* category after 5:40 p.m. until the beginning of the pre-opening session of the following trading day may take place at a price that must be within the closing auction price plus or minus 1%.

Euronext Paris may temporarily interrupt trading in a security admitted to trading on the Euronext Paris Market if purchases and sales recorded in the system would inevitably result in a price beyond a certain threshold, determined on the basis of a percentage fluctuation from a reference price. With respect to shares belonging to the *continu* category, once trading has commenced, volatility interruptions for a reservation period of 2 minutes (subject to extension by Euronext Paris) are possible if the price varies either by more than 5% from a reference price (e.g., opening auction price) or by more than 2% (with respect to CAC 40 issuers) from the last trade on such securities. Euronext Paris may also suspend trading of a security admitted to trading on the Euronext Paris Market in certain circumstances including the occurrence of unusual trading activity in a security. In addition, in exceptional cases, including, for example, upon announcement of a takeover bid, the French market regulator (*Autorité des marchés financiers* or AMF ) may also require Euronext Paris to suspend trading.

Trades of securities admitted to trading on the Euronext Paris Market are settled on a cash basis on the third day following the trade. For certain securities, market intermediaries are also permitted to offer investors the opportunity to place orders through a deferred settlement service (*Ordres Stipulés à Règlement-Livraison Différés* OSRD) for a fee. The deferred settlement service is only available for trades in securities that have both a total market capitalization of at least 1 billion and a daily average volume of trades of at least 1 million. Investors can elect on or before the determination date (*jour de liquidation*), which is the fifth trading day before the end of the month, either to settle by the last trading day of the month or to pay an additional fee and postpone the settlement decision to the determination date of the following month. At the date of this annual report, our shares are currently eligible for the deferred settlement service.



## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Equity securities traded on a deferred settlement basis are considered to have been transferred only after they have been recorded in the purchaser's account. Under French securities regulations, if the sale takes place before, but during the month of, a dividend payment date, the purchaser's account will be credited with an amount equal to the dividend paid.

## **Table of Contents**

Prior to any transfer of securities listed on the Euronext Paris Market held in registered form, the securities must be converted into bearer form and accordingly recorded in an account maintained by an accredited intermediary with Euroclear France S.A., a registered central security depository. Transactions in securities are initiated by the owner giving the instruction (through an agent, if appropriate) to the relevant accredited intermediary. Trades of securities listed on the Euronext Paris Market are cleared through LCH.Clearnet and settled through Euroclear France using a continuous net settlement system. A fee or commission is payable to the accredited intermediary or other agent involved in the transaction.

## **Participating Shares Series A**

Further to a public offer to exchange ordinary shares for PSSAs in 1993, a tender offer to purchase for cash all of the outstanding PSSA-ADSs in 1995 and repurchases in private transactions since that date, there are only 3,296 PSSAs outstanding as of December 31, 2008, of which substantially all were represented by PSSA-ADSs. In view of the small number of PSSAs that remain outstanding, at some time in the future, sanofi-aventis intends to terminate the Deposit Agreement for the PSSA-ADSs and apply to the U.S. Securities and Exchange Commission to terminate registration of the PSSAs and the PSSA-ADSs under the Securities Exchange Act of 1934, as amended.

We are not aware of any non-U.S. trading market for our Participating Shares Series A. In the United States, the PSSAs exist in the form of American Depositary Shares issued by The Bank of New York Mellon, formerly known as the Bank of New York, as depository, each representing one-quarter of a PSSA. We are not aware of any U.S. trading market for the PSSA-ADSs since their suspension from trading on the NYSE on May 18, 1995, and their subsequent removal from listing on the NYSE on July 31, 1995. Prior to their delisting, the PSSA-ADSs traded on the NYSE under the symbol RP PrA.

## **Trading Practices and Trading in own Shares**

Under French law, a company may not issue shares to itself, but it may purchase its own shares in the limited cases described at Item 10. Additional Information B. Memorandum and Articles of Association Trading in Our Own Shares.

### ***D. Selling Shareholders***

N/A

### ***E. Dilution***

N/A

### ***F. Expenses of the Issue***

N/A

140

**Table of Contents**

**Item 10. Additional Information**

***A. Share Capital***

N/A

***B. Memorandum and Articles of Association***

**General**

Our Company is a *société anonyme*, a form of limited liability company, organized under the laws of France.

In this section, we summarize material information concerning our share capital, together with material provisions of applicable French law and our *statuts*, an English translation of which has been filed as an exhibit to this annual report. For a description of certain provisions of our *statuts* relating to our Board of Directors and statutory auditors, see Item 6. Directors, Senior Management and Employees. You may obtain copies of our *statuts* in French from the *greffe* (Clerk) of the *Registre du Commerce et des Sociétés de Paris* (Registry of Commerce and Companies of Paris, France, registration number: 395 030 844). Please refer to that full document for additional details.

Our *statuts* specify that our corporate affairs are governed by:

applicable laws and regulations (in particular, Title II of the French Commercial Code), and

the *statuts* themselves.

Article 3 of our *statuts* specifies that the Company's corporate purposes, in France and abroad, are:

Acquiring interests and holdings, in any form whatsoever, in any company or enterprise, in existence or to be created, connected directly or indirectly with the health and fine chemistry sectors, human and animal therapeutics, nutrition and bio-industry;

in the following areas :

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Purchase and sale of all raw materials and products necessary for these activities;

Research, study and development of new products, techniques and processes;

Manufacture and sale of all chemical, biological, dietary and hygienic products;

Obtaining or acquiring all intellectual property rights related to results obtained and, in particular, filing all patents, trademarks and models, processes or inventions;

Operating directly or indirectly, purchasing, and transferring for free or for consideration pledging or securing all intellectual property rights, particularly all patents, trademarks and models, processes or inventions;

Obtaining, operating, holding and granting all licenses; and

Within the framework of a group-wide policy and subject to compliance with the relevant legislation, participating in treasury management transactions, whether as lead company or otherwise, in the form of centralized currency risk management or intra-group netting, or any other form permitted under the relevant laws and regulations;

And, more generally:

All commercial, industrial, real or personal property, financial or other transactions, connected directly or indirectly, totally or partially, with the activities described above and with all similar or related activities or having any other purposes likely to encourage or develop the company's activities.

## **Table of Contents**

### **Directors**

#### *Transactions in which Directors Are Materially Interested*

Under French law, any agreement entered into (directly or through an intermediary) between our Company and any one of the members of the Board of Directors that is not entered into (i) in the ordinary course of our business and (ii) under normal conditions is subject to the prior authorization of the disinterested members of the Board of Directors. The same provision applies to agreements between our Company and another company if one of the members of the Board of Directors is the owner, general partner, manager, director, general manager or member of the executive or supervisory board of the other company, as well as to agreements in which one of the members of the Board of Directors has an indirect interest.

The Board of Directors must also authorize any undertaking taken by our Company for the benefit of our Chairman, Chief Executive Officer (*directeur général*) or his delegates (*directeurs généraux délégués*) pursuant to which such persons will or may be granted compensation, benefit or any other advantage as a result of the termination or change in their offices or following such termination or change.

In addition, such termination package, except any non-compete indemnity and certain pension benefits: (i) must be authorized by our shareholders by adopting a separate general shareholders meeting resolution for each such beneficiary, which has to be renewed at each renewal of such beneficiary's mandate, and (ii) cannot be paid to such beneficiary unless the Board of Directors decides that such beneficiary has satisfied certain conditions, linked to such beneficiary's performances measured by our Company's performances, that must have been defined by the Board of Directors when granting such package, and such decision is made publicly available.

#### *Directors' Compensation*

The aggregate amount of attendance fees (*jetons de présence*) of the Board of Directors is determined at the ordinary general meeting of the shareholders. The Board of Directors then divides this aggregate amount up among its members, by a simple majority vote. In addition, exceptional compensation (*rémunérations exceptionnelles*) may be granted to directors on a case-by-case basis for special assignments. The Board may also authorize the reimbursement of travel and accommodation expenses, as well as other expenses incurred by Directors in the corporate interest. See also Item 6. Directors, Senior Management and Employees.

#### *Board of Directors' Borrowing Powers*

All loans or borrowings may be decided by the Board of Directors within the limits, if any, duly authorized by the general meeting of the shareholders.

#### *Directors' Age Limits*

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

For a description of the provisions of our *statuts* relating to age limits applicable to our Directors, see Item 6. Directors, Senior Management and Employees.

### *Directors Share Ownership Requirements*

For a description of the provisions of our *statuts* relating to the number of shares which our Directors are required to hold, see Item 6. Directors, Senior Management and Employees.

### **Share Capital**

As of December 31, 2008, our share capital amounted to 2,631,050,926, divided into 1,315,525,463 outstanding shares with a par value of 2 per share. All of our outstanding shares are of the same class and are fully paid. Of these shares, we or entities controlled by us held 10,014,971 shares (or 0.76% of our outstanding share capital), as treasury shares as of such date. As of December 31, 2008, the book value of such shares was 552 million.

At an extraordinary general meeting held on May 31, 2007, our shareholders authorized our Board of Directors to increase our share capital, through the issuance of shares or other securities giving access to the share capital with or without preemptive rights, by an aggregate maximum nominal amount of 1.6 billion. See Changes in Share Capital Increases in Share Capital, below.

## **Table of Contents**

The maximum total amount of authorized but unissued shares as of December 31, 2008 was 863.5 million, reflecting the unused part of the May 31, 2007 shareholder authorization and outstanding options to subscribe for shares.

## **Stock Options**

### *Stock Options*

#### Types of Stock Options

We have two types of stock options outstanding: options to subscribe for shares (*options de souscription d'actions*) and options to purchase shares (*options d'achat d'actions*). Upon exercise of an option to subscribe for shares, we issue new shares, whereas upon exercise of an option to purchase shares, the option holder receives existing shares. We purchase our shares on the market prior to the grant of the options to purchase in order to provide the option holder with shares upon exercise. Following the merger of Aventis with and into sanofi-aventis, all previously granted options for the shares of Aventis were converted into options for our shares.

Because the exercise of options to purchase shares will be satisfied with existing shares repurchased on the market or held in treasury, the exercise of options to purchase shares has no impact on our equity capital.

#### Stock Option Plans

Our ordinary and extraordinary shareholders' meeting of May 31, 2007 authorized our Board of Directors for 26 months to grant options to subscribe for shares and options to purchase shares to members of our salaried staff and/or corporate officers as well as to members of salaried staff and/or corporate officers of companies or economic interest groups related to our Company under the conditions referred to in Article L.225-180 of the French Commercial Code.

The aggregate number of options to subscribe for shares and options to purchase shares that may be granted under this authorization may not give entitlement to a total number of shares exceeding 2.5% of the share capital as of the day the decision to grant options is made by the Board. Under such a resolution, the price payable on the exercise of options may not be lower than the average of the first quoted prices of sanofi-aventis ordinary shares on Euronext Paris during the 20 consecutive trading days preceding the date on which the options are granted.

The authorization entails the express waiver by the shareholders, in favor of the grantees of options to subscribe for shares, of their preemptive rights in respect of shares that are to be issued as and when options are exercised.

The Board of Directors sets the terms on which options are granted and the arrangements as regards the dividend entitlement of the shares.



See Item 6. Directors, Senior Management and Employees E. Share Ownership for a description of our option plans currently in force.

### **Changes in Share Capital in 2008**

See Note D.15.1 to our consolidated financial statements included at Item 18 of this annual report.

### **Voting Rights**

In general, each shareholder is entitled to one vote per share at any general shareholders meeting. However, our *statuts* provide that any fully paid-up shares that have been held in registered form under the name of the same shareholder for at least two years acquire double voting rights. As of December 31, 2008, there were 282,058,863 shares that were entitled to double voting rights, representing 21.44% of our total share capital, approximately 35.53% of our voting rights held by holders other than us and our subsidiaries, and 35.31% of our total voting rights.

Double voting rights are not taken into account in determining whether a quorum exists.

## **Table of Contents**

Under the French Commercial Code, shares of a company held in treasury or by entities controlled by that company are not entitled to voting rights and do not count for quorum purposes.

Our *statuts* allow us to obtain from Euroclear France the name, nationality, address and number of shares held by holders of our securities that have, or may in the future have, voting rights. If we have reason to believe that a person on any list provided by Euroclear France holds securities on behalf of another person, our *statuts* allow us to request such information regarding beneficial ownership directly from such person. See Memorandum and Articles of Association Form, Holding and Transfer of Shares below.

Our *statuts* provide that Board members are elected on a rolling basis for a maximum tenure of four years. Our *statuts* do not provide for cumulative voting rights.

## **Shareholders Agreement**

We are not aware of any shareholder s agreement currently in force concerning our shares.

## **Shareholders Meetings**

### ***General***

In accordance with the French Commercial Code, there are three types of shareholders meetings: ordinary, extraordinary and special.

Ordinary general meetings of shareholders are required for matters such as:

electing, replacing and removing directors;

appointing independent auditors;

approving the annual financial statements;

declaring dividends or authorizing dividends to be paid in shares, provided the *statuts* contain a provision to that effect; and

approval of share repurchase programs.

Extraordinary general meetings of shareholders are required for approval of matters such as amendments to our *statuts*, including any amendment required in connection with extraordinary corporate actions. Extraordinary corporate actions include:

changing our Company's name or corporate purpose;

increasing or decreasing our share capital;

creating a new class of equity securities;

authorizing the issuance of securities giving access to our share capital or giving the right to receive debt instruments;

establishing any other rights to equity securities;

selling or transferring substantially all of our assets; and

the voluntary liquidation of our Company.

Special meetings of shareholders of a certain category of shares or shares with certain specific rights (such as shares with double voting rights) are required for any modification of the rights derived from that category of shares. The resolutions of the shareholders' general meeting affecting these rights are effective only after approval by the relevant special meeting.

### ***Annual Ordinary Meetings***

The French Commercial Code requires the Board of Directors to convene an annual ordinary general meeting of shareholders for approval of the annual financial statements. This meeting must be held within

## **Table of Contents**

six months of the end of each fiscal year. This period may be extended by an order of the President of the Commercial Court. The Board of Directors may also convene an ordinary or extraordinary general meeting of shareholders upon proper notice at any time during the year. If the Board of Directors fails to convene a shareholders meeting, our independent auditors may call the meeting. In case of bankruptcy, the liquidator or court-appointed agent may also call a shareholders meeting in some instances. In addition, any of the following may request the court to appoint an agent for the purpose of calling a shareholders meeting:

one or several shareholders holding at least 5% of our share capital;

duly qualified associations of shareholders who have held their shares in registered form for at least two years and who together hold at least 1% of our voting rights;

the works council in cases of urgency; or

any interested party in cases of urgency.

### ***Notice of Shareholders Meetings***

We must announce general meetings at least 35 days in advance by means of a preliminary notice (*avis de réunion*), which is published in the *Bulletin des Annonces Légales Obligatoires*, or *BALO*. The preliminary notice must first be sent to the AMF. The AMF also recommends that, prior to or simultaneously with the publication of the preliminary notice, we publish a summary of the notice indicating the date and place of the meeting in a newspaper of national circulation in France. The preliminary notice must contain, among other things, the agenda, a draft of the resolutions to be submitted to the shareholders and the procedure for voting by mail.

At least 15 days prior to the date set for a first call, and at least six days prior to any second call, we must send a final notice (*avis de convocation*) containing the final agenda, the date, time and place of the meeting and other information for the meeting. Such final notice must be sent by mail to all registered shareholders who have held shares in registered form for more than one month prior to the date of the final notice and by registered mail, if shareholders have asked for it and paid the corresponding charges. The final notice must also be published in a newspaper authorized to publish legal announcements in the local administrative department (*département*) in which our Company is registered as well as in the *BALO*, with prior notice having been given to the AMF. If no shareholder has proposed any new resolutions to be submitted to the vote of the shareholders at the meeting and provided that the Board of Directors has not altered the draft resolutions included in the preliminary notice, we are not required to publish the final notice; publishing a preliminary notice that stipulates that it shall be deemed to be equivalent to a final notice will be deemed sufficient.

In general, shareholders can only take action at shareholders meetings on matters listed on the agenda. As an exception to this rule, shareholders may take action with respect to the dismissal of directors even though this action has not been included on the agenda. Additional resolutions to be submitted for approval by the shareholders at the meeting may be proposed to the Board of Directors, for recommendation to the shareholders, as from the publication of the preliminary notice in the *BALO* and until 25 days prior to the general meeting or, alternatively within 20 days following the publication of the preliminary notice in the *BALO* if such preliminary notice was published more than 45 days prior to the general meeting:

one or several shareholders together holding a specified percentage of shares;

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

a duly qualified association of shareholders who have held their shares in registered form for at least two years and who together hold at least 1% of our voting rights; or

the works council.

The Board of Directors must submit these resolutions to a vote of the shareholders after having made a recommendation thereon.

Following the date on which documents must be made available to the shareholders, shareholders may submit written questions to the Board of Directors relating to the agenda for the meeting until the fourth business day prior to the general meeting. The Board of Directors must respond to these questions during the meeting.

## **Table of Contents**

### **Attendance at Shareholders Meetings; Proxies and Votes by Mail**

In general, all shareholders may participate in general meetings either in person or by proxy. Shareholders may vote in person, by proxy or by mail.

The right of shareholders to participate in general meetings is subject to the recording (*enregistrement comptable*) of their shares on the third business day, zero hour (Paris time), preceding the general meeting:

for holders of registered shares: in the registered shareholder account held by the Company or on its behalf by an agent appointed by it; and

for holders of bearer shares: in the bearer shareholder account held by the accredited financial intermediary with whom such holders have deposited their shares; such financial intermediaries shall deliver to holders of bearer shares a shareholding certificate (*attestation de participation*) enabling them to participate in the general meeting.

### ***Attendance in Person***

Any shareholder may attend ordinary general meetings and extraordinary general meetings and exercise its voting rights subject to the conditions specified in the French Commercial Code and our *statuts*.

### ***Proxies and Votes by Mail***

Proxies are sent to any shareholder upon request received between the publication of the final notice of meeting and six days before the general meeting. In order to be counted, such proxies must be received at our registered office, or at any other address indicated on the notice convening the meeting, prior to the date of the meeting (in practice, we request that shareholders return proxies at least three business days prior to the meeting). A shareholder may grant proxies only to his or her spouse or to another shareholder. A shareholder that is a corporation may grant proxies to a legal representative. Alternatively, the shareholder may send us a blank proxy without nominating any representative. In this case, the chairman of the meeting will vote the blank proxies in favor of all resolutions proposed or approved by the Board of Directors and against all others.

With respect to votes by mail, we must send shareholders a voting form upon request. The completed form must be returned to us at least three days prior to the date of the shareholders meeting.

### **Quorum**

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

The French Commercial Code requires that shareholders together holding at least 20% of the shares entitled to vote must be present in person, or vote by mail or by proxy, in order to fulfill the quorum requirement for:

an ordinary general meeting; and

an extraordinary general meeting where the only resolutions pertain to either (a) an increase in our share capital is proposed through incorporation of reserves, profits or share premium, or (b) the potential issuance of free share warrants in the event of a public offering on our shares (article L. 233-32 of the French Commercial Code).

For any other extraordinary general meeting the quorum requirement is at least 25% of the shares entitled to vote, present in person, or voting by mail or by proxy.

For a special meeting of holders of a certain category of shares, the quorum requirement is one third of the shares entitled to vote in that category, present in person, or voting by mail or by proxy.

If a quorum is not present at a meeting, the meeting is adjourned. However, only questions that were on the agenda of the adjourned meeting may be discussed and voted upon.

When an adjourned meeting is resumed, there is no quorum requirement for meetings cited in the first paragraph of this *Quorum* section. In the case of any other reconvened extraordinary general meeting or special meeting, the quorum requirement is 20% of the shares entitled to vote (or voting shares belonging to the relevant category for special meetings of holders of shares of such specific category), present in person or voting by mail or by proxy. If a quorum is not present, the reconvened meeting may be adjourned for a maximum of two months with the same quorum requirement. No deliberation or action by the shareholders may take place without a quorum.

## **Table of Contents**

### **Votes Required for Shareholder Action**

A simple majority of shareholders may pass a resolution at either an ordinary general meeting or an extraordinary general meeting where the only resolution(s) pertain to either (a) an increase in our share capital is proposed through incorporation of reserves, profits or share premium, or (b) the potential issuance of free share warrants in the event of a public offering on our shares (article L. 233-32 of the French Commercial Code). At any other extraordinary general shareholders meeting and at any special meeting of holders of a specific category of shares, a two-thirds majority of the shareholder votes cast is required.

Abstention from voting by those present or those represented by proxy or voting by mail is counted as a vote against the resolution submitted to a shareholder vote.

### **Changes to Shareholders Rights**

Under French law, a two-thirds majority vote at the extraordinary shareholders meeting is required to change our *statuts*, which set out the rights attaching to our shares except for capital increases through incorporation of reserves, profits or share premium, or through the issuance of free share warrants in the event of a public offering on our shares (article L. 233-32 of the French Commercial Code).

The rights of a class of shareholders can be amended only after a special meeting of the class of shareholders affected has taken place. The voting requirements applicable to this type of special meeting are the same as those applicable to an extraordinary general shareholders meeting. The quorum requirements for a special meeting are one third of the voting shares, or 20% upon resumption of an adjourned meeting.

A unanimous shareholder vote is required to increase the liabilities of shareholders.

### **Financial Statements and Other Communications with Shareholders**

In connection with any shareholders meeting, we must provide a set of documents including our annual report and a summary of the financial results of the five previous fiscal years to any shareholder who so requests.

### **Dividends**

We may only distribute dividends out of our distributable profits, plus any amounts held in our reserve that the shareholders decide to make available for distribution, other than those reserves that are specifically required by law or our *statuts*. Distributable profits consist of our unconsolidated net profit in each fiscal year, as increased or reduced by any profit or loss carried forward from prior years, less any contributions to the reserve accounts pursuant to law or our *statuts*.



*Legal Reserve*

The French Commercial Code requires us to allocate 5% of our unconsolidated statutory net profit for each year to our legal reserve fund before dividends may be paid with respect to that year. Funds must be allocated until the amount in the legal reserve is equal to 10% of the aggregate par value of the issued and outstanding share capital. This restriction on the payment of dividends also applies to each of our French subsidiaries on an unconsolidated basis. At December 31, 2008, our legal reserve amounted to 282,280,863 representing 10.73% of the aggregate par value of our issued and outstanding share capital as of that date. The legal reserve of any company subject to this requirement may only be distributed to shareholders upon liquidation of the company.

*Approval of Dividends*

According to the French Commercial Code, our Board of Directors may propose a dividend for approval by the annual general meeting of shareholders. If we have earned distributable profits since the end of the preceding fiscal year, as reflected in an interim income statement certified by our independent auditors, our Board of Directors may distribute interim dividends to the extent of the distributable profits for the period covered by the interim income statement. Our Board of Directors exercises this authority subject to French law and regulations and may do so without obtaining shareholder approval.

## **Table of Contents**

### ***Distribution of Dividends***

Dividends are distributed to shareholders pro rata according to their respective holdings of shares. In the case of interim dividends, distributions are made to shareholders on the date of our Board of Directors' meeting in which the distribution of interim dividends is approved. The actual dividend payment date is decided by the shareholders at an ordinary general shareholders meeting or by our Board of Directors in the absence of such a decision by the shareholders. Shareholders that own shares on the actual payment date are entitled to the dividend.

Dividends may be paid in cash or, if the shareholders' meeting so decides, in kind, provided that all shareholders receive a whole number of assets of the same nature paid in lieu of cash. Our *statuts* provide that, upon a decision of the shareholders' meeting taken by ordinary resolution, each shareholder may be given the choice to receive his dividend in cash or in shares.

### ***Timing of Payment***

According to the French Commercial Code, we must pay any existing dividends within nine months of the end of our fiscal year, unless otherwise authorized by court order. Dividends on shares that are not claimed within five years of the date of declared payment revert to the French State.

## **Changes in Share Capital**

### ***Increases in Share Capital***

As provided by the French Commercial Code, our share capital may be increased only with the shareholders' approval at an extraordinary general shareholders meeting following the recommendation of our Board of Directors. Increases in our share capital may be effected by:

issuing additional shares;

increasing the par value of existing shares;

creating a new class of equity securities; or

exercise of rights attached to securities giving access to the share capital.

Increases in share capital by issuing additional securities may be effected through one or a combination of the following:

in consideration for cash;

in consideration for assets contributed in kind;

through an exchange offer;

by conversion of previously issued debt instruments;

by capitalization of profits, reserves or share premium; or

subject to various conditions, in satisfaction of debt incurred by our Company.

Decisions to increase the share capital through the capitalization of reserves, profits and/or share premium or through the issuance of free share warrants in the event of a public offering on our shares (article L. 233-32 of the French Commercial Code) require the approval of an extraordinary general shareholders meeting, acting under the quorum and majority requirements applicable to ordinary shareholders' meetings. Increases effected by an increase in the par value of shares require unanimous approval of the shareholders, unless effected by capitalization of reserves, profits or share premium. All other capital increases require the approval of an extraordinary general shareholders meeting acting under the regular quorum and majority requirements for such meetings. See *Quorum and Votes Required for Shareholder Action* above.

Since the entry into force of order 2004-604 of June 24, 2004, the shareholders may delegate to our Board of Directors either the authority (*délégation de compétence*) or the power (*délégation de pouvoir*) to carry out any increase in share capital. Our Board of Directors may further delegate this power to our Chief Executive Officer or, subject to our Chief Executive Officer's approval, to his delegates (*directeurs généraux délégués*).

---

**Table of Contents**

On May 31, 2007, our shareholders approved different resolutions delegating to the Board of Directors the authority to increase our share capital through the issuance of shares or securities giving access to the share capital, subject to an overall cap set at 1.6 billion. This cap applies to all the resolutions whereby the extraordinary shareholders meeting delegated to the Board of Directors the authority to increase the share capital, it being also specified that:

- the maximum aggregate par value amount of capital increases that may be carried out with preemptive rights maintained was set at 1.4 billion;
- the maximum aggregate par value amount of capital increases that may be carried out without preemptive rights was set at 800 million;
- the maximum aggregate par value amount of capital increases that may be carried out by capitalization of share premium, reserves, profits or other items was set at 500 million; and
- capital increases resulting in the issuance of securities to employees, early retirees or retirees under our employee savings plans are limited to 2% of the share capital as computed on the date of the Board's decision, and such issuances may be made at a discount of 20% (or 30% if certain French law restrictions on resales were to apply);

On May 31, 2007, our shareholders also approved resolutions delegating to the Board of Directors the authority to increase the share capital by granting options or free shares to our employees and/or corporate officers, subject to the overall cap mentioned above and under the following terms and conditions:

- authorization, for a period of 26 months, to grant options to purchase or to subscribe for our shares to employees and/or corporate officers; such options may not give entitlement to a total number of shares exceeding 2.5% of the share capital as computed on the day of the Board's decision; See "Stock Options and Warrants" above;
- authorization, for a period of 38 months, to grant existing or new shares free of consideration to employees and/or corporate officers, up to a limit of 1% of the share capital as computed on the day of the Board's decision.

See also "Item 6. Directors, Senior Management and Employees - E. Share Ownership".

***Decreases in Share Capital***

According to the French Commercial Code, any decrease in our share capital requires approval by the shareholders entitled to vote at an extraordinary general meeting. The share capital may be reduced either by decreasing the par value of the outstanding shares or by reducing the number of outstanding shares. The number of outstanding shares may be reduced either by an exchange of shares or by the repurchase and cancellation of shares. Holders of each class of shares must be treated equally unless each affected shareholder agrees otherwise.

In addition, specific rules exist to permit the cancellation of treasury shares, by which the shareholders meeting may authorize the cancellation of up to 10% of a company's share capital per 24-month period. On May 31, 2007, our shareholders delegated the right to our Board of Directors to

reduce our share capital by canceling our own shares.

On April 29, 2008, our Board of Directors cancelled 51,437,419 shares, of which 70,919 had been allocated to stock purchase options which had elapsed and 51,366,500 had been held with a view to their future cancellation.

### **Preemptive Rights**

According to the French Commercial Code, if we issue additional securities to be paid in cash, current shareholders will have preemptive rights to these securities on a pro rata basis. These preemptive rights require us to give priority treatment to current shareholders. The rights entitle the individual or entity that holds them to subscribe to the issuance of any securities that may increase the share capital of our Company by means of a cash payment or a set-off of cash debts. Preemptive rights are transferable during the subscription period relating to a particular offering. These rights may also be listed on Euronext Paris.

## **Table of Contents**

Preemptive rights with respect to any particular offering may be waived by a vote of shareholders holding a two-thirds majority of the shares entitled to vote at an extraordinary general meeting. Our Board of Directors and our independent auditors are required by French law to present reports that specifically address any proposal to waive preemptive rights. In the event of a waiver, the issue of securities must be completed within the period prescribed by law. Shareholders also may notify us that they wish to waive their own preemptive rights with respect to any particular offering if they so choose.

The shareholders may decide at extraordinary general meetings to give the existing shareholders a non-transferable priority right to subscribe to the new securities, for a limited period of time.

In the event of a capital increase without preemptive rights to existing shareholders, French law requires that the capital increase be made at a price equal to or exceeding the weighted average market prices of the shares for the last three trading days on Euronext Paris prior to the determination of the subscription price of the capital increase less 5%.

## **Form, Holding and Transfer of Shares**

### ***Form of Shares***

Our *statuts* provide that the shares may be held in either bearer form or registered form at the option of the holder.

### ***Holding of Shares***

In accordance with French law relating to the dematerialization of securities, shareholders' ownership rights are represented by book entries instead of share certificates. We maintain a share account with Euroclear France (a French clearing system, which holds securities for its participants) for all shares in registered form, which is administered by BNP Paribas Securities Services. In addition, we maintain separate accounts in the name of each shareholder either directly or, at a shareholder's request, through the shareholder's accredited intermediary. Each shareholder account shows the name of the holder and the number of shares held. BNP Paribas Securities Services issues confirmations (*attestations d'inscription en compte*) to each registered shareholder as to shares registered in the shareholder's account, but these confirmations are not documents of title.

Shares of a listed company may also be issued in bearer form. Shares held in bearer form are held and registered on the shareholder's behalf in an account maintained by an accredited financial intermediary and are credited to an account at Euroclear France maintained by such intermediary. Each accredited financial intermediary maintains a record of shares held through it and issues certificates of inscription for the shares it holds. Transfers of shares held in bearer form may only be made through accredited financial intermediaries and Euroclear France.

Shares held by persons who are not domiciled in France may be registered in the name of intermediaries who act on behalf of one or more investors. When shares are so held, we are entitled to request from such intermediaries the names of the investors. Also, we may request any legal person (*personne morale*) who holds more than 2.5% of our shares or voting rights, to disclose the name of any person who owns, directly

or indirectly, more than one third of its share capital or of its voting rights. A person not providing the complete requested information in time, or who provides incomplete or false information, will be deprived of its voting rights at shareholders' meetings and will have its payment of dividends withheld until it has provided the requested information in strict compliance with French law. If such person acted willfully, the person may be deprived by a French court of either its voting rights or its dividends or both for a period of up to five years.

*Transfer of Shares*

Our *statuts* do not contain any restrictions relating to the transfer of shares.

Registered shares must be converted into bearer form before being transferred on Euronext Paris on the shareholders' behalf and, accordingly, must be registered in an account maintained by an accredited financial intermediary on the shareholders' behalf. A shareholder may initiate a transfer by giving instructions to the

## **Table of Contents**

relevant accredited financial intermediary. A fee or commission is payable to the broker involved in the transaction, regardless of whether the transaction occurs within or outside France. No registration duty is normally payable in France unless a transfer instrument has been executed in France.

## **Redemption of Shares**

Under French law, our Board of Directors is entitled to redeem a set number of shares as authorized by the extraordinary shareholders' meeting. In the case of such an authorization, the shares redeemed must be cancelled within one month after the end of the offer to purchase such shares from shareholders. However, shares redeemed on the open market need not be cancelled if the company redeeming the shares grants options on or awards those shares to its employees within one year of the acquisition. See also "Trading in Our Own Shares" below.

## **Sinking Fund Provisions.**

Our *statuts* do not provide for any sinking fund provisions.

## **Liability to Further Capital Calls**

Shareholders are liable for corporate liabilities only up to the par value of the shares they hold; they are not liable to further capital calls.

## **Liquidation Rights**

If we are liquidated, any assets remaining after payment of our debts, liquidation expenses and all of our remaining obligations will first be distributed to repay in full the par value of our shares. Any surplus will be distributed *pro rata* among shareholders in proportion to the par value of their shareholdings.

## **Requirements for Holdings Exceeding Certain Percentages**

The French Commercial Code provides that any individual or entity, acting alone or in concert with others, that becomes the owner, directly or indirectly, of more than 5%, 10%, 15%, 20%, 25%, 33 1/3%, 50%, 66 2/3%, 90% or 95% of the outstanding shares or voting rights of a listed company in France, such as our Company, or that increases or decreases its shareholding or voting rights above or below any of those percentages, must notify the company, within five trading days of the date it crosses the threshold, of the number of shares it holds and their voting rights. The individual or entity must also notify the AMF within five trading days of the date it crosses the threshold. The AMF makes the notice public.



## Edgar Filing: SANOFI-AVENTIS - Form 20-F

French law and AMF regulations impose additional reporting requirements on persons who acquire more than 10% or 20% of the outstanding shares or voting rights of a listed company. These persons must file a report with the company and the AMF within ten trading days of the date they cross the threshold. In the report, the acquirer must specify if it acts alone or in concert with others and specify its intentions for the following 12-month period, including whether or not it intends to continue its purchases, to acquire control of the company in question or to seek representation on to the board of directors. The AMF makes the report public. The acquirer may amend its stated intentions, provided that it does so on the basis of significant changes in its own situation or shareholding. Upon any change of intention, it must file a new report.

Starting August 1, 2009, the requirements of the preceding paragraph will be expanded. They will also apply to persons who acquire more than 15% or 25% of the outstanding shares or voting rights of a listed company, and file the report with the company and the AMF within a number of days of the date they cross the threshold as determined by law. The content of the report will be expanded and the duration of its validity shortened. In the report, the acquirer will have to specify if it acts alone or in concert with others and specify the means of financing of the acquisition, its intentions for the following 6-month period, including whether or not it intends to continue its purchases, to acquire control of the company in question, the strategy it contemplates vis-à-vis the issuer and the way it intends to implement it, any agreement for the temporary transfer of shares or voting rights, and whether it seeks representation on to the board of directors. Upon any change of intention, it will have to file a new report for the following 6-month period.

## **Table of Contents**

In order to permit shareholders to give the required notice, we must each month publish on our website and send the AMF a written notice setting forth the total number of our shares and voting rights (including treasury shares) whenever they vary from the figures previously published.

If any shareholder fails to comply with the legal notification requirement, the shares in excess of the relevant threshold will be deprived of voting rights for all shareholders' meetings until the end of a two-year period following the date on which the owner complies with the notification requirements. In addition, any shareholder who fails to comply with these requirements may have all or part of its voting rights suspended for up to five years by the Commercial Court at the request of our Chairman, any shareholder or the AMF, and may be subject to criminal fines.

Under AMF regulations, and subject to limited exemptions granted by the AMF, any person or entity, acting alone or in concert, that crosses the threshold of 33 1/3% of the share capital or voting rights of a French listed company must initiate a public tender offer for the balance of the shares and securities giving access to the share capital or voting rights of such company.

In addition, our *statuts* provide that any person or entity, acting alone or in concert with others, who becomes the owner of 1%, or any multiple of 1% of our share capital or our voting rights must notify us by certified mail, return receipt requested, within five trading days of the total number of shares and securities giving access to our share capital and voting rights that such person then owns. The same provisions of our *statuts* apply whenever such owner increases or decreases its ownership of our share capital or our voting rights to such extent that it respectively went above or below one of the thresholds described in the preceding sentence. Any person or entity that fails to comply with such notification requirements, will, upon the request of one or more shareholders holding at least 5% of our share capital or of our voting rights made at the general shareholders' meeting, be deprived of voting rights with respect to the shares in excess of the relevant threshold for all shareholders' meetings until the end of a two-year period following the date on which such person or entity complies with the notification requirements.

## **Change in Control/Anti-takeover**

There are no provisions in our *statuts* that would have the effect of delaying, deferring or preventing a change in control of our Company or that would operate only with respect to a merger, acquisition or corporate restructuring involving our Company or any of our subsidiaries. Further, there are no provisions in our *statuts* that allow for the issuance of preferred stock upon the occurrence of a takeover attempt or the addition of other anti-takeover measures without a shareholder vote.

Our *statuts* do not include any provisions discriminating against any existing or prospective holder of our securities as a result of such shareholder owning a substantial number of shares.

## **Trading in Our Own Shares**

Under French law, sanofi-aventis may not issue shares to itself. However, we may, either directly or through a financial intermediary acting on our behalf, acquire up to 10% of our issued share capital within a maximum period of 18 months, provided our shares are listed on a regulated market. Prior to acquiring our shares, we must publish a description of the share repurchase program (*descriptif du programme de rachat d'actions*).

We may not cancel more than 10% of our issued share capital over any 24-month period. Our repurchase of shares must not result in our Company holding, directly or through a person acting on our behalf, more than 10% of our issued share capital. We must hold any shares that we repurchase in registered form. These shares must be fully paid up. Shares repurchased by us continue to be deemed issued under French law but are not entitled to dividends or voting rights so long as we hold them directly or indirectly, and we may not exercise the preemptive rights attached to them.

The shareholders, at an extraordinary general shareholders meeting, may decide not to take these shares into account in determining the preemptive rights attached to the other shares. However, if the shareholders decide to take them into account, we must either sell the rights attached to the shares we hold on the market before the end of the subscription period or distribute them to the other shareholders on a pro rata basis.

## **Table of Contents**

On May 14, 2008, our shareholders approved a resolution authorizing us to repurchase up to 10% of our shares over an 18-month period. Under this authorization, the purchase price for each sanofi-aventis ordinary share may not be greater than 100.00 and the maximum amount that sanofi-aventis may pay for the repurchases is 13,659,166,440. A description of this share repurchase program as adopted by the Board of Directors on May 14, 2008 (*descriptif du programme de rachat d'actions*) was published on March 6, 2008.

### ***Purposes of Share Repurchase Programs***

European regulation n°2273/2003, dated December 22, 2003 (which we refer to in this section as the Regulation), in application of European directive 2003/6/EC, dated January 28, 2003, known as the Market Abuse Directive (the Directive) relating to share repurchase programs and the stabilization of financial instruments, came into effect on October 13, 2004.

The entry into force of the Regulation has resulted in changes in the manner in which share repurchase programs are implemented. Under the Regulation, an issuer will benefit from a safe harbor for share transactions that comply with certain conditions relating in particular to the pricing, volume and timing of transactions (see below) and that are made in connection with a share repurchase program the purpose of which is:

to reduce the share capital through the cancellation of treasury shares; and/or

to meet obligations arising from debt instruments exchangeable into equity instruments and/or the implementation of employee share option programs or other employee share allocation plans.

Safe harbor transactions will by definition not be considered market abuses under the Regulation. Transactions that are carried out for other purposes than those mentioned above do not qualify for the safe harbor. However, as permitted by the Directive, which provides for the continuation of existing practices that do not constitute market manipulation and that conform with certain criteria set forth in European directive 2004/72, dated April 29, 2004, the AMF published exceptions on March 22, 2005 to permit the following existing market practices:

transactions pursuant to a liquidity agreement entered into with a financial services intermediary that complies with the ethical code (*charte de déontologie*) approved by the AMF; and

the purchase of shares that are subsequently used as acquisition currency in a business combination transaction.

The AMF confirmed that all transactions directed at maintaining the liquidity of an issuer's shares must be conducted pursuant to a liquidity agreement with a financial services intermediary acting independently.

Additionally, our program could be used for any purpose that is authorized or could be authorized under applicable laws and regulations.

### ***Pricing, Volume and Other Restrictions***

In order to qualify for the safe harbor, the issuer must generally comply with the following pricing and volume restrictions:

a share purchase must not be made at a price higher than the higher of the price of the last independent trade and the highest current independent bid on the trading venues where the purchase is carried out;

subject to certain exceptions for illiquid securities, the issuer must not purchase more than 25% of the average daily volume of the shares in any one day on the regulated market on which the purchase is carried out. The average daily volume figure must be based on the average daily volume traded in the month preceding the month of public disclosure of the share repurchase program and fixed on that basis for the authorized period of that program. If the program does not make reference to this volume, the average daily volume figure must be based on the average daily volume traded in the 20 trading days preceding the date of purchase.

## **Table of Contents**

In addition, an issuer must not:

resell the shares acquired pursuant to the repurchase program (without prejudice to the right of the issuer to meet its obligations under employee share option programs or other employee share allocation plans or to use shares as acquisition currency as mentioned above); it being further specified that such prohibition is not applicable if the share repurchase program is implemented by a financial services intermediary pursuant to a liquidity agreement as mentioned above;

effect any transaction during a blackout period imposed by the applicable law of the Member State in which the transaction occurs (*i.e.*, under French law, during the period between the date on which the company is aware of insider information and the date on which such information is made public and during the 15-day period preceding the date of publication of annual and interim financial statements), without prejudice to transactions carried out pursuant to a liquidity agreement as mentioned above; or

effect any transaction in securities with respect to which the issuer has decided to defer disclosure of any material, non-public information.

### ***Use of Share Repurchase Programs***

Pursuant to the AMF rules, issuers must immediately allocate the repurchased shares to one of the purposes provided for in the Regulation and must not subsequently use the shares for a different purpose. As an exception to the foregoing, shares repurchased with a view to covering stock option plans may, if no longer needed for this purpose, be re-allocated for cancellation or sold in compliance with AMF requirements relating in particular to blackout periods. Shares repurchased in connection with one of the market practices authorized by the AMF (see above) may also be re-allocated to one of the purposes contemplated by the Regulation or sold in compliance with AMF requirements. Shares repurchased with a view to their cancellation must be cancelled within 24 months following their acquisition.

During the year ended December 31, 2008, we used the authority delegated by our shareholders to repurchase our shares on the stock market. The shares repurchased during the year end December 31, 2008 were acquired with a view to cancellation. We repurchased 23,862,169 shares at an average cost of 51.457 per share, *i.e.* an overall cost of 1,227,689,566, including 1,061,076 of transaction costs not including corporate income tax.

As of December 31, 2008, we directly owned 9,647,801 sanofi-aventis shares with an aggregate par value of 19,295,602 (representing around 0.73% of our share capital and with a value estimated at the share price upon purchase of 538,825,311).

In 2008, of the 8,359,206 shares allocated to stock purchase option plans outstanding at December 31, 2007, 94,816 shares were transferred to grantees of options, comprising:

89,201 shares transferred directly by us;

5,615 shares transferred indirectly (by Hoechst GmbH).

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Following these transfers, the shares owned directly or indirectly by us were allocated as follows:

8,193,471 shares were allocated to outstanding stock purchase option plans comprising:

7,826,301 directly-owned shares, representing 0.59% of our share capital;

367,170 indirectly-owned shares, representing 0.03% of our share capital.

1,821,500 shares were allocated to cancellation, representing 0.14% of our share capital.

On April 29, 2008, our Board of Directors cancelled 51,437,419 shares, of which 70,919 had been allocated to stock purchase options that had elapsed and 51,366,500 had been held with a view to their future cancellation.

There has been no reallocation.

## **Table of Contents**

### ***Reporting obligations***

Pursuant to the AMF Regulation and the French Commercial Code, issuers trading in their own shares are subject to the following reporting obligations:

Issuers must report all transactions in their own shares publicly within seven trading days of the transaction in a prescribed format, unless such transactions are carried out pursuant to a liquidity agreement that complies with the ethical code approved by the AMF; and

Issuers must declare to the AMF on a monthly basis all transactions completed under the share repurchase program unless they provide the same information on a weekly basis.

### **Ownership of Shares by Non-French Persons**

The French Commercial Code and our *statuts* currently do not limit the right of non-residents of France or non-French persons to own or, where applicable, to vote our securities. However, non-residents of France must file an administrative notice with the French authorities in connection with the acquisition of a controlling interest in our Company. Under existing administrative rulings, ownership of 33 1/3% or more of our share capital or voting rights is regarded as a controlling interest, but a lower percentage might be held to be a controlling interest in certain circumstances depending upon factors such as:

the acquiring party's intentions;

the acquiring party's ability to elect directors; or

financial reliance by the company on the acquiring party.

### **Enforceability of Civil Liabilities**

We are a limited liability company (*société anonyme*) organized under the laws of France, and most of our directors and officers reside outside the United States. In addition, a substantial portion of our assets is located in France. As a result, it may be difficult for investors to effect service of process within the United States on such persons. It may also be difficult to enforce against them, either inside or outside the United States, judgments obtained against them in U.S. courts, or to enforce in U.S. courts, judgments obtained against them in courts in jurisdictions outside the United States, in any action based on civil liabilities under the U.S. federal securities laws. There is doubt as to the enforceability against such persons in France, whether in original actions or in actions to enforce judgments of U.S. courts, of liabilities based solely on the U.S. federal securities laws. Actions for enforcement of foreign judgments against such persons would require such persons who are of French nationality to waive their right under Article 15 of the French Civil Code to be sued only in France. We believe that no such French persons have waived such right with respect to actions predicated solely upon U.S. federal securities laws. In addition, actions in the United States under the U.S. federal securities laws could be affected under certain circumstances by the French law of July 26, 1968, as amended, which may preclude or restrict the obtaining of evidence in France or from French persons in connection with such actions. Additionally, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in France.



***C. Material Contracts***

N/A

***D. Exchange Controls***

French exchange control regulations currently do not limit the amount of payments that we may remit to non-residents of France. Laws and regulations concerning foreign exchange controls do require, however, that all payments or transfers of funds made by a French resident to a non-resident be handled by an accredited intermediary. In France, all registered banks and most credit establishments are accredited intermediaries.

***E. Taxation***

**General**

The following generally summarizes the material French and U.S. federal income tax consequences to U.S. holders (as defined below) of owning and disposing of our ADSs, ordinary shares, PSSAs and PSSA-ADSs

---

## Table of Contents

(collectively the Securities ). This discussion is intended only as a descriptive summary and does not purport to be a complete analysis or listing of all potential tax effects of the purchase, ownership or disposition of our Securities.

*This summary does not constitute a legal opinion or tax advice. Holders are urged to consult their own tax advisers regarding the tax consequences of the purchase, ownership and disposition of Securities in light of their particular circumstances, including the effect of any U.S. federal, state, local or other national tax laws.*

The description of the French and U.S. federal income tax consequences set forth below is based on the laws (including, for U.S. federal income tax purposes, the Internal Revenue Code of 1986, as amended (the Code ), final, temporary and proposed U.S. Treasury Regulations promulgated thereunder and administrative and judicial interpretations thereof) in force as of the date of this annual report, the Convention Between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income and Capital of August 31, 1994 (the Treaty ), which entered into force on December 30, 1995 (as amended by any subsequent protocols), and the tax regulations issued by the French tax authorities (the Regulations ) in force as of the date of this report. All of the foregoing is subject to change. Such changes could apply retroactively and could affect the consequences described below.

In particular, the United States and France signed a protocol on January 13, 2009, that, upon ratification, will make several changes to the Treaty, including changes to the Limitation on Benefits provision. The provisions of the protocol will be effective as soon as the ratification occurs in both jurisdictions, and with respect to withholding taxes will be effective for amounts paid or accrued on or after the first day of the year in which the protocol enters into force. *U.S. holders are advised to consult their own tax advisers regarding the effect the protocol may have on their eligibility for Treaty benefits in light of their own particular circumstances.*

For the purposes of this discussion, a U.S. holder is a beneficial owner of Securities that is (i) an individual who is a U.S. citizen or resident for U.S. federal income tax purposes, (ii) a U.S. domestic corporation or certain other entities created or organized in or under the laws of the United States or any state thereof, including the District of Columbia, or (iii) otherwise subject to U.S. federal income taxation on a net income basis in respect of Securities. A non-U.S. holder is a person other than a U.S. holder.

If a partnership holds Securities, the tax treatment of a partner generally will depend upon the status of the partner and the activities of the partnership. *If a U.S. holder is a partner in a partnership that holds Securities, the holder is urged to consult its own tax adviser regarding the specific tax consequences of acquiring, owning and disposing of Securities.*

This discussion is intended only as a general summary and does not purport to be a complete analysis or listing of all potential tax effects of the acquisition, ownership or disposition of the Securities to any particular investor, and does not discuss tax considerations that arise from rules of general application or that are generally assumed to be known by investors. The discussion applies only to investors that hold our Securities as capital assets, that have the U.S. dollar as their functional currency, that are entitled to Treaty benefits under the Limitation on Benefits provision contained in the Treaty, and whose ownership of the Securities is not effectively connected to a permanent establishment or a fixed base in France. Certain holders (including, but not limited to, U.S. expatriates, partnerships or other entities classified as partnerships for U.S. federal income tax purposes, banks, insurance companies, regulated investment companies, tax-exempt organizations, financial institutions, persons subject to the alternative minimum tax, persons who acquired the Securities pursuant to the exercise of employee stock options or otherwise as compensation, persons that own (directly, indirectly or by attribution) 5% or more of our voting stock or 10% or more of our outstanding share capital, dealers in securities or currencies, persons that elect to mark their securities to market for U.S. federal income tax purposes and persons holding Securities as a position in a synthetic security, straddle or conversion transaction) may be subject to special rules not discussed below. *Holders of Securities are advised to consult their own tax advisers with regard to the application of French tax law and U.S. federal income tax law to their particular situations, as well as any tax consequences arising under the laws of any state, local or other foreign jurisdiction.*



## **Table of Contents**

### **French Taxes**

#### *New Tax Distribution Regime*

Holders of Securities should be aware that the French Finance Bill for 2004 (No. 2003-1311 dated December 30, 2003) provided for the suppression of the *avoir fiscal* and the *précompte* with respect to dividends paid on or after January 1, 2005. However, non-individual shareholders were already no longer entitled to use the *avoir fiscal* as of January 1, 2005.

#### *Estate and Gift Taxes and Transfer Taxes*

In general, a transfer of Securities by gift or by reason of death of a U.S. holder that would otherwise be subject to French gift or inheritance tax, respectively, will not be subject to such French tax by reason of the Convention between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Estates, Inheritances and Gifts, dated November 24, 1978, unless the donor or the transferor is domiciled in France at the time of making the gift or at the time of his or her death, or the Securities were used in, or held for use in, the conduct of a business through a permanent establishment or a fixed base in France.

Generally, transfers of Securities (other than ordinary shares) are not subject to French registration or stamp duty. Generally, transfers of ordinary shares will not be subject to French registration or stamp duty if such transfers are not evidenced by a written agreement or if such an agreement is executed outside of France.

#### *Wealth Tax*

The French wealth tax *impôt de solidarité sur la fortune* does not generally apply to the Securities if the holder is a U.S. resident, as defined pursuant to the provisions of the Treaty.

### **U.S. Taxes**

#### *Ownership of the Securities*

Deposits and withdrawals by a U.S. holder of ordinary shares in exchange for ADSs, or of PSSAs in exchange for PSSA-ADSs (including in connection with the intended termination of the deposit agreement with respect to the PSSA-ADSs), will not be taxable events for U.S. federal income tax purposes. For U.S. tax purposes, holders of ADSs will be treated as owners of the ordinary shares represented by such ADSs, and holders of PSSA-ADSs will be treated as owners of the PSSAs represented by such PSSA-ADSs. Accordingly, the discussion that follows regarding the U.S. federal income tax consequences of acquiring, owning and disposing of ordinary shares and PSSAs is equally applicable to

ADSs and PSSA-ADSs, respectively.

*Information Reporting and Backup Withholding Tax*

Distributions made to holders and proceeds paid from the sale, exchange, redemption or disposal of Securities may be subject to information reporting to the Internal Revenue Service. Such payments may be subject to backup withholding taxes unless the holder (i) is a corporation or other exempt recipient or (ii) provides a taxpayer identification number and certifies that no loss of exemption from backup withholding has occurred. Holders that are not U.S. persons generally are not subject to information reporting or backup withholding. However, such a holder may be required to provide a certification of its non-U.S. status in connection with payments received within the United States or through a U.S.-related financial intermediary to establish that it is an exempt recipient. Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a holder's U.S. federal income tax liability. A holder may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the Internal Revenue Service and furnishing any required information.

*State and Local Taxes*

In addition to U.S. federal income tax, U.S. holders of Securities may be subject to U.S. state and local taxes with respect to such Securities. *Holders of Securities are advised to consult their own tax advisers with regard to the application of U.S. state and local income tax law to their particular situation.*

## **Table of Contents**

### **ADSs-Ordinary Shares**

### **French Taxes**

#### *Taxation of Dividends*

Dividends received by French resident individuals are either included in their total income and subject to the progressive income tax, or they can alternatively be subject to an 18% levy at source at the option of the beneficiary.

When no option is exercised by the French resident individuals, they are only taxed on 60% of dividends received (by application of a first 40% allowance) and, in addition to a second fixed annual allowance of 3,050 for couples subject to joint taxation and 1,525 for single persons, widows, widowers or divorced persons, are entitled to a tax credit equal to 50% of all dividends received within one year (the Tax Credit). The Tax Credit is capped for all dividends received within one year at 230 for married couples and members of a civil union agreement subject to joint taxation and 115 for single persons, widows or widowers, divorced or married persons subject to separate taxation.

As a result of the French Finance Bill for 2008, French resident individuals can elect to have all or part of the dividends received subject to an 18% levy at source at the irrevocable option of the shareholder exercised no later than at the time of payment if it occurs in France. If the option is exercised only for a portion of the dividends received during the year (whether they are distributed by sanofi-aventis or any other company), the remaining dividends subject to the progressive income tax lose the benefit of the aforementioned allowances and the Tax Credit.

Dividends paid to non-residents are not normally eligible for the Tax Credit described above. However, under the Treaty, qualifying non-resident individuals may benefit from a refund of the Tax Credit (net of applicable withholding tax) under certain conditions, subject to compliance with the procedures for claiming benefits under the Treaty. The French tax authorities have not yet issued any guidance with regard to the procedures for claiming the refund of the Tax Credit to non-resident individuals. Individual U.S. holders are urged to consult their own tax advisers in this respect.

When the new protocol to the Treaty becomes effective, the Treaty will no longer specifically provide for any entitlement to a refund of the Tax Credit, and individual U.S. holders will not continue to benefit from such a refund.

Under French law, dividends paid by a French corporation, such as sanofi-aventis, to non-residents of France are generally subject to French withholding tax at a rate of 25% (18% for distributions made as from January 1, 2008 to individuals that are resident in the European Economic Area, except Liechtenstein). Under the Treaty, the rate of French withholding tax on dividends paid to an eligible U.S. holder whose ownership of the ordinary shares or ADSs is not effectively connected with a permanent establishment or fixed base that such U.S. holder has in France is reduced to 15% and a U.S. holder may claim a refund from the French tax authorities of the amount withheld in excess of the Treaty rate of 15%, if any. For U.S. holders that are not individuals, the requirements for eligibility for Treaty benefits, including the reduced 15% withholding tax rate, contained in the Limitation on Benefits provision of the Treaty are complicated, and there are certain technical changes being made to these requirements by the new protocol. U.S. holders are advised to consult their own tax advisors regarding their eligibility for Treaty benefits, and whether the protocol may affect their eligibility, in light of their own particular circumstances.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Dividends paid to an eligible U.S. holder are immediately subject to the reduced rate of 15%, provided that such holder establishes before the date of payment that it is a U.S. resident under the Treaty by completing and providing the depositary with a treaty form (Form 5000). Dividends paid to a U.S. holder that has not filed the Form 5000 before the dividend payment date will be subject to French withholding tax at the rate of 25% and then reduced at a later date to 15%, provided that such holder duly completes and provides the French tax authorities with the treaty forms Form 5000 and Form 5001 before December 31 of the second calendar year following the year during which the dividend is paid. Pension funds and certain other tax-exempt entities are subject to the same general filing requirements as other U.S. holders except that they may have to supply additional documentation evidencing their entitlement to these benefits.

## **Table of Contents**

Form 5000 and Form 5001, together with instructions, will be provided by the depositary to all U.S. holders registered with the depositary and is also available from the U.S. Internal Revenue Service. The depositary will arrange for the filing with the French Tax authorities of all such forms properly completed and executed by U.S. holders of ordinary shares or ADSs and returned to the depositary in sufficient time that they may be filed with the French tax authorities before the distribution so as to obtain immediately a reduced withholding tax rate.

The withholding tax refund, if any, ordinarily is paid within 12 months of filing the applicable French Treasury Form, but not before January 15 of the year following the calendar year in which the related dividend is paid.

### *Tax on Sale or Other Disposition*

In general, under the Treaty, a U.S. holder who is a U.S. resident for purposes of the Treaty will not be subject to French tax on any capital gain from the redemption, sale or exchange of ordinary shares or ADSs unless the ordinary shares or the ADSs form part of the business property of a permanent establishment or fixed base that the U.S. holder has in France. Special rules apply to individuals who are residents of more than one country.

## **U.S. Taxes**

### *Taxation of Dividends*

For U.S. federal income tax purposes, the gross amount of any distribution and Tax Credit (as defined above) paid to U.S. holders (that is, the net distribution received plus any tax withheld therefrom) will be treated as ordinary dividend income to the extent paid or deemed paid out of the current or accumulated earnings and profits of sanofi-aventis (as determined under U.S. federal income tax principles). Dividends paid by sanofi-aventis will not be eligible for the dividends-received deduction generally allowed to corporate U.S. holders.

Subject to certain exceptions for short-term and hedged positions, the U.S. dollar amount of dividends received by an individual U.S. holder with respect to taxable years beginning before January 1, 2011, with respect to the ADSs or our ordinary shares will be subject to taxation at a maximum rate of 15% if the dividends are qualified dividends. Dividends paid on the ordinary shares or ADSs will be treated as qualified dividends if (i) the issuer is eligible for the benefits of a comprehensive income tax treaty with the United States that the Internal Revenue Service has approved for the purposes of the qualified dividend rules and (ii) the issuer was not, in the year prior to the year in which the dividend was paid, and is not, in the year in which the dividend is paid, a passive foreign investment company ( PFIC ). The Treaty has been approved for the purposes of the qualified dividend rules. Based on our audited financial statements and relevant market and shareholder data, we believe sanofi-aventis was not a PFIC for U.S. federal income tax purposes with respect to its 2008 taxable year. In addition, based on its audited financial statements and current expectations regarding the value and nature of its assets, the sources and nature of its income, and relevant market and shareholder data, we do not anticipate that sanofi-aventis will become a PFIC for its 2009 taxable year.  *Holders of ordinary shares and ADSs should consult their own tax advisers regarding the availability of the reduced dividend tax rate in light of their own particular circumstances.*

If you are a U.S. holder, dividend income received by you with respect to ADSs or ordinary shares generally will be treated as foreign source income for foreign tax credit purposes. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. Distributions out of earnings and profits with respect to the ADSs or ordinary shares generally will be treated as passive category



## Edgar Filing: SANOFI-AVENTIS - Form 20-F

income (or, in the case of certain U.S. holders, general category income). Subject to certain limitations, French income tax withheld in connection with any distribution with respect to the ADSs or ordinary shares may be claimed as a credit against the U.S. federal income tax liability of a U.S. holder if such U.S. holder elects for that year to credit all foreign income taxes. Alternatively, such French withholding tax may be taken as a deduction against taxable income. Foreign tax credits will not be allowed for withholding taxes imposed in respect of certain short-term or hedged positions in Securities and may not be allowed in respect of certain arrangements in which a U.S. holder's expected economic profit is insubstantial. *The U.S. federal income tax rules governing the availability and computation of foreign tax credits are complex. U.S. holders should consult their own tax advisers concerning the implications of these rules in light of their particular circumstances.*

## **Table of Contents**

To the extent that an amount received by a U.S. holder exceeds the allocable share of our current and accumulated earnings and profits, such excess will be applied first to reduce such U.S. holder's tax basis in its ordinary shares or ADSs and then, to the extent it exceeds the U.S. holder's tax basis, it will constitute capital gain from a deemed sale or exchange of such ordinary shares or ADSs (see Tax on Sale or Other Disposition, below).

The amount of any distribution or Tax Credit paid in euros will be equal to the U.S. dollar value of the euro amount distributed, calculated by reference to the exchange rate in effect on the date the dividend is received by a U.S. holder of ordinary shares (or by the depositary, in the case of ADSs) regardless of whether the payment is in fact converted into U.S. dollars on such date. *U.S. holders should consult their own tax advisers regarding the treatment of foreign currency gain or loss, if any, on any euros received by a U.S. holder or depositary that are converted into U.S. dollars on a date subsequent to receipt.*

### *Tax on Sale or Other Disposition*

In general, for U.S. federal income tax purposes, a U.S. holder that sells, exchanges or otherwise disposes of its ordinary shares or ADSs will recognize capital gain or loss in an amount equal to the U.S. dollar value of the difference between the amount realized for the ordinary shares or ADSs and the U.S. holder's adjusted tax basis (determined in U.S. dollars and under U.S. federal income tax rules) in the ordinary shares or ADSs. Such gain or loss generally will be U.S.-source gain or loss, and will be treated as long-term capital gain or loss if the U.S. holder's holding period in the ordinary shares or ADSs exceeds one year at the time of disposition. If the U.S. holder is an individual, any capital gain generally will be subject to U.S. federal income tax at preferential rates (currently a maximum of 15%) if specified minimum holding periods are met. The deductibility of capital losses is subject to significant limitations.

## **Participating Shares Series A (PSSAs) and PSSA-ADSs**

### **French Taxes**

#### *Taxation of Annual Payments and Any Reorganization Payment*

Under French law, no French withholding tax is imposed on Annual Payments on the Participating Shares Series A (PSSAs). Pursuant to Article 131 quater of the French General Tax Code, the withholding tax exemption on Annual Payments is not subject to any filing requirement because the PSSAs have been offered exclusively outside France. In the event that French law should change and a French withholding tax becomes applicable to the Annual Payments, (i) sanofi-aventis or an affiliate shall be obligated, to the extent it may lawfully do so, to gross up such payments (with certain exceptions relating to the holder's connection with France, failure to claim an exemption or failure to present timely such shares for payment) so that, after the payment of such withholding tax, the holder will receive an amount equal to the amount which the holder would have received had there been no withholding or (ii) sanofi-aventis may redeem the PSSAs.

#### *Taxation of Redemption*

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

In general, under the Treaty, a U.S. holder who is a U.S. resident for purposes of the Treaty will not be subject to French tax on any capital gain from the redemption, sale or exchange of PSSAs or PSSA-ADSs. Special rules apply to individuals who are residents of more than one country.

### **U.S. Taxes**

#### *Taxation of Annual Payments*

For U.S. federal income tax purposes, the gross amount of the annual payments paid to U.S. holders entitled thereto will be treated as ordinary dividend income (in an amount equal to the cash or fair market value of the property received) to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Such dividends generally will be foreign-source income and generally will be treated as *passive category* (or, in the case of certain U.S. holders, *general category*) income for foreign tax credit purposes. Dividends paid by sanofi-aventis will not be eligible for the dividends-received deduction generally allowed to corporate U.S. holders.

**Table of Contents**

Subject to certain exceptions for short-term and hedged positions, the U.S. dollar amount of dividends received by a U.S. holder that is an individual with respect to taxable years beginning before January 1, 2011 with respect to the PSSAs or PSSA-ADSs will be subject to taxation at a maximum rate of 15% if the dividends are qualified dividends. Dividends paid on the PSSAs or PSSA-ADSs will be treated as qualified dividends if (i) the issuer is eligible for the benefits of a comprehensive income tax treaty with the United States that the Internal Revenue Service has approved for the purposes of the qualified dividend rules and (ii) the issuer was not, in the year prior to the year in which the dividend was paid, and is not, in the year in which the dividend is paid, a passive foreign investment company (PFIC). The Treaty has been approved for the purposes of the qualified dividend rules. Based on our audited financial statements and relevant market and shareholder data, we believe we were not a PFIC for U.S. federal income tax purposes with respect to our 2008 taxable year. In addition, based on our audited financial statements and current expectations regarding the value and nature of our assets, the sources and nature of our income, and relevant market and shareholder data, we do not anticipate that we will become a PFIC for our 2009 taxable year. *Holders of PSSAs and PSSA-ADSs should consult their own tax advisers regarding the availability of the reduced dividend tax rate in light of their own particular circumstances.*

To the extent that an amount received by a U.S. holder exceeds the allocable share of our current and accumulated earnings and profits, such excess will be applied first to reduce such U.S. holder's tax basis in its PSSAs or PSSA-ADSs and then, to the extent it exceeds the U.S. holder's tax basis, it will constitute gain from a deemed sale or exchange of such PSSAs or PSSA-ADSs (see Tax on Sale or Other Disposition (Including Redemption) , below).

The amount of any distribution paid in euros will be equal to the U.S. dollar value of the distributed euros, calculated by reference to the exchange rate in effect on the date the dividend is received by a U.S. holder of PSSAs (or by the depository, in the case of PSSA-ADSs), regardless of whether the payment is in fact converted into U.S. dollars on such date. *U.S. holders should consult their own tax advisers regarding the treatment of foreign currency gain or loss, if any, on any euros received by a U.S. holder or depository that are converted into U.S. dollars on a date subsequent to receipt.*

*Tax on Sale or Other Disposition (Including Redemption)*

In general, for U.S. federal income tax purposes, a U.S. holder that sells, exchanges or otherwise disposes of PSSAs or PSSA-ADSs will recognize capital gain or loss in an amount equal to the U.S. dollar value of the difference between the amount realized for the PSSAs or PSSA-ADSs and the holder's adjusted tax basis (determined in U.S. dollars) in the PSSAs or PSSA-ADSs. Such gain or loss generally will be U.S.-source gain or loss, and will be treated as long-term capital gain or loss if the U.S. holder's holding period in the PSSAs or PSSA-ADSs exceeds one year at the time of disposition. If the U.S. holder is an individual, any capital gain generally will be subject to U.S. federal income tax at preferential rates (currently a maximum of 15%) if specified minimum holding periods are met. The deductibility of capital losses is subject to significant limitations.

If, however, a U.S. holder's PSSAs or PSSA-ADSs are redeemed and it has a direct or indirect stock interest in sanofi-aventis after such redemption, then amounts received in a redemption could, under applicable U.S. tax rules, be treated as a distribution taxable as a dividend that is measured by the full amount of cash received by such U.S. holder (to the extent of the current and accumulated earnings and profits of sanofi-aventis, as described above in Taxation of Annual Payments ). *U.S. holders should consult their own tax advisers as to the application of these rules to any such redemption.*

**F. Dividends and Paying Agents**

N/A

*G. Statement by Experts*

N/A

## **Table of Contents**

### ***H. Documents on Display***

We are subject to the information requirements of the U.S. Securities Exchange Act of 1934, as amended, and, in accordance therewith, we are required to file reports, including annual report on Form 20-F, and other information with the U.S. Securities and Exchange Commission by electronic means. Our public filings are available to the public over the Internet at the Commission's Website at <http://www.sec.gov> (these documents are not incorporated by reference in this annual report).

### ***I. Subsidiary Information***

N/A

## **Item 11. Quantitative and Qualitative Disclosures about Market Risk<sup>(1)</sup>**

### **General Policy**

Liquidity risk, foreign exchange risk and interest rate risk, as well as related counterparty risk, are managed centrally by our dedicated treasury team within the Group Finance Department. Where it is not possible to manage these risks centrally, in particular due to regulatory restrictions (such as foreign exchange controls) or local tax restrictions, credit facilities and/or currency lines guaranteed by the parent company are contracted by our subsidiaries locally with banks, under the supervision of the central treasury team.

Our investment and financing strategies, as well as our interest rate and currency hedging strategies, are reviewed monthly by the Group Finance Department.

Our policy on derivatives prohibits speculative exposure.

### **Liquidity Risk**

We operate a centralized treasury platform according to which all surplus cash and financing needs of our subsidiaries are invested with or funded by the parent company (where permitted by local legislation), at market conditions. The central treasury department manages the Group's current and projected financing (debt, net of cash and cash equivalents), and ensures that the Group is able to meet its financial commitments by maintaining sufficient cash and confirmed credit facilities for the size of our operations and the maturity of our debt.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

As of December 31, 2008, cash and cash equivalents amounted to 4,226 million. The Group tends to diversify its short term investments with leading banks on monetary supports with a maturity of less than three months. As of December 31, 2008, these short term investments were comprised of:

Bank term deposits with a maturity of less than two months and Certificates of Deposit with a maturity of less than three months. These short-term investments are entered into with leading financial institutions.

Mutual fund deposits classified as *monétaires euros* (Euro Money-Market) by the AMF, subject to a limit of 10% of invested assets.

As of December 31, 2008, the Group had 10.8 billion of undrawn confirmed credit facilities that were not allocated to outstanding commercial paper drawdowns, of which 6.7 billion expire in 2012, 0.3 billion in 2011, 3.7 billion in 2010 and 0.1 billion in 2009. Our credit facilities are not subject to financial covenant ratios.

Our policy is to diversify our sources of funding and optimize our cost of funding on a recurring basis through public or private issuances of debt securities, in particular under our Euro Medium Term Note program, and by issuing commercial paper in France and the United States. Short-term commercial paper programs (U.S. dollar-denominated commercial paper swapped into euro and euro-denominated commercial paper) are used to

<sup>(1)</sup> Information in this section is complementary to Note B.8.8 to our consolidated financial statements included at Item 18 of this annual report, with regards to information required by IFRS 7, and is covered by our independent registered public accounting firms' report on the consolidated financial statements.

**Table of Contents**

meet our short-term financing needs. Drawdowns under these programs are generally renewed for periods of three months and their total outstanding amounts as of December 31, 2008 were 0.7 billion. The commercial paper programs are backed by confirmed credit facilities (expiring in 2009 and 2010) totaling 4.5 billion, to permit the Group to continue to access financing if raising funds via commercial paper is no longer possible (for more information, see Note D.17 to the consolidated financial statements).

In the context of a market-wide liquidity crisis, the Group could be exposed to a scarcity of its sources of funding including the above-mentioned programs, or to a deterioration of their conditions. This situation could damage the capacity of the Group to refinance its debt or to issue new debt at reasonable conditions. Please refer to Item 3. Key Information D. Risk Factors Liquidity Risk.

**Interest Rate Risk**

Our interest rate risk exposure arises from the fact that most of our debt is floating-rate (credit facilities, commercial paper and floating rate notes), with reference to Eonia, U.S. Libor and Euribor. To optimize the cost of our short-term and medium-term debt and reduce its volatility, we use interest rate swaps, cross-currency swaps, and, if the case arises, interest rate options (purchases of caps, or combined purchases of caps and sales of floors) to alter the structure of our debt. (see Note D.20. to our consolidated financial statements included at Item 18 of this annual report).

As of December 31, 2008, 43% of our total debt (amounting to 5,938 million), was floating-rate and 57% was fixed-rate after taking account of interest rate derivatives. Our cash and cash equivalents (amounting to 4,226 million) are fully floating rate.

As of December 31, 2008, the sensitivity of the total debt to interest rate fluctuations is detailed in the table below on a yearly basis:

Change in 3-month Euribor	Impact on pre-tax net income (in million)
+100 bp	(17)
+ 25 bp	(4)
- 25 bp	4
- 100 bp	17

**Foreign Exchange Risk*****a. Operational Foreign Exchange Risk***

A substantial proportion of our net sales is generated in countries in which the euro, which is our reporting currency, is not the functional currency. In 2008, for example, 31.2% of our consolidated net sales were generated in the United States. Although we also incur expenses in those countries, the impact of those expenses is not enough wholly to offset the impact of exchange rates on net sales. Consequently, our operating income may be materially affected by fluctuations in the exchange rate between the euro and other currencies, primarily the U.S. dollar.



We operate a foreign exchange risk hedging policy to reduce the exposure of our operating income to exchange rate movements. This policy involves regular assessments of our worldwide foreign currency exposure, based on budget estimates of foreign-currency transactions to be carried out by the parent company and its subsidiaries. These transactions mainly comprise sales, purchases, research costs, co-marketing and co-promotion expenses, and royalties. To reduce the exposure of these transactions to exchange rate movements, we contract currency hedges using liquid financial instruments such as forward purchases and sales of currency as well as call and put options, and combinations of currency options (collars).

The table below shows operational currency hedging derivatives in place as of December 31, 2008, with the notional amount translated into euros at the relevant closing exchange rate. See also Note D.20. to our consolidated financial statements included at Item 18 of this annual report for the accounting classification of these instruments as of December 31, 2008.

**Table of Contents****Operational foreign exchange derivatives as of December 31, 2008 <sup>(1)</sup>:**

(in million)	Notional amount	Fair value
<b>Forward currency sales</b>	<b>3,305</b>	<b>219</b>
<i>of which: U.S. dollar</i>	2,461	182
<i>Japanese yen</i>	191	(5)
<i>Russian rouble</i>	134	15
<i>Pound sterling</i>	104	6
<i>Saudi Arabian rial</i>	58	5
<i>Polish zloty</i>	53	6
<b>Forward currency purchases</b>	<b>601</b>	<b>(11)</b>
<i>of which: Hungarian forint</i>	175	(1)
<i>U.S. dollar</i>	140	3
<i>Pound sterling</i>	75	(6)
<i>Russian rouble</i>	72	(6)
<i>Canadian dollar</i>	51	(1)
<b>Put options purchased</b>	<b>24</b>	
<b>Call options written</b>	<b>48</b>	<b>(7)</b>
<b>Total</b>	<b>3,978</b>	<b>201</b>

<sup>(1)</sup> As of December 31, 2007, the notional amount of forward currency sales was 2,205 million with a fair value of 30 million (including forward sales of U.S. dollars of a notional amount of 1,288 million with a fair value of 20 million). As of December 31, 2007, the notional amount of forward currency purchases was 464 million with an immaterial fair value (including forward sales of U.S. dollars of a notional amount of 48 million with a fair value of - 1 million). In addition, as of December 31, 2007, the Group portfolio included purchased put options of a notional amount of 409 million with a fair value of 4 million, written call options of a notional amount of 741 million with a fair value of - 1 million and written put options of a notional amount of 12 million with an immaterial fair value.

As of December 31, 2008, none of these instruments had an expiry date after December 31, 2009.

These positions hedge:

future foreign-currency cash flows arising after the balance sheet date in relation to transactions carried out during the year ended December 31, 2008 and recognized in the balance sheet at that date. Gains and losses on derivative instruments (forward contracts) have been and will continue to be calculated and recognized in parallel with the recognition of gains and losses on the hedged items. Due to this hedging relationship, the foreign exchange gain or loss on these items (derivative instruments and underlying assets) will be close to zero in 2009; and

forecast foreign-currency cash flows relating to commercial transactions to be carried out in 2009. These hedges (forward contracts and options) cover approximately 20% to 40% of the expected net cash flows for 2009 in currencies subject to budgetary hedging. The portfolio of derivatives relating to 2009 dollar U.S. denominated cash flows consists entirely of forward contracts and accounts for one-third of the expected cash flows. Given that these forward contracts were designated as cash flow hedges as of December 31, 2008, the sensitivity of the foreign exchange gain or loss and the impact on equity related to these instruments would be as follows:

**Constant euro/U.S. dollar**

Edgar Filing: SANOFI-AVENTIS - Form 20-F

exchange rate over 2009	Foreign exchange gain/(loss) on U.S. dollar hedging in million	Impact on equity
Depreciation of 10% in the U.S. dollar ( 1 = \$1.5309)	234.1	123.5
Exchange rate maintained at the December 31, 2008 rate ( 1 = \$1.3917)	110.7	
Appreciation of 10% in the U.S. dollar ( 1 = \$1.2525)	(40.2)	(150.9)

**Table of Contents****b. Financial Foreign Exchange Risk**

Some of our financing activities, such as the cash pooling arrangements for foreign subsidiaries outside the euro zone and our U.S. commercial paper issues (equivalent value: 0.7 billion as of December 31, 2008), expose certain entities, especially the sanofi-aventis parent company, to financial foreign exchange risk (*i.e.*, the risk of changes in the value of loans and borrowings denominated in a currency other than the functional currency of the lender or borrower). The net foreign exchange exposure for each currency and entity is hedged by firm financial instruments, usually currency swaps. (see Note D.20. to our consolidated financial statements included at Item 18 of this annual report).

The table below shows financial currency hedging instruments in place as of December 31, 2008, calculated using exchange rates prevailing as of that date.

**Financial foreign exchange derivatives as of December 31, 2008 <sup>(1)</sup>:**

(in million)	Notional amount	Fair value	Expiry
<b>Forward currency purchases</b>	<b>9,210</b>	<b>(80)</b>	
<i>of which: U.S. dollar <sup>(*)</sup></i>	8,256	(66)	2009
<i>Pound Sterling</i>	235	(4)	2009
<i>Canadian dollar</i>	189	(13)	2009
<b>Forward currency sales</b>	<b>1,954</b>	<b>(22)</b>	
<i>of which: U.S. dollar</i>	1,043	(23)	2009
<i>Japanese yen</i>	665	(7)	2009
<i>Hungarian forint</i>	95	1	2009
<b>Total</b>	<b>11,164</b>	<b>(102)</b>	

<sup>(\*)</sup> Includes 7,537 million used to hedge U.S. dollar intra-group deposits placed with the sanofi-aventis parent company.

<sup>(1)</sup> As of December 31, 2007, the notional amount of forward currency purchases was 8,261 million with a fair value of - 179 million (including forward purchases of U.S. dollars of a notional amount of 7,348 million with a fair value of - 167 million). As of December 31, 2007, the notional amount of forward currency sales was 1,563 million with a fair value of 26 million (including forward sales of U.S. dollars of a notional amount of 936 million with a fair value of 20 million).

These swaps generate a net foreign exchange financial result corresponding to the difference between the interest rates of the hedged currency and the euro. As regards the U.S. dollar, the interest rate spread related to forward currency purchases, positive in 2007, became negative in 2008, leading to an unfavorable variation of the financial foreign exchange profit and loss for 119 million. The change in value of short-term financial assets and liabilities denominated in foreign currencies due to movements in exchange rate is compensated by the change of intrinsic value of derivative instruments.

As of December 31, 2008, none of the instruments had an expiry date after January 31, 2009.

We may also hedge some future foreign-currency investment or divestment cash flows.

*c. Other Foreign Exchange Risks*

A significant proportion of our consolidated net assets is denominated in U.S. dollars. For a breakdown of net assets see Note D.35.2 to the consolidated financial statement. As a result, any fluctuation in the U.S. dollar against the euro affects shareholders' equity as expressed in euros. As of December 31, 2008, we had no derivative instruments in place to limit the effect of such fluctuations.

**Counterparty Risk**

Our financing and investing operations as well as our currency and interest rate hedges, are contracted with leading banks. Concerning the investing operations and the derivative instruments, a limit is set for each financial institution, depending on its rating. The respect of the limits, computed on the basis of the notional amounts of the operations and level-headed by the remaining duration and the nature of the commitment, is subject to a daily follow-up.

**Table of Contents**

As of December 31, 2008, the distribution of the exposure by rating and the percentage committed to the dominant counterparty were as follows:

	AA- ratings and higher	A+, A- and A ratings	BBB ratings and not rated	% / rating of the dominant counterparty as of December 31, 2008
Cash equivalents (excluding mutual funds) <sup>(1)</sup>	801	322		27% / AA-
Notional amounts of currency hedges <sup>(2)</sup>	6,789	8,619		14% / A+
Notional amounts of interest rate hedges <sup>(2)</sup>	1,372	681		24% / AA-
Credit facilities	6,275	6,236		11% / A+

<sup>(1)</sup> Cash equivalents include 2,601 million of mutual fund deposits classified as *monétaires euros* (Euro money-market) by the AMF.

<sup>(2)</sup> The notional amounts are computed on the basis of the forward rates negotiated at the initiation date of the derivative instruments.

Materialization of counterparty risk could impact the Group's liquidity in certain circumstances.

**Stock Market Risk**

It is our policy not to trade on the stock market for speculative purposes.

**Item 12. Descriptions of Securities other than Equity Securities**

N/A

**Table of Contents**

**PART II**

**Item 13. Defaults, Dividend Arrearages and Delinquencies**

N/A

**Item 14. Material Modifications to the Rights of Security Holders**

N/A

**Item 15. Controls and Procedures**

(a) Our Chief Executive Officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) as of the end of the period covered by this Form 20-F, have concluded that, as of such date, our disclosure controls and procedures were effective to ensure that material information relating to sanofi-aventis was timely made known to them by others within the Group.

(b) Report of Management on Internal Control Over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Management assessed the effectiveness of internal control over financial reporting as of December 31, 2008 based on the framework in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Based on that assessment, management has concluded that the Company's internal control over financial reporting was effective as of December 31, 2008 to provide reasonable assurance regarding the reliability of its financial reporting and the preparation of its financial statements for external purposes, in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and with IFRS adopted by the European Union as of December 31, 2008.

Due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements, and can only provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

The effectiveness of the Company's internal control over financial reporting has been audited by PricewaterhouseCoopers Audit and Ernst & Young Audit, independent registered public accounting firms, as stated in their report on the Company's internal control over financial reporting as of December 31, 2008, which is included herein. See paragraph (c) of the present Item 15, below.

(c) See report of PricewaterhouseCoopers Audit and Ernst & Young Audit, independent registered public accounting firms, included under Item 18. Financial Statements on page F-3.

(d) There were no changes to our internal control over financial reporting that occurred during the period covered by this Form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### **Item 16.**

[Reserved]

#### ***A. Audit Committee Financial Expert***

Our Board of Directors has determined that Gérard Van Kemmel and Klaus Pohle, independent directors serving on the Audit Committee, are financial experts. The Board of Directors determined that Mr. Van Kemmel



**Table of Contents**

qualifies as an independent financial expert based on his experience as a partner at an international accounting firm. The Board of Directors held on May 2, 2008 also qualified Mr. Klaus Pohle as an independent financial expert taking into account his education and professional experience in financial matters, accountancy and internal control.

**B. Code of Ethics**

We have adopted a financial code of ethics, as defined in Item 16.B. of Form 20-F under the Exchange Act. Our financial code of ethics applies to our Chief Executive Officer, Chief Financial Officer, Chief Accounting Officer and other officers performing similar functions, as designated from time to time. Our financial code of ethics is available on our Website at [www.sanofi-aventis.com](http://www.sanofi-aventis.com) (information on our website is not incorporated by reference in this annual report). A copy of our financial code of ethics may also be obtained without charge by addressing a written request to the attention of Individual Shareholder Relations at our headquarters in Paris. We will disclose any amendment to the provisions of such financial code of ethics on our website.

**C. Principal Accountants Fees and Services**

See Note E to our consolidated financial statements included at Item 18 of this annual report.

**D. Exemptions from the Listing Standards for Audit Committees**

N/A

**E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

In 2008, sanofi-aventis made the following purchases of ordinary shares of sanofi-aventis.

Period	(a) Total Number of Shares Purchased	(b) Average Price Paid per Share	(c) Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	(d) Approximate Value of Shares that May Yet Be Purchased Under the Plans or Programs <sup>(1)</sup>
January 2008	4,200,000	63.46	4,200,000	983,311,226 <sup>(2)</sup>
February 2008	5,300,000	52.05	5,300,000	707,446,226
March 2008	8,450,000	47.11	8,450,000	309,336,726
April 2008	4,090,669	48.68	4,090,669	110,232,959
May 2008	1,011,500	50.74	1,011,500	3,000,000,000 <sup>(3)</sup>
June 2008	760,000	44.12	760,000	2,966,468,800
July 2008				2,966,468,800

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

August 2008	50,000	46.95	50,000	2,964,121,300
September 2008				2,964,121,300
October 2008				2,964,121,300
November 2008				2,964,121,300
December 2008				2,964,121,300

- (1) Measured at month end.
- (2) As of year end 2007, a residual authorization of 1.2 billion remained available under the 3 billion share repurchase program established by the Company on August 1, 2007 in implementation of the shareholders resolution adopted at the Annual Shareholders Meeting of May 31, 2007.
- (3) The prior program was replaced by a new share repurchase program of up to 3 billion following the Annual Shareholders Meeting of May 31, 2008 which authorized the Board of Directors to repurchase up to 10% of the Company's capital subject to specified conditions and expiring after 18 months.

### ***F. Change in Registrant's Certifying Accountant***

N/A

### ***G. Corporate Governance***

Sanofi-aventis is incorporated under the laws of France, with securities publicly traded on markets in the United States (New York Stock Exchange) and France (Euronext Paris). Consequently, as described further in

## Table of Contents

our annual report, our corporate governance framework reflects the mandatory provisions of French corporate law, the securities laws and regulations of France and the United States and the rules of the aforementioned public markets. In addition, we generally follow the so-called AFEP-MEDEF corporate governance recommendations for French listed issuers. As a result, our corporate governance framework is similar in many respects to, and provides investor protections that are comparable to or in some cases, more stringent than the corresponding rules of the New York Stock Exchange. Nevertheless, there are important differences to keep in mind.

In line with New York Stock Exchange rules applicable to domestic issuers, a majority of sanofi-aventis board members are independent. Sanofi-aventis evaluates the independence of members of our Board of Directors using the standards of the French AFEP-MEDEF corporate governance recommendations as the principal reference. We believe that AFEP-MEDEF's overarching criteria for independence no relationship of any kind whatsoever with the Company, its group or the management of either that is such as to color a Board member's judgment are on the whole consistent with the goals of the New York Stock Exchange's rules although the specific tests proposed under the two standards may vary on some points. Additionally, we have complied with the audit committee independence and other requirements of the Rule 10A-3 under the U.S. Securities Exchange Act of 1934, as amended, adopted pursuant to the Sarbanes-Oxley Act of 2002.

Under French law, the committees of our Board of Directors are advisory only, and where the New York Stock Exchange Listed Company Manual would vest certain decision-making powers with specific committees by delegation (e.g., nominating or audit committees), our Board of Directors remains by law the only competent body to take such decisions, albeit taking into account the recommendation of the relevant committees. Additionally, under French corporate law, it is the shareholder meeting of sanofi-aventis that is competent to appoint our auditors upon the proposal of our Board of Directors, although our internal rules provide that the Board of Directors will make its proposal on the basis of the recommendation of our Audit Committee. We believe that this requirement of French law, together with the additional legal requirement that two sets of statutory auditors be appointed, share the New York Stock Exchange's underlying goal of ensuring that the audit of our accounts be conducted by auditors independent from company management.

In addition to the oversight role of our Compensation Committee for questions of management compensation including by way of equity, under French law any option plans or other share capital increases, whether for the benefit of top management or employees, may only be adopted by management pursuant to and within the limits of a shareholder resolution approving the related capital increase and delegating to the board the authority to implement such operations.

As described above, a number of issues, which could be resolved directly by a board or its committees in the United States, require the additional protection of direct shareholder consultation in France. On the other hand, there is not a tradition of non-executive Board of Director sessions. Our audit committee is entirely composed of independent directors as that term is defined in Rule 10A-3 under the U.S. Securities Exchange Act of 1934, as amended, adopted pursuant to the Sarbanes-Oxley Act of 2002. The composition of our Compensation Committee, and Appointments and Governance Committee includes directors who are also officers of our principal shareholders.

As a foreign private issuer under the U.S. securities laws, our Chief Executive Officer and our Chief Financial Officer issue the certifications required by §302 and §906 of the Sarbanes Oxley Act of 2002 on an annual basis (with the filing of our annual report on U.S. Form 20-F) rather than on a quarterly basis as would be the case of a U.S. corporation filing quarterly reports on U.S. Form 10-Q.

French corporate law provides that the Board of Directors must vote to approve a broadly defined range of transactions that could potentially create conflicts of interest between sanofi-aventis on the one hand and its directors and officers on the other hand. This legal safeguard operates in place of certain provisions of the NYSE Listed Company Manual.



**Table of Contents**

**PART III**

**Item 17. Financial Statements**

See Item 18.

**Item 18. Financial Statements**

See pages F-1 through F-110 incorporated herein by reference.

**Item 19. Exhibits**

- 1.1 Bylaws (statuts) of sanofi-aventis (English translation)
- 2.1 Form of Deposit Agreement between sanofi-aventis and JPMorgan Chase Bank, N.A., as depositary (*incorporated herein by reference to Exhibit A to the Registration Statement on Form F-6 dated August 7, 2007 relating to our American Depositary Shares, SEC File No. 333-145177*)
- 2.2 Instrument defining rights of holders of American Depositary Shares each representing one quarter of a Participating Share Series A (*incorporated by reference to Item. 3 Exhibit (a) of the Registration Statement on Form F-6 (Registration No. 33-31904) dated November 21, 1989*)
- 8.1 List of significant subsidiaries, see Item 4. Information on the Company C. Organizational Structure
- 12.1 Certification by Christopher Viehbacher, Chief Executive Officer, required by Section 302 of the Sarbanes-Oxley Act of 2002
- 12.2 Certification by Laurence Debroux, Principal Financial Officer, required by Section 302 of the Sarbanes-Oxley Act of 2002
- 13.1 Certification by Christopher Viehbacher, Chief Executive Officer, required by Section 906 of the Sarbanes-Oxley Act of 2002
- 13.2 Certification by Laurence Debroux, Principal Financial Officer, required by Section 906 of the Sarbanes-Oxley Act of 2002
- 23.1 Consent of Ernst & Young Audit dated March 3, 2009
- 23.2 Consent of PricewaterhouseCoopers Audit dated March 3, 2009
- 99.1 Report of the Chairman of the Board of Directors for 2008 as required by Art. 225-37 paragraph 6 of the French Commercial Code
- 99.2 Extract from the Internal Rules of the Board of Directors

**Table of Contents**

**Signatures**

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

by: /s/ CHRISTOPHER VIEHBACHER  
**Christopher Viehbacher**

**Chief Executive Officer**

Date: March 3, 2009

---

**Table of Contents**

**ANNUAL CONSOLIDATED FINANCIAL STATEMENTS**

**The financial statements are presented in accordance with**

**International Financial Reporting Standards (IFRS)**

<b><u>REPORTS OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRMS</u></b>	<b>F-2 - F-3</b>
<b><u>CONSOLIDATED BALANCE SHEETS</u></b>	<b>F-4 - F-5</b>
<b><u>CONSOLIDATED INCOME STATEMENTS</u></b>	<b>F-6</b>
<b><u>CONSOLIDATED STATEMENTS OF CASH FLOWS</u></b>	<b>F-7</b>
<b><u>CONSOLIDATED STATEMENTS OF RECOGNIZED INCOME AND EXPENSE</u></b>	<b>F-8</b>
<b><u>NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS</u></b>	<b>F-9</b>
<b><u>- A. Basis of preparation</u></b>	<b>F-9 - F-10</b>
<b><u>- B. Summary of significant accounting policies</u></b>	<b>F-10 - F-31</b>
<b><u>- C. Alliances</u></b>	<b>F-31 - F-33</b>
<b><u>- D. Detailed notes to the financial statements</u></b>	<b>F-33 - F-106</b>
<b><u>- E. Principal Accountants Fees and Services</u></b>	<b>F-106</b>
<b><u>- F. List of principal companies included in the consolidation for the year ended December 31, 2008</u></b>	<b>F-107 - F-110</b>

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED  
PUBLIC ACCOUNTING FIRMS**

**SANOFI-AVENTIS**

To the Board of Directors and Shareholders of sanofi-aventis,

We have audited the accompanying consolidated balance sheets of sanofi-aventis and its subsidiaries (together the Group) as of December 31, 2008, 2007 and 2006, and the related consolidated statements of income, cash flows and recognized income and expense for each of the three years in the period ended December 31, 2008. These financial statements are the responsibility of the Group's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States), (the PCAOB). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Group as of December 31, 2008, 2007 and 2006, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

We also have audited, in accordance with the standards of the PCAOB, the effectiveness of the Group's internal control over financial reporting as of December 31, 2008, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 3, 2009 expressed an unqualified opinion thereon.

Neuilly-sur-Seine and Paris-La Défense, March 3, 2009

PricewaterhouseCoopers Audit

Ernst & Young Audit

Catherine Pariset

Philippe Vogt

Gilles Puissochet

Jacques Pierres



**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED  
PUBLIC ACCOUNTING FIRMS**

**SANOFI-AVENTIS**

To the Board of Directors and Shareholders of sanofi-aventis,

We have audited internal control over financial reporting of sanofi-aventis and its subsidiaries (together the Group ) as of December 31, 2008, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). The Group’s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Report of Management on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company’s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States), (the PCAOB ). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company’s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Group maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on the COSO criteria.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

We also have audited, in accordance with the standards of the PCAOB, the consolidated balance sheets of the Group as of December 31, 2008, 2007 and 2006, and the related consolidated statements of income, cash flows and recognized income and expense for each of the three years in the period ended December 31, 2008 and our report dated March 3, 2009 expressed an unqualified opinion thereon.

Neuilly-sur-Seine and Paris-La Défense, March 3, 2009

PricewaterhouseCoopers Audit

Ernst & Young Audit

Catherine Pariset

Philippe Vogt

Gilles Puissochet

Jacques Pierres

F-3

**Table of Contents****CONSOLIDATED BALANCE SHEETS**

<i>( million)</i>	<i>Note</i>	December 31, 2008	December 31, 2007	December 31, 2006
<b>ASSETS</b>				
Property, plant and equipment	<b>D.3.</b>	6,961	6,538	6,219
Goodwill	<b>D.4.</b>	28,163	27,199	28,472
Intangible assets	<b>D.4.</b>	15,260	19,182	23,738
Investments in associates	<b>D.6.</b>	2,459	2,493	2,637
Financial assets non-current	<b>D.7.</b>	821	1,037	1,045
Deferred tax assets	<b>D.14.</b>	2,920	2,912	3,492
<b>Non-current assets</b>		<b>56,584</b>	<b>59,361</b>	<b>65,603</b>
Assets held for sale	<b>D.8.</b>			
Inventories	<b>D.9.</b>	3,590	3,729	3,659
Accounts receivable	<b>D.10.</b>	5,303	4,904	5,032
Other current assets	<b>D.11.</b>	1,881	2,126	2,208
Financial assets current	<b>D.12.</b>	403	83	108
Cash and cash equivalents	<b>D.13.-D.17.</b>	4,226	1,711	1,153
<b>Current assets</b>		<b>15,403</b>	<b>12,553</b>	<b>12,160</b>
<b>TOTAL ASSETS</b>		<b>71,987</b>	<b>71,914</b>	<b>77,763</b>

The accompanying notes on pages F-9 to F-110 are an integral part of the consolidated financial statements.

**Table of Contents****CONSOLIDATED BALANCE SHEETS**

<i>( million)</i>	<i>Note</i>	December 31, 2008	December 31, 2007	December 31, 2006
<b>LIABILITIES &amp; EQUITY</b>				
Equity attributable to equity holders of the Company	<b>D.15.2.</b>	44,866	44,542	45,600
Minority interests	<b>D.16.</b>	205	177	220
<b>Total equity</b>		<b>45,071</b>	<b>44,719</b>	<b>45,820</b>
Long-term debt	<b>D.17.</b>	4,173	3,734	4,499
Provisions and other non-current liabilities	<b>D.18.</b>	7,730	6,857	7,920
Deferred tax liabilities	<b>D.14.</b>	5,668	6,935	9,246
<b>Non-current liabilities</b>		<b>17,571</b>	<b>17,526</b>	<b>21,665</b>
Liabilities related to assets held for sale	<b>D.8.</b>			
Accounts payable		2,791	2,749	3,008
Other current liabilities	<b>D.19.</b>	4,721	4,713	4,825
Short-term debt and current portion of long-term debt	<b>D.17.</b>	1,833	2,207	2,445
<b>Current liabilities</b>		<b>9,345</b>	<b>9,669</b>	<b>10,278</b>
<b>TOTAL LIABILITIES &amp; EQUITY</b>		<b>71,987</b>	<b>71,914</b>	<b>77,763</b>

The accompanying notes on pages F-9 to F-110 are an integral part of the consolidated financial statements.

**Table of Contents****CONSOLIDATED INCOME STATEMENTS**

<i>( million)</i>	<i>Note</i>	Year ended December 31, 2008	Year ended December 31, 2007	Year ended December 31, 2006
<b>Net sales</b>	<b>D.35.1.</b>	<b>27,568</b>	<b>28,052</b>	<b>28,373</b>
Other revenues		1,249	1,155	1,116
Cost of sales		(7,337)	(7,571)	(7,587)
<b>Gross profit</b>		<b>21,480</b>	<b>21,636</b>	<b>21,902</b>
Research and development expenses		(4,575)	(4,537)	(4,430)
Selling and general expenses		(7,168)	(7,554)	(8,020)
Other operating income	<b>D.25.</b>	556	522	391
Other operating expenses	<b>D.26.</b>	(353)	(307)	(116)
Amortization of intangibles		(3,483)	(3,654)	(3,998)
<b>Operating income before restructuring, impairment of property, plant and equipment and intangibles, gains and losses on disposals, and litigation</b>		<b>6,457</b>	<b>6,106</b>	<b>5,729</b>
Restructuring costs	<b>D.27.</b>	(585)	(137)	(274)
Impairment of property, plant and equipment and intangibles	<b>D.5.</b>	(1,554)	(58)	(1,163)
Gains and losses on disposals, and litigation	<b>D.28.</b>	76		536
<b>Operating income</b>		<b>4,394</b>	<b>5,911</b>	<b>4,828</b>
Financial expenses	<b>D.29.</b>	(335)	(329)	(455)
Financial income	<b>D.29.</b>	103	190	375
<b>Income before tax and associates</b>		<b>4,162</b>	<b>5,772</b>	<b>4,748</b>
Income tax expense	<b>D.30.</b>	(682)	(687)	(800)
Share of profit/loss of associates	<b>D.31.</b>	812	597	451
<b>Net income</b>		<b>4,292</b>	<b>5,682</b>	<b>4,399</b>
Net income attributable to minority interests	<b>D.32.</b>	441	419	393
<b>Net income attributable to equity holders of the Company</b>		<b>3,851</b>	<b>5,263</b>	<b>4,006</b>
Average number of shares outstanding (million)		1,309.3	1,346.9	1,346.8
Average number of shares outstanding after dilution (million)	<b>D.15.9.</b>	1,310.9	1,353.9	1,358.8
- Basic earnings per share (in euros)		2.94	3.91	2.97
- Diluted earnings per share (in euros)		2.94	3.89	2.95

The accompanying notes on pages F-9 to F-110 are an integral part of the consolidated financial statements.

**Table of Contents****CONSOLIDATED STATEMENTS OF CASH FLOWS**

<i>( million)</i>	<i>Note</i>	Year ended December 31, 2008	Year ended December 31, 2007	Year ended December 31, 2006
<b>Net income attributable to equity holders of the Company</b>		<b>3,851</b>	<b>5,263</b>	<b>4,006</b>
Minority interests, excluding BMS <sup>(1)</sup>		19	16	18
Share of undistributed earnings of associates		19	133	96
Depreciation, amortization and impairment of property, plant and equipment and intangible assets		5,985	4,664	6,113
Gains and losses on disposals of non-current assets, net of tax <sup>(2)</sup>		(45)	(64)	(558)
Net change in deferred taxes		(1,473)	(1,476)	(2,463)
Net change in provisions		56	(247)	284
Cost of employee benefits (stock options and capital increase)		125	134	149
Impact of workdown of Aventis inventories remeasured at fair value, net of tax				21
Unrealized gains and losses recognized in income		(13)	(506) <sup>(5)</sup>	(56)
<b>Operating cash flow before changes in working capital</b>		<b>8,524</b>	<b>7,917</b>	<b>7,610</b>
(Increase)/decrease in inventories		(84)	(89)	(372)
(Increase)/decrease in accounts receivable		(309)	(60)	(241)
Increase/(decrease) in accounts payable and accrued expenses		(28)	(156)	(77)
Net change in other current assets, financial assets current and other current liabilities		420	(506)	(316)
<b>Net cash provided by operating activities <sup>(3)</sup></b>		<b>8,523</b>	<b>7,106</b>	<b>6,604</b>
Acquisitions of property, plant and equipment and intangible assets	<b>D.3. - D.4.</b>	(1,606)	(1,610)	(1,454)
Acquisitions of investments in consolidated undertakings, net of cash acquired	<b>D.1.</b>	(661)	(214)	(509)
Acquisitions of available-for-sale financial assets	<b>D.1.</b>	(6)	(221)	(4)
Proceeds from disposals of property, plant and equipment, intangible assets and other non-current assets, net of tax <sup>(4)</sup>	<b>D.2.</b>	123	329	1,174
Net change in loans and other non-current financial assets		(4)		3
<b>Net cash used in investing activities</b>		<b>(2,154)</b>	<b>(1,716)</b>	<b>(790)</b>
Issuance of sanofi-aventis shares	<b>D.15.</b>	51	271	307
Dividends paid:				
to sanofi-aventis shareholders	<b>D.15.2.</b>	(2,702)	(2,364)	(2,042)
to minority shareholders, excluding BMS <sup>(1)</sup>		(6)	(9)	(8)
Additional long-term borrowings	<b>D.17.</b>	765	1,639	864
Repayments of long-term borrowings	<b>D.17.</b>	(1,253)	(2,065)	(1,351)
Net change in short-term borrowings	<b>D.17.</b>	557	(509)	(3,674)
Acquisition of treasury shares	<b>D.15.4.</b>	(1,227)	(1,806)	
Disposals of treasury shares, net of tax	<b>D.15.2.</b>	6	23	50
<b>Net cash provided by/(used in) financing activities</b>		<b>(3,809)</b>	<b>(4,820)</b>	<b>(5,854)</b>
<b>Impact of exchange rates on cash and cash equivalents</b>		<b>(45)</b>	<b>(12)</b>	<b>(56)</b>
<b>Net change in cash and cash equivalents</b>		<b>2,515</b>	<b>558</b>	<b>(96)</b>
<b>Cash and cash equivalents, beginning of period</b>		<b>1,711</b>	<b>1,153</b>	<b>1,249</b>
<b>Cash and cash equivalents, end of period</b>	<b>D.13.</b>	<b>4,226</b>	<b>1,711</b>	<b>1,153</b>

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

- (1) See Note C.1. (i)
- (2) Including available-for-sale financial assets
- (3) Including:

Income tax paid	(2,317)	(3,030)	(3,223)
Interest paid	(317)	(315)	(434)
Interest received	132	88	82
Dividends received	5	3	1

- (4) Property, plant and equipment, intangible assets, investments in consolidated subsidiaries and participating interests
- (5) Arising primarily on the translation of surplus U.S. dollar cash from American subsidiaries transferred to the sanofi-aventis parent company

The accompanying notes on pages F-9 to F-110 are an integral part of the consolidated financial statements.

F-7

**Table of Contents****CONSOLIDATED STATEMENTS OF RECOGNIZED INCOME AND EXPENSE**

<i>( million)</i>	Year ended December 31, 2008	Year ended December 31, 2007	Year ended December 31, 2006
Change in fair value of available-for-sale financial assets <sup>(1)</sup>	(132)	(5)	(27)
Change in fair value of derivatives designated as hedging instruments <sup>(1)</sup>	104	8	57
Actuarial gains and (losses) <sup>(1)</sup>	(829)	282	346
Tax effect of items recognized directly in equity <sup>(1)</sup>	132	(119)	(160)
Change in cumulative translation difference recognized in equity	948	(2,764)	(3,197)
<b>Total income/(expense) recognized directly in equity <sup>(2)</sup></b>	<b>223</b>	<b>(2,598)</b>	<b>(2,981)</b>
<b>Net income for the period</b>	<b>4,292</b>	<b>5,682</b>	<b>4,399</b>
<b>Total recognized income/(expense) for the period</b>	<b>4,515</b>	<b>3,084</b>	<b>1,418</b>
<i>Attributable to equity holders of the Company</i>	<i>4,090</i>	<i>2,666</i>	<i>1,028</i>
<i>Attributable to minority interests</i>	<i>425</i>	<i>418</i>	<i>390</i>

<sup>(1)</sup> See analysis in Note D.15.7.

<sup>(2)</sup> See the consolidated statements of changes in shareholders' equity provided in Note D.15.2.

The accompanying notes on pages F-9 to F-110 are an integral part of the consolidated financial statements.



**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**Year ended December 31, 2008**

***INTRODUCTION***

The sanofi-aventis Group (sanofi-aventis and its subsidiaries) is a leading player in the world pharmaceuticals industry, engaged in the development, manufacture and marketing of healthcare products in seven major therapeutic fields: thrombosis, cardiovascular, metabolic disorders, oncology, central nervous system, internal medicine and vaccines.

Its international R&D effort provides a platform for the Group to develop leadership positions in its markets.

Sanofi-aventis, the parent company, is a *société anonyme* (a form of limited liability company) incorporated under the laws of France. The registered office is at 174, avenue de France, 75013 Paris, France.

Sanofi-aventis is listed in Paris (Euronext: SAN) and New York (NYSE: SNY).

The consolidated financial statements for the year ended December 31, 2008, and the notes thereto, were adopted by the sanofi-aventis Board of Directors on February 10, 2009.

***A. BASIS OF PREPARATION***

**A.1. International Financial Reporting Standards (IFRS)**

The consolidated financial statements cover the twelve-month periods ended December 31, 2008, 2007 and 2006.

In accordance with Regulation No. 1606/2002 of the European Parliament and Council of July 19, 2002 on the application of international accounting standards, sanofi-aventis has presented its consolidated financial statements in accordance with IFRS since January 1, 2005. The term IFRS refers collectively to international accounting and financial reporting standards (IASs and IFRSs) and to interpretations of the interpretations committees (SIC and IFRIC), mandatorily applicable as of December 31, 2008.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

The consolidated financial statements of sanofi-aventis as of December 31, 2008 have been prepared in compliance with IFRS as issued by the International Accounting Standards Board (IASB) and with IFRS adopted by the European Union as of December 31, 2008. Pronouncements issued by the IASB but not yet adopted by the European Union are not applicable to sanofi-aventis.

IFRS adopted by the European Union as of December 31, 2008 are available under the heading IASs/IFRSs, SICs and IFRICs adopted by the Commission via the web link [http://ec.europa.eu/internal\\_market/accounting/ias\\_en.htm](http://ec.europa.eu/internal_market/accounting/ias_en.htm).

The consolidated financial statements have been prepared in accordance with the IFRS general principles of fair presentation, going concern, accrual basis of accounting, consistency of presentation, materiality, and aggregation.

New standards, amendments and interpretations applied in the consolidated financial statements for the first time in the year ended December 31, 2008 are described in Note A.2. Standards, amendments and interpretations issued by the IASB but not mandatorily applicable in 2008 are described in Note B.28.

### **A.2. New standards, amendments and interpretations applicable in 2008**

In October and November 2008, the IASB issued two amendments to IAS 39 and IFRS 7, respectively, allowing entities to reclassify non-derivative financial assets out of the fair value through profit or loss category in particular circumstances, with retrospective effect from July 1, 2008. These amendments applied with immediate effect, and were adopted immediately by the European Union. Sanofi-aventis did not identify any assets that required such reclassification, and hence did not use the option offered by these amendments during the second half of 2008.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

The following interpretations became mandatorily applicable in 2008:

IFRIC 11 (Group and Treasury Share Transactions), which relates to options awarded within a group of companies and treasury shares acquired to meet obligations under stock option plans. This interpretation confirms the treatment to be applied by an entity in its separate financial statements, and hence has no effect on the sanofi-aventis consolidated financial statements.

IFRIC 12 (Service Concession Arrangements), not yet adopted by the European Union, which does not apply to the Group's activities.

IFRIC 14 (The Limit on a Defined Benefit Asset, Minimum Funding Requirements and their Interaction), issued in July 2007, was adopted by the European Union in December 2008. This interpretation specifies the criteria for measuring the economic benefit available as a refund or as a reduction in future contributions that may be recognized as a pension plan surplus under IAS 19. Applying IFRIC 14 has no material effect on the sanofi-aventis consolidated financial statements for the year ended December 31, 2008.

**A.3. Use of estimates**

The preparation of financial statements requires management to make reasonable estimates and assumptions, based on information available at the date of preparation of the financial statements, that may affect the reported amounts of assets, liabilities, revenues and expenses in the financial statements, and disclosures of contingent assets and contingent liabilities.

Examples include:

amounts deducted from sales for projected sales returns, chargeback incentives, rebates and price reductions (see Note B.14.);

the extent of impairment of accounts receivable (see Note B.8.2.) and of provisions for product claims (see Note D.22.);

impairment of property, plant and equipment, goodwill, intangible assets and investments in associates (see Note B.6.);

the valuation of goodwill and the valuation and useful life of acquired intangible assets (see Notes B.3. and B.4.3.);

the amount of post-employment benefit obligations (see Note B.23.);

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

the amount of provisions for restructuring, tax risks, environmental risks and litigation (see Note B.12.);

share-based payment expenses (see Note B.24.1.);

the fair values of derivative financial instruments (see Note B.8.).

Actual results could differ from these estimates.

### ***B. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES***

#### **B.1. Basis of consolidation**

The consolidated financial statements include the accounts of sanofi-aventis and subsidiaries controlled by sanofi-aventis, using the full consolidation method. The existence of effectively exercisable or convertible potential voting rights is taken into account in determining whether control exists.

Joint ventures are accounted for by the equity method in accordance with the option in IAS 31 (Interests in Joint Ventures).

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

Companies over which sanofi-aventis exercises significant influence are accounted for by the equity method.

Material transactions between consolidated companies and intragroup profits are eliminated.

Companies are consolidated from the date on which control (exclusive or joint) or significant influence is transferred to the Group. The Group's share of post-acquisition profits or losses is taken to the income statement, and post-acquisition movements in the acquiree's reserves are taken to consolidated reserves. Companies are excluded from consolidation from the date on which the Group transfers control or significant influence.

**B.2. Foreign currency translation**

**Accounting for transactions in foreign currencies in individual company accounts**

Non-current assets (other than receivables) and inventories acquired in foreign currencies are translated into the functional currency using the exchange rate prevailing at the date of acquisition.

All amounts receivable or payable in foreign currencies are translated using the exchange rate prevailing at the balance sheet date. The resulting gains and losses are recorded in the income statement. However, foreign exchange gains and losses arising from the translation of advances between consolidated subsidiaries for which settlement is neither planned nor likely to occur in the foreseeable future are recognized directly in equity in *Cumulative translation difference*.

**Foreign currency translation of the financial statements of foreign subsidiaries**

In accordance with IAS 21 (The Effects of Changes in Foreign Exchange Rates), each Group subsidiary translates foreign currency transactions into the currency that is most representative of its economic environment (the functional currency).

All assets and liabilities are translated into euros using the exchange rate of the subsidiary's functional currency prevailing at the balance sheet date. Income statements are translated using a weighted average exchange rate for the period. The resulting translation difference is shown as a separate component of equity and is recognized in the income statement only when the subsidiary is sold or is wholly or partially liquidated.

Under the exemptions allowed by IFRS 1, sanofi-aventis elected to eliminate through equity all cumulative translation differences for foreign operations at the January 1, 2004 IFRS transition date.

### **B.3. Business combinations**

#### **B.3.1. Accounting treatment**

Business combinations consummated subsequent to the IFRS transition date (January 1, 2004) are accounted for by the purchase method in accordance with IFRS 3 (Business Combinations).

Under this method, the acquiree's identifiable assets, liabilities and contingent liabilities that satisfy the recognition criteria of IFRS 3 are measured initially at their fair values as at the date of acquisition, except for non-current assets classified as held for sale, which are measured at fair value less costs to sell.

Only identifiable liabilities that satisfy the criteria for recognition as a liability by the acquiree are recognized in a business combination. Consequently, restructuring liabilities are not recognized as a liability of the acquiree unless the acquiree has an obligation as at the date of the acquisition to carry out the restructuring.

Adjustments to the values of assets and liabilities initially determined provisionally (pending the results of independent valuations or further analysis) are recognized as a retrospective adjustment to goodwill if they are made within twelve months of the acquisition date. Once this twelve-month period has elapsed, the effects of any adjustments are recognized directly in the income statement, unless they qualify as an error correction.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

Under the exemptions allowed by IFRS 1, sanofi-aventis elected not to restate in accordance with IFRS 3 any business combinations that were consummated prior to the January 1, 2004 transition date. This includes the combination between Sanofi and Synthélabo that took place in 1999.

**B.3.2. Goodwill**

The difference between the cost of an acquisition (including any costs directly attributable to the acquisition) and the Group's interest in the fair value of the identifiable assets, liabilities and contingent liabilities of the acquiree is recognized as goodwill at the date of the business combination.

Goodwill arising on the acquisition of subsidiaries is shown as a separate line in the balance sheet under *Goodwill*, whereas goodwill arising on the acquisition of associates is recorded in *Investments in associates*.

Goodwill arising on the acquisition of foreign entities is measured in the functional currency of the acquired entity and translated using the exchange rate prevailing at the balance sheet date.

In accordance with IFRS 3 and with IAS 36 (Impairment of Assets), goodwill is carried at cost less accumulated impairment.

Goodwill is tested for impairment annually and whenever events or circumstances indicate that impairment might exist. Such events or circumstances include significant changes liable to have an other-than-temporary impact on the substance of the original investment.

**B.4. Intangible assets**

Intangible assets are initially measured at acquisition cost or production cost, including any directly attributable costs of preparing the asset for its intended use, or (in the case of assets acquired in a business combination) at fair value as at the date of the combination. They are amortized on a straight line basis over their useful lives.

The useful lives of intangible assets are reviewed at each reporting date. The effect of any adjustment to useful lives is recognized prospectively as a change of accounting estimate.

Amortization of intangible assets is recognized in the income statement under *Amortization of intangibles* with the exception of amortization of acquired or internally-developed software, which is recognized on the relevant line of the income statement according to the purpose for which the software is used.

Sanofi-aventis does not own any intangible assets with an indefinite useful life.

Intangible assets are carried at cost less accumulated amortization and accumulated impairment, if any, in accordance with IAS 36 (see Note B.6.).

#### **B.4.1. Research and development not acquired in a business combination**

##### Internally generated research and development

In accordance with IAS 38 (Intangible Assets), internally generated research expenditure is expensed as incurred under *Research and development expenses*.

Under IAS 38, internally generated development expenses are recognized as an intangible asset if, and only if, all the following six criteria can be demonstrated: (a) the technical feasibility of completing the development project; (b) the Group's intention to complete the project; (c) the Group's ability to use the project; (d) the probability that the project will generate future economic benefits; (e) the availability of adequate technical, financial and other resources to complete the project; and (f) the ability to measure the development expenditure reliably.



**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

Due to the risks and uncertainties relating to regulatory approval and to the research and development process, the six criteria for capitalization are considered not to have been met until marketing approval has been obtained from the regulatory authorities. Consequently, internally generated development expenses arising before marketing approval has been obtained, mainly the cost of clinical trials, are expensed as incurred under *Research and development expenses*.

Chemical industrial development expenses incurred to develop a second-generation process are incurred after initial regulatory approval has been obtained, in order to improve the industrial process for an active ingredient. To the extent that the six IAS 38 criteria are considered as being met, these expenses are capitalized under *Intangible assets* as incurred.

Separately acquired research and development

Payments for separately acquired research and development are capitalized under *Intangible assets* provided that they meet the definition of an intangible asset: a resource that is (i) controlled by the Group, (ii) expected to provide future economic benefits, and (iii) identifiable, i.e. is either separable or arises from contractual or legal rights. Under paragraph 25 of IAS 38, the first condition for capitalization (the probability that the expected future economic benefits will flow to the entity) is considered to be satisfied for separately acquired research and development. Because the amount of the payments is determinable, the second condition for capitalization (the cost can be measured reliably) is also met.

Consequently, rights to pharmaceutical products acquired from third parties prior to receipt of regulatory approval to market the products are recognized as intangible assets, and are amortized on a straight line basis over their useful lives from the date on which regulatory approval is obtained.

Payments under research and development arrangements relating to access to technology or to databases and payments made to purchase generics files are also capitalized, and amortized over the useful life of the intangible asset.

Subcontracting arrangements, payments for research and development services and continuous payments under research and development collaborations unrelated to the outcome of the research and development efforts are expensed over the service term.

**B.4.2. Other intangible assets**

Patents are capitalized at acquisition cost and amortized over the shorter of the period of legal protection or their useful life.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Licenses other than those related to pharmaceutical products and research projects, in particular software licenses, are capitalized at acquisition cost, including any directly attributable cost of preparing the software for its intended use. Software licenses are amortized on a straight line basis over their useful lives (three to five years).

Internally generated costs incurred to develop or upgrade software are capitalized if the IAS 38 criteria for recognition as an intangible asset are satisfied, and amortized on a straight line basis over the useful life of the software from the date on which the software is ready for use.

### **B.4.3. Intangible assets acquired in a business combination**

Intangible assets acquired in a business combination (in particular the acquisition of Aventis) which relate to in-process research and development and are reliably measurable are separately identified from goodwill and capitalized in *Intangible assets* in accordance with IFRS 3 (Business Combinations) and IAS 38 (Intangible Assets). The related deferred tax liability is also recognized.

In-process research and development acquired in a business combination is amortized on a straight line basis over its useful life from the date of receipt of regulatory approval for the product derived from the research and development work.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

Rights to products sold by the Group, mainly acquired through the acquisition of Aventis, are amortized on a straight line basis over their useful lives, which are calculated on the basis of cash flow forecasts that take account of (among other factors) the period of legal protection of the related patents. On this basis, the average initial amortization period for products sold by the Group is eight years.

**B.5. Property, plant and equipment**

Property, plant and equipment is initially measured and recognized at acquisition cost, including any directly attributable cost of preparing the asset for its intended use, or (in the case of assets acquired in a business combination) at fair value as at the date of the acquisition. The component-based approach to accounting for property, plant and equipment is applied. Under this approach, each component of an item of property, plant and equipment with a cost which is significant in relation to the total cost of the item and which has a different useful life from the other components must be depreciated separately.

After initial measurement, property, plant and equipment is carried at cost less accumulated depreciation and impairment, except for land which is carried at cost less impairment.

Subsequent costs are not recognized as assets unless (i) it is probable that future economic benefits associated with these costs will flow to the Group and (ii) the costs can be measured reliably.

Day-to-day maintenance costs of property, plant and equipment are expensed as incurred.

Borrowing costs attributable to the financing of items of property, plant and equipment and incurred during the construction period of such items are capitalized as part of the acquisition cost of the item.

Government grants relating to non-current assets are deducted from the acquisition cost of the asset to which they relate.

In accordance with IAS 17 (Leases), items of property, plant and equipment leased by sanofi-aventis as lessee under finance leases are recognized as an asset in the balance sheet, with the related lease obligation recognized as a liability. A lease qualifies as a finance lease if it transfers substantially all the risks and rewards of ownership of the asset to the Group. Assets held under finance leases are carried at the lower of the fair value of the leased asset or the present value of the minimum lease payments, and are depreciated over the shorter of the useful life of the asset or the term of the lease.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

The depreciable amount of items of property, plant and equipment, net of any residual value, is depreciated on a straight line basis over the useful life of the asset. The useful life of an asset is usually equivalent to its economic life.

The useful lives of property, plant and equipment are as follows:

Buildings	15 to 40 years
Fixtures	10 to 20 years
Plant and equipment	5 to 15 years
Other tangible assets	3 to 15 years

Useful lives and residual values of property, plant and equipment are reviewed annually. The effect of any adjustment to useful lives or residual values is recognized prospectively as a change of accounting estimate.

Depreciation of property, plant and equipment is recognized as an expense in the income statement, in the relevant classification of expense by function.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

**B.6. Impairment of property, plant and equipment, goodwill, intangible assets, and investments in associates**

**B.6.1. Impairment of property, plant and equipment, goodwill and intangible assets**

Assets that generate separate cash flows and assets included in cash-generating units (CGUs) are assessed for impairment in accordance with IAS 36 (Impairment of Assets) when events or changes in circumstances indicate that the asset or CGU may be impaired.

A CGU is the smallest identifiable group of assets that generates cash inflows that are largely independent of the cash inflows from other assets or groups of assets.

Quantitative and qualitative indications of impairment (primarily relating to pharmacovigilance, patent protection and the launch of competing products) are reviewed at each reporting date. If there is any internal or external indication of impairment, the Group estimates the recoverable amount of the asset or CGU.

Property, plant and equipment and intangible assets not yet available for use (such as capitalized in-process research and development), and CGUs that include goodwill, are tested for impairment annually whether or not there is any indication of impairment, and more frequently if any event or circumstance indicates that they might be impaired. These assets are not amortized.

When there is an internal or external indication of impairment, the Group estimates the recoverable amount of the asset and recognizes an impairment loss when the carrying amount of the asset exceeds its recoverable amount. Where it is not possible to estimate the recoverable amount of any particular asset, the Group determines the recoverable amount of the CGU to which the asset belongs. The recoverable amount of the asset is the higher of its fair value less costs to sell or its value in use. To determine the value in use, the Group uses estimates of future cash flows generated by the asset or CGU, prepared using the same methods as those used in the initial measurement of the asset or CGU on the basis of the medium-term plans of each business activity.

In the case of goodwill, estimates of future cash flows are based on a five-year strategic plan, plus an extrapolation of the cash flows for the next five years, plus a terminal value. In the case of intangible assets, the period used is based on the shorter of the period of patent protection or the economic life of the asset. Any cash flows beyond this period are estimated by applying a positive or negative growth rate to future periods.

Estimated cash flows are discounted at long-term market interest rates that reflect the best estimate by sanofi-aventis of the time value of money, the risks specific to the asset or CGU, and economic conditions in the geographical regions in which the business activity associated with the asset or CGU is located.

Certain assets and liabilities that are not directly attributable to a specific CGU, and goodwill, are allocated between CGUs on a reasonable and consistent basis.

Goodwill is tested for impairment by being allocated to CGUs. Given the international nature of the Group's operating activities, the CGUs used for the allocation and impairment testing of goodwill are the same business segments and geographical segments as used for segmental reporting.

Impairment losses in respect of property, plant and equipment and intangible assets are recognized under *Impairment of property, plant and equipment and intangibles* in the income statement.

#### **B.6.2. Impairment of investments in associates**

In accordance with IAS 28 (Investments in Associates), the Group applies the criteria specified in IAS 39 (see Note B.8.2.) to determine whether an investment in an associate may be impaired. If an investment is impaired, the amount of the impairment loss is determined by applying IAS 36 (see Note B.6.1.) and recognized in *Share of profit/loss of associates*.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

**B.6.3. Reversals of impairment losses charged against property, plant and equipment, intangible assets, and investments in associates**

At each reporting date, the Group assesses if events or changes in circumstances indicate that an impairment loss recognized in a prior period in respect of an asset (other than goodwill) or an investment in an associate can be reversed. If this is the case, and the recoverable amount as determined based on the new estimates exceeds the carrying amount of the asset, the Group reverses the impairment loss only to the extent of the carrying amount that would have been determined had no impairment loss been recognized for the asset.

Reversals of impairment losses in respect of property, plant and equipment and intangible assets are recognized in the income statement under *Impairment of property, plant and equipment and intangibles*, while reversals of impairment losses in respect of investments in associates are recognized in the income statement under *Share of profit/loss of associates*. Impairment losses taken against goodwill are never reversed, unless the goodwill relates to an investment in an associate.

**B.7. Assets held for sale**

Under IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations), non-current assets held for sale are defined as assets that will be realized through sale rather than continuing use. Once they have been classified as such, non-current assets held for sale are measured at the lower of carrying amount or fair value less costs to sell net of any impairment losses, and are not depreciated or amortized.

**B.8. Financial instruments**

**B.8.1. Financial assets**

Under IFRS, and in accordance with IAS 39 and IAS 32, sanofi-aventis has adopted the following classification for participating interests and investment securities, based on management intent at the date of acquisition (except for investments already held at the transition date and reclassified at that date in accordance with IFRS 1). The designation and classification of these investments is carried out at initial recognition and reassessed at each reporting date.

Purchases of investments are recognized on the date when sanofi-aventis becomes party to the contractual terms of such investments. On initial recognition, financial assets are measured at fair value, plus direct transaction costs in the case of financial assets not designated as fair value through profit or loss.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Classification, presentation and subsequent measurement of financial assets are as follows:

Financial assets at fair value through profit or loss

These assets are classified in the balance sheet under *Financial assets – current* and *Cash and cash equivalents*.

Financial assets at fair value through profit or loss comprise financial assets held for trading and financial instruments designated as fair value through profit and loss on initial recognition, in accordance with the conditions for application of the fair value option. This category consists of financial assets acquired principally for the purpose of selling them in the near term (usually within less than 12 months). Derivative instruments are classified as held for trading unless they are designated as hedging instruments.

These financial assets are carried at fair value, without any deduction for transaction costs that may be incurred on sale. Realized and unrealized gains and losses resulting from changes in the fair value of these assets are recognized in the income statement, in *Financial income* or *Financial expenses*.

Realized and unrealized foreign exchange gains and losses on financial assets in currencies other than the euro are recognized in the income statement in *Financial income* or *Financial expenses*.



**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

Available-for-sale financial assets

Available-for-sale financial assets are non-derivative financial assets that are (i) designated by management as available-for-sale or (ii) not classified as financial assets at fair value through profit or loss, held-to-maturity investments or loans and receivables. This category includes participating interests in quoted or unquoted companies (other than investments in associates and joint ventures) that management intends to hold on a long-term basis. Available-for-sale financial assets are classified in non-current assets under ***Financial assets - non-current***.

Available-for-sale financial assets are measured at fair value, without any deduction for transaction costs that may be incurred on sale. Gains and losses arising from changes in the fair value of these assets, including unrealized foreign exchange gains and losses, are recognized directly in equity in the consolidated statement of recognized income and expense in the period in which they occur except for impairment losses and foreign exchange gains and losses on debt instruments. On derecognition of an available-for-sale financial asset, or on recognition of an impairment loss on such an asset, the cumulative gains and losses previously recognized in equity are recognized in the income statement for the period under ***Financial income*** or ***Financial expenses***.

Interest income and dividends on equity instruments are recognized in the income statement under ***Financial income*** when the Group is entitled to receive payment.

Available-for-sale financial assets in the form of participating interests in companies not quoted in an active market are measured at cost if their fair value cannot be determined.

Realized foreign exchange gains and losses are recognized in the income statement under ***Financial income*** or ***Financial expenses***.

Held-to-maturity investments

Held-to-maturity investments are non-derivative financial assets with fixed or determinable payments and fixed maturities that the Group has the positive intention and ability to hold to maturity.

These investments are measured at amortized cost using the effective interest method.

Sanofi-aventis did not hold any such investments during the years ended December 31, 2008, 2007 or 2006.

Loans and receivables

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They are presented in current assets, under *Other current assets* in the case of loans and under *Accounts receivable* in the case of receivables. Loans with a maturity of more than 12 months are presented in Long-term loans and advances under *Financial assets non current*. Loans and receivables are measured at amortized cost using the effective interest method.

Realized and unrealized foreign exchange gains and losses are recognized in the income statement under *Financial expenses* or *Financial income*.

**B.8.2. Impairment of financial assets**

Indicators of impairment are reviewed for all financial assets at each reporting date. Such indicators include default in contractual payments, significant financial difficulties of the issuer or debtor, probability of bankruptcy, or prolonged or significant decline in quoted market price. An impairment loss is recognized in the income statement when there is objective evidence that an asset is impaired.

Impairment losses are measured and recognized as follows.

The impairment loss on loans and receivables, which are measured at amortized cost, is the difference between the carrying amount of the asset and the present value of estimated future cash flows discounted at the financial asset's original effective interest rate.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

When an impairment loss is identified on an available-for-sale financial asset, the cumulative losses previously recognized directly in equity are recorded in the income statement. The loss recognized in the income statement is the difference between the acquisition cost (net of principal repayment and amortization) and the fair value at the time of impairment, less any impairment loss previously recognized in the income statement.

The impairment loss on investments in companies that are not quoted in an active market and are measured at cost is the difference between the carrying amount of the investment and the present value of its estimated future cash flows discounted at the current market interest rate for similar financial assets.

Impairment losses in respect of loans are recognized under *Financial expenses* in the income statement.

Impairment losses in respect of receivables are recognized in the relevant classification of expense by function in the income statement.

Impairment losses on investments in companies that are not quoted in an active market and are measured at cost, and on equity instruments classified as available-for-sale financial assets, cannot be reversed through the income statement.

**B.8.3. Derivative instruments**

Derivative instruments not designated as hedges of operating transactions are initially and subsequently measured at fair value, with changes in fair value recognized in the income statement, under *Financial income* or *Financial expenses*, in the period when they arise.

Derivative instruments qualifying as hedging instruments are measured in accordance with the hedge accounting requirements of IAS 39 (see Note B.8.4.).

**B.8.4. Hedging**

Hedging involves the use of derivative financial instruments. Changes in the fair value of these instruments are intended to offset the exposure of the hedged items to changes in fair value.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

As part of its overall interest rate risk and foreign exchange risk management policy, the Group enters into various transactions involving derivative instruments. Derivative instruments used in connection with the Group's hedging policy may include forward exchange contracts, currency options, interest rate swaps and interest rate options.

Derivative financial instruments qualify as hedging instruments for hedge accounting purposes when (a) at the inception of the hedge there is formal designation and documentation of the hedging relationship and of the risk management strategy and objective; (b) the hedge is expected to be highly effective in offsetting the risk; (c) the forecast transaction being hedged is highly probable and presents an exposure to variations in cash flows that could ultimately affect profit or loss; (d) the effectiveness of the hedge can be reliably measured; and (e) the hedge is assessed on an ongoing basis and determined actually to have been highly effective throughout the reporting periods for which the hedge was designated.

These criteria are applied when the Group uses derivative instruments designated as a fair value hedge, a cash flow hedge or a hedge of a net investment in a foreign operation.

### Fair value hedge

A fair value hedge is a hedge of the exposure to changes in fair value of a recognized asset or liability or unrecognized firm commitment that could affect profit or loss.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

Changes in fair value of the hedging instrument and changes in fair value of the hedged item attributable to the hedged risk are recognized in the income statement, under ***Other operating income*** for hedges of operating activities and under ***Financial income*** or ***Financial expenses*** for hedges of investing or financing activities.

Cash flow hedge

A cash flow hedge is a hedge of the exposure to variability in cash flows attributable to a particular risk associated with a recognized asset or liability, or a highly probable forecast transaction, that could affect profit or loss.

Changes in fair value of the hedging instrument attributable to the effective portion of the hedge are recognized directly in equity in the consolidated statement of recognized income and expense. Changes in fair value attributable to the ineffective portion of the hedge are recognized in the income statement under ***Other operating income*** for hedges of operating activities, and under ***Financial income*** or ***Financial expenses*** for hedges of investing or financing activities.

Cumulative changes in fair value of the hedging instrument previously recognized in equity are transferred to the income statement when the hedged transaction affects profit or loss. These transferred gains and losses are recorded under ***Other operating income*** for hedges of operating activities and ***Financial income*** or ***Financial expenses*** for hedges of investing or financing activities.

When a forecast transaction results in the recognition of a non-financial asset or liability, cumulative changes in the fair value of the hedging instrument previously recognized in equity are included in the initial measurement of the asset or liability.

When the hedging instrument expires or is sold, terminated or exercised, the cumulative gain or loss previously recognized in equity remains separately recognized in equity until the forecast transaction occurs. However, if the Group no longer expects the forecast transaction to occur, the cumulative gain or loss previously recognized in equity is recognized immediately in the income statement.

Hedge of a net investment in a foreign operation

A hedge of a net investment in a foreign operation is accounted for in the same way as a cash flow hedge. Changes in fair value of the hedging instrument attributable to the effective portion of the hedge are recognized directly in equity in the consolidated statement of recognized income and expense. Changes in fair value attributable to the ineffective portion of the hedge are recognized in the income statement under ***Financial income*** or ***Financial expenses***. When the investment in the foreign operation is sold, or wholly or partially liquidated, the changes in the fair value of the hedging instrument previously recognized in equity are transferred to the income statement under ***Financial income*** or ***Financial expenses***.

Hedge accounting is discontinued when (a) the hedging instrument expires or is sold, terminated or exercised, or (b) the hedge no longer meets the criteria for hedge accounting, or (c) the Group revokes the hedge designation, or (d) management no longer expects the forecast transaction to occur.

#### **B.8.5. Financial liabilities**

Bank borrowings and debt instruments are initially measured at fair value of the consideration received, net of directly attributable transaction costs.

Subsequently, they are measured at amortized cost using the effective interest method. All costs related to the issuance of borrowings or debt instruments, and all differences between the issue proceeds net of transaction costs and the value on redemption, are recognized under *Financial expenses* in the income statement over the term of the debt using the effective interest method.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

**B.8.6. Fair value of financial instruments**

Fair value is the amount for which an asset could be exchanged, or a liability settled, between knowledgeable, willing parties in an arm's length transaction.

The fair value of financial assets and liabilities that are traded in an active market is determined by reference to stock market prices at the balance sheet date in the case of participating interests and investment securities, and by reference to market prices at the balance sheet date in the case of derivative instruments traded in an active market. The fair value of financial assets or liabilities that are not quoted in an active market is based on various valuation methods and assumptions made by sanofi-aventis with reference to market conditions prevailing at the balance sheet date.

Because of the short maturity of non-derivative current financial assets, the Group regards their carrying amount in the balance sheet (historical cost less any provisions for credit risk) as equivalent to fair value.

**B.8.7. Derecognition of financial instruments**

Sanofi-aventis derecognizes financial assets when the contractual rights to cash flows from these assets have ended or have been transferred and when the Group has transferred substantially all risks and rewards of ownership of these assets. If the Group has neither transferred nor retained substantially all the risks and rewards of ownership of these assets, they are derecognized if the Group does not retain the control of these assets.

Financial liabilities are derecognized when the Group's contractual obligations in respect of such liabilities are discharged or cancelled or expire.

**B.8.8. Risks relating to financial instruments**

Market risks in respect of non-current financial assets, cash equivalents, derivative instruments and debt are described in the risk factors presented in Item 3.D. and Item 11.

Credit risk is the risk that customers may fail to pay their debts. This risk also arises as a result of the concentration of the Group's sales with its largest customers, in particular certain wholesalers in the United States. Customer credit risk is described in the risk factors presented in Item 3.D.

**B.9. Inventories**

Inventories are measured at the lower of cost or net realizable value. Cost is calculated using the weighted average cost method or the first-in, first-out method, depending on the nature of the inventory.

The cost of finished goods inventories includes costs of purchase, costs of conversion and other costs incurred in bringing the inventories to their present location and condition.

Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale.

**B.10. Cash and cash equivalents**

Cash and cash equivalents as shown in the consolidated balance sheet and statement of cash flows comprise cash, plus liquid short-term investments that are (i) readily convertible into cash and (ii) subject to an insignificant risk of changes in value in the event of movements in interest rates.

**B.11. Treasury shares**

In accordance with IAS 32, sanofi-aventis treasury shares are deducted from equity irrespective of the purpose for which they are held. No gain or loss is recognized in the income statement on the purchase, sale, impairment or cancellation of treasury shares.



**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

**B.12. Provisions for risks**

In accordance with IAS 37 (Provisions, Contingent Liabilities and Contingent Assets), sanofi-aventis records a provision where it has a present obligation, whether legal or constructive, as a result of a past event; it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation; and a reliable estimate can be made of the amount of the outflow of resources. If the obligation is expected to be settled more than twelve months after the balance sheet date, or has no definite settlement date, the provision is recorded under *Provisions and other non-current liabilities*.

Contingent liabilities are not recognized, but are disclosed in the notes to the financial statements unless the possibility of an outflow of economic resources is remote.

Provisions are estimated on the basis of events and circumstances related to present obligations at the balance sheet date, of past experience, and to the best of management's knowledge at the date of preparation of the financial statements.

Reimbursements offsetting the probable outflow of resources are recognized as assets only if it is virtually certain that they will be received. Contingent assets are not recognized.

Restructuring provisions are recognized if the Group has a detailed, formal restructuring plan at the balance sheet date and has announced its intention to implement this plan to those affected by it.

No provisions are recorded for future operating losses.

Sanofi-aventis records long-term provisions for certain obligations such as legal environmental obligations and litigation where an outflow of resources is probable. Where the effect of the time value of money is material, these provisions are measured at the present value of the expenditures expected to be required to settle the obligation, calculated using a discount rate that reflects an estimate of the time value of money and the risks specific to the obligation.

Increases in provisions to reflect the effects of the passage of time are recognized in *Financial expenses*.

**B.13. Emission rights**

Under international agreements, the European Union has committed to reducing greenhouse gas emissions and instituted an emissions allowance trading scheme. Approximately ten sanofi-aventis sites in Europe are covered by the scheme. Sanofi-aventis accounts for emission allowances as follows: the annual allowances allocated by government are recognized as intangible assets measured at fair value at the date of initial recognition, with a matching liability recognized to reflect the government grant effectively arising from the fact that allowances are issued free of charge. As and when allowances are consumed, they are transferred to Deliverable allowances in order to recognize the liability to government in respect of actual CO<sub>2</sub> emissions. If the allocated allowances are insufficient to cover actual emissions, an expense is recognized in order to reflect the additional allowances deliverable; this expense is measured at the market value of the allowances.

#### **B.14. Revenue recognition**

Revenue arising from the sale of goods is presented in the income statement under *Net sales*. Net sales comprise revenue from sales of pharmaceutical products, vaccines, and active ingredients, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities.

Revenue is recognized when all of the following conditions have been met: the risks and rewards of ownership have been transferred to the customer; the Group no longer has effective control over the goods sold;

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

the amount of revenue and costs associated with the transaction can be measured reliably; and it is probable that the economic benefits associated with the transaction will flow to the Group, in accordance with IAS 18 (Revenue).

Sanofi-aventis offers various types of price reductions on its products. In particular, products sold in the United States are covered by various governmental programs (such as Medicare and Medicaid) under which products are sold at a discount. Rebates are granted to healthcare authorities, and under contractual arrangements with certain customers. Some wholesalers are entitled to chargeback incentives based on the selling price to the end customer, under specific contractual arrangements. Cash discounts may also be granted for prompt payment.

Returns, discounts, incentives and rebates as described above are recognized in the period in which the underlying sales are recognized, as a reduction of sales revenue.

These amounts are calculated as follows:

Provisions for chargeback incentives are estimated on the basis of the relevant subsidiary's standard sales terms and conditions, and in certain cases on the basis of specific contractual arrangements with the customer. They represent management's best estimate of the ultimate amount of chargeback incentives that will eventually be claimed by the customer.

Provisions for rebates based on attainment of sales targets are estimated and accrued as each of the underlying sales transactions is recognized.

Provisions for price reductions under Government and State programs, largely in the United States, are estimated on the basis of the specific terms of the relevant regulations and/or agreements, and accrued as each of the underlying sales transactions is recognized.

Provisions for sales returns are calculated on the basis of management's best estimate of the amount of product that will ultimately be returned by customers.

In each case, the provisions are subject to continuous review and adjustment as appropriate based on the most recent information available to management.

The Group believes that it has the ability to measure each of the above provisions reliably, using the following factors in developing its estimates:

the nature and patient profile of the underlying product;

the applicable regulations and/or the specific terms and conditions of contracts with governmental authorities, wholesalers and other customers;

historical data relating to similar contracts, in the case of qualitative and quantitative rebates and chargeback incentives;

past experience and sales growth trends for the same or similar products;

actual inventory levels in distribution channels, monitored by the Group using internal sales data and externally provided data;

the shelf life of the Group's products;

market trends including competition, pricing and demand;

the possibility of reusing returned goods.

Non-product revenues, mainly comprising royalty income from license arrangements that constitute ongoing operations of the Group (see Note C.), are presented in *Other revenues*.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

**B.15. Cost of sales**

Cost of sales consists primarily of the industrial cost of goods sold, payments made under licensing agreements, and distribution costs.

**B.16. Research and development expenses**

Internally generated research costs are expensed as incurred.

Internally generated pharmaceutical development costs are also expensed as incurred; they are not capitalized, because the criteria for capitalization are considered not to have been met until marketing approval for the related product has been obtained from the regulatory authorities. Recharges to or contributions from alliance partners are recorded as a reduction in *Research and development expenses*.

Note B.4.1., Research and development not acquired in a business combination, and Note B.4.3., Intangible assets acquired in a business combination, describe the principles applied to the recognition of separately acquired research and development.

**B.17. Other operating income**

*Other operating income* includes the share of profits that sanofi-aventis is entitled to receive from alliance partners, principally Procter & Gamble Pharmaceuticals, in respect of product marketing agreements (see Note C.2.). It also includes revenues generated under certain complex agreements, which may include partnership and co-promotion agreements.

Upfront payments received are deferred for as long as a service obligation remains. Milestone payments are assessed on a case by case basis, and recognized in the income statement on delivery of the products and/or provision of the services in question. Revenue generated in connection with these services is recognized on the basis of delivery of the goods or provision of the services to the other contracting party.

This line also includes realized and unrealized foreign exchange gains and losses on operating activities (see Note B.8.4.), and operating gains on disposals not regarded as major disposals (see Note B.20.).

**B.18. Other operating expenses**

*Other operating expenses* mainly comprise the share of profits that alliance partners are entitled to receive from sanofi-aventis under product marketing agreements.

**B.19. Amortization of intangibles**

The expenses recorded on this line mainly comprise amortization of product rights (see Note D.4.), which are presented as a separate item because the benefit of these rights to the Group's commercial, industrial and development functions cannot be separately identified.

Amortization of software is recognized as an expense in the income statement, in the relevant classification of expense by function.

**B.20. Operating income before restructuring, impairment of property, plant and equipment and intangibles, gains and losses on disposals, and litigation**

Operating income before restructuring, impairment of property, plant and equipment and intangibles, gains and losses on disposals, and litigation is presented as a separate line item in the consolidated income statement in accordance with paragraph 83 of IAS 1 (Presentation of Financial Statements), because it is relevant to an

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

understanding of the Group's financial performance. This line item allows the Group to present separately items which, although they are components of operating income, nonetheless have a low degree of predictability because of their nature, frequency and/or materiality, and which if not presented separately would impair the understanding of the Group's financial performance.

This line item corresponds to operating income before the three items described below:

**Restructuring costs**

*Restructuring costs* include early retirement benefits, compensation for early termination of contracts, and rationalization costs relating to restructured sites. Asset impairment losses directly attributable to restructuring are also recorded on this line. Restructuring costs included on this line relate only to unusual and major restructuring plans.

**Impairment of property, plant and equipment and intangibles**

This line includes major impairment losses (other than those directly attributable to restructuring) on property, plant and equipment and intangibles, including goodwill. It also includes any reversals of such losses.

**Gains and losses on disposals, and litigation**

This line comprises gains and losses on major disposals of property, plant and equipment and intangible assets, and costs and provisions related to major litigation.

**B.21. Financial expenses/income**

**B.21.1. Financial expenses**

*Financial expenses* mainly comprise interest charges on debt financing, negative changes in the fair value of financial instruments (where changes in fair value are taken to the income statement), realized and unrealized foreign exchange losses on financing and investing activities, and impairment losses on financial instruments. They also include any reversals of impairment losses on financial instruments.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

*Financial expenses* also include the expenses arising from the unwinding of discount on long-term provisions, except provisions for retirement benefits and other long-term employee benefits. This line does not include cash discounts, which are deducted from net sales.

### **B.21.2. Financial income**

*Financial income* includes interest and dividend income, positive changes in the fair value of financial instruments (where changes in fair value are taken to the income statement), realized and unrealized foreign exchange gains on financing and investing activities, and gains or losses on disposals of financial assets.

### **B.22. Income tax expense**

*Income tax expense* includes all current and deferred taxes of consolidated companies.

Sanofi-aventis accounts for deferred taxes in accordance with IAS 12 (Income Taxes), using the methods described below.

Deferred tax assets and liabilities are recognized on taxable and deductible temporary differences, and tax loss carryforwards. Temporary differences are differences between the carrying amount of an asset or liability in the balance sheet and its tax base.



**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

Deferred tax assets and liabilities are calculated using the tax rate expected to apply in the period when a temporary difference is expected to reverse, based on tax rates enacted or substantively enacted at the balance sheet date.

Unused tax losses and unused tax credits are recognized as deferred tax assets to the extent that it is probable that future taxable profits will be available against which they can be utilized.

Sanofi-aventis recognizes a deferred tax liability for temporary differences relating to investments in subsidiaries and associates and to interests in joint ventures except when the Group is able to control the timing of the reversal of the temporary differences. This applies in particular when the Group is able to control dividend policy and it is probable that the temporary differences will not reverse in the foreseeable future.

No deferred tax is recognized on intragroup transfers of investments in subsidiaries or associates.

For consolidation purposes, each tax entity calculates its own net deferred tax position. All net deferred tax asset and liability positions are then aggregated and shown as separate line items on the assets and liabilities sides of the consolidated balance sheet respectively. Deferred tax assets and liabilities can be offset only if (i) the Group has a legally enforceable right to set off current tax assets and current tax liabilities, and (ii) the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority.

Deferred taxes are not discounted, except implicitly in the case of deferred taxes on assets and liabilities which are themselves discounted.

Withholding taxes on intragroup royalties and dividends, and on royalties and dividends collected from third parties, are accounted for as current income taxes.

In accounting for business combinations, sanofi-aventis complies with IFRS 3 as regards the recognition of deferred tax assets after the initial accounting period. This means that if any deferred tax assets are recognized by the acquiree after the end of this period on temporary differences or tax loss carryforwards existing at the date of the combination, a corresponding reduction is made to the amount of goodwill.

**B.23. Employee benefit obligations**

Sanofi-aventis offers retirement benefits to employees and retirees of the Group. These benefits are accounted for in accordance with IAS 19 (Employee Benefits).

These benefits are in the form of either defined-contribution plans or defined-benefit plans.

In the case of defined-contribution plans, the contributions paid by sanofi-aventis are expensed in the period in which they occur, and no actuarial estimate is performed.

In the case of defined-benefit plans, sanofi-aventis recognizes its obligations to employees as a liability, based on an actuarial estimate of the rights vested and/or currently vesting in employees and retirees using the projected unit credit method, net of the estimated fair value of plan assets.

These estimates are performed at least once a year, and rely on assumptions about life expectancy, employee turnover, and salary increases. The estimated obligation is discounted.

Obligations in respect of other post-employment benefits (healthcare, life insurance) offered by Group companies to employees are also recognized as a liability based on an actuarial estimate of the rights vested or currently vesting in employees and retirees at the balance sheet date.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

Actuarial gains and losses relating to defined-benefit plans (pensions and other post-employment benefits), arising from the effects of changes in actuarial assumptions and experience adjustments, are recognized in equity net of deferred taxes via the consolidated statement of recognized income and expense, under the option allowed by the amendment to IAS 19. All unrecognized actuarial gains and losses at the transition date (January 1, 2004) were recognized in retained earnings at that date in accordance with the optional treatment allowed in IFRS 1 (First-time Adoption of International Financial Reporting Standards).

Past service cost is recognized as an expense on a straight-line basis over the average period until the benefits become vested. If benefits are already vested on the introduction of, or changes to, a defined benefit plan, past service cost is recognized immediately.

Actuarial gains and losses relating to other long-term employee benefits are recognized immediately in the income statement.

**B.24. Share-based payment**

**B.24.1. Stock option plans**

Sanofi-aventis has granted a number of equity-settled share-based payment plans (stock option plans) to some of its employees.

In accordance with IFRS 2 (Share-Based Payment), services received from employees as consideration for stock options are recognized as an expense in the income statement, with the matching entry recognized in equity. The expense corresponds to the fair value of the stock option plans, and is charged to income on a straight-line basis over the three-year or four-year vesting period of the plan.

The fair value of stock option plans is measured at the date of grant using the Black-Scholes valuation model, taking into account the expected life of the options. In recognizing this fair value as an expense, allowance is made for the expected cancellation rate of the options. The expense is adjusted over the vesting period to reflect the actual cancellation rates resulting from the departure of the holders of the options.

**B.24.2. Employee share ownership plans**

The sanofi-aventis Group may offer its employees the opportunity to subscribe to reserved share issues at a discount to the reference market price. Shares allotted to employees under these plans fall within the scope of IFRS 2. The discount is measured at the subscription date and recognized as an expense, with no reduction for any lock-up period.

**B.25. Earnings per share**

Basic earnings per share is calculated using the weighted average number of shares outstanding during the reporting period, adjusted on a time-weighted basis from the acquisition date to reflect the number of sanofi-aventis shares held by the Group. Diluted earnings per share is calculated on the basis of the weighted average number of ordinary shares, computed using the treasury stock method.

This method assumes that (a) all outstanding dilutive options and warrants are exercised and (b) the Group acquires its own shares at the quoted market price for an amount equivalent to the cash received as consideration for the exercise of the options or warrants, plus the expense arising on unamortized stock options.

In the event of a stock split or consideration free issue of shares, earnings per share for prior periods is adjusted accordingly.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

**B.26. Segment information**

In accordance with IAS 14 (Segment Reporting), the Group reports information by business segment and geographical segment.

The primary level of the Group's segment reporting is the business segment.

A business segment is a distinguishable component of the Group that is engaged in providing a group of related products and services and is subject to different risks and returns from those of other business segments. The Group has two business segments: Pharmaceuticals and Vaccines (human vaccines).

The secondary level of segment reporting is the geographical segment. A geographical segment is a distinguishable component of the Group that is engaged in providing a group of related products and services within a particular economic environment and is subject to different risks and returns from those of components operating in other economic environments. The Group has three geographical segments: Europe, the United States, and Other Countries.

The split between these segments is based on the organizational and management structure, and on indicators used for internal management reporting purposes.

**B.27. Management of capital**

In order to maintain or adjust the capital structure, the Group can adjust the amount of dividends paid to shareholders, or repurchase its own shares, or issue new shares, or issue securities giving access to its capital.

The following objectives are defined under the terms of the Group's share repurchase programs:

the implementation of any stock option plan giving entitlement to purchase shares in the sanofi-aventis parent company;

the allotment or sale of shares to employees under statutory profit-sharing schemes and employee savings plans;

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

the allotment of consideration free shares;

the cancellation of some or all of the repurchased shares;

market-making in the secondary market in the shares by an investment services provider under a liquidity contract in compliance with the ethical code recognized by the *Autorité des Marchés Financiers*;

the delivery of shares on the exercise of rights attached to securities giving access to the capital by redemption, conversion, exchange, presentation of a warrant or any other means;

the delivery of shares (in exchange, as payment, or otherwise) in connection with mergers and acquisitions;

the execution by an investment services provider of purchases, sales or transfers by any means, in particular via off-market trading;

or any other purpose that is or may in future be authorized under the applicable laws and regulations.

The Group is not subject to any constraints on equity capital imposed by third parties.

The gearing ratio (the ratio of debt, net of cash and cash equivalents to total equity) is a non-GAAP financial indicator used by management to measure overall net indebtedness and to manage the Group's equity capital.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

Total equity includes equity attributable to equity holders of the Company and minority interests, as shown on the consolidated balance sheet. See Note D.15.2. for a consolidated statement of changes in equity.

Debt, net of cash and cash equivalents is defined as short-term debt plus long-term debt, minus cash and cash equivalents.

For trends in this ratio, see Note D.17.

**B.28. New IASB standards, amendments and interpretations applicable from 2009 onwards**

New standards and interpretations applied in the consolidated financial statements for the first time in 2008 are described in Note A.2. The note below describes standards, amendments and interpretations issued by the IASB that will be mandatorily applicable in 2009 or subsequent years, and the Group's position regarding future application.

*Standards and amendments applicable to the consolidated financial statements of sanofi-aventis*

An amendment to IFRS 2 (Share-based Payment) has been issued, dealing with the definition of vesting conditions and the accounting treatment of cancellations. This amendment, which has been adopted by the European Union, states that only service and performance conditions are vesting conditions and hence included in the stock option expense for the period. Conversely, market conditions are not vesting conditions, and hence must be included in the fair value of the stock option plan at the date of grant. The amendment also specifies that the same accounting treatment must be applied to all cancellations, irrespective of whether cancellation is due to the actions of the entity or a third party or to failure by the entity or the employee to meet a vesting condition. The Group will apply this amendment from the 2009 financial year, and does not anticipate that it will have a material impact on the consolidated financial statements.

Early in 2008, the IASB issued a revised IFRS 3 (Business Combinations) and amendments to IAS 27 (Consolidated and Separate Financial Statements). These revised and amended standards are mandatorily applicable in 2010 at the latest, and may be early adopted provided that they are applied simultaneously. The principal changes to IFRS 3 and IAS 27 are described below:

The revised IFRS 3 alters the way in which the purchase method is applied to business combinations. First, it allows an option to calculate the goodwill on a partial acquisition by reference either to the fair value of the acquired entity or to the proportionate interest in the net assets acquired; this option can be applied individually to each acquisition. Second, it requires that in the case of a step acquisition, the previously-held equity interest must be remeasured at fair value on the date when control is acquired, with any difference relative to the carrying amount of that equity interest recognized in profit or loss along with any components of comprehensive income relating to the equity interest that are reclassifiable to profit or loss. Third, contingent consideration must be

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

recognized at fair value at the acquisition date irrespective of the probability of payment, with the resulting obligation recognized as debt or equity; subsequent adjustments must be recognized in profit or loss or in equity, depending on the original accounting treatment. Finally, acquisition-related costs must be recognized as expenses at the acquisition date, and deferred tax assets not recognized at the acquisition date (or during the twelve-month measurement period in which goodwill may be adjusted) must be recognized as a gain.

The amended IAS 27 alters the accounting treatment of transactions with non-controlling interests: if such transactions do not result in a change of control, they are accounted for as equity transactions. In addition, in the case of a partial disposal leading to loss of control, the investment retained must be remeasured at fair value, while the gain on disposal will include the effect of this remeasurement and the gain or loss on the shares sold, including any items previously recognized in equity that must be reclassified to profit or loss.



---

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

These changes will apply to new acquisitions and disposals with effect from the application date elected by the Group, except for the recognition of deferred tax assets subsequent to the acquisition date (because in such cases, the gain must be recognized even if the acquisition predates the application date of the revised IFRS 3; this applies, for example, to the acquisition of Aventis). The Group is currently considering the possibility of early adoption of the revised IFRS 3 and of the amendments to IAS 27 with effect from the 2009 financial year, subject to their adoption by the European Union.

IAS 14 (Segment Reporting) has been replaced by IFRS 8 (Operating Segments), which has been adopted by the European Union and is mandatorily applicable from January 1, 2009 but has not been early adopted by sanofi-aventis. IFRS 8 requires financial information to be reported on the same basis as is used internally for evaluating operating segment performance and deciding how to allocate resources to operating segments. It also specifies new criteria for identifying reportable segments. The information reported by sanofi-aventis for its primary segments under IAS 14 is already derived from information used internally.

The revised IAS 1 (Presentation of Financial Statements), issued in 2007, is mandatorily applicable in 2009 and has been adopted by the European Union. The revised standard requires the separate reporting of (i) transactions with the owners of the entity (the shareholders), presented in the statement of changes in equity and (ii) other changes in equity, presented either in a single statement of comprehensive income or in two statements (a separate income statement and a statement of comprehensive income). Because sanofi-aventis applies the option allowed by the amendment to IAS 19 (Employee Benefits) to recognize actuarial gains and losses in equity, comprehensive income is already presented separately from the consolidated income statement, in the consolidated statement of recognized income and expense. Consequently, the main impact of applying the revised IAS 1 in 2009 will be the presentation of the additional information required by the revised standard, in particular the presentation of a balance sheet as at the beginning of the earliest comparative reporting period when the balance sheet has been retrospectively restated; disclosure of income tax relating to each component of comprehensive income; and disclosure of amounts reclassified from equity to profit or loss.

The amended IAS 23 (Borrowing Costs) is applicable from 2009 and has been adopted by the European Union. This amendment requires entities to recognize borrowing costs generated by the acquisition or the in-house construction of items of property, plant and equipment as an asset, and removes the option of recognizing these costs as an expense. Because the Group elected to recognize such borrowing costs as assets on first-time adoption of IFRS, applying this amendment in 2009 will have no impact on the consolidated financial statements.

The IASB has issued an amendment to IAS 39 relating to eligible hedged items. This amendment has not yet been adopted by the European Union. It specifies the conditions required for the inflation risk of a debt instrument to be eligible as a hedged item for accounting purposes, and the treatment of hedge ineffectiveness relating to the time value of options designated as hedges. This amendment will have no impact on the consolidated financial statements, because sanofi-aventis has no inflation index-linked debt instruments in issue and because the accounting treatment applied by the Group to the time value of options designated as hedges already complies with the treatment required by the amendment.

In May 2008, the IASB published the first Improvements to IFRSs, part of an annual process of revision and improvements to standards.

Improvements to IFRSs comprises a series of amendments to various standards, with effective dates and transition arrangements specific to each amendment, and was adopted by the European Union in January 2009. The amendments described below are those that are most relevant to sanofi-aventis. These amendments are intended to clarify the existing standards, and hence are not inconsistent with those standards. All are applicable from 2009 onwards, and none has any impact on the consolidated financial statements because the accounting treatment applied by

the Group is already consistent with that specified in the relevant amendment.

Amendments to IAS 28 (Investments in Associates), IAS 32 (Financial Instruments: Presentation), and IFRS 7 (Financial Instruments: Disclosures) relating to the accounting treatment of provisions for

F-29

---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

impairment of an investment in an associate. These amendments specify that if an investment in an associate is impaired, the impairment loss should not be allocated to any asset that forms part of the investment, including goodwill. Consequently, the impairment loss can be reversed if the recoverable amount subsequently increases.

Amendment to IAS 20 (Accounting for Government Grants and Disclosure of Government Assistance) relating to the accounting treatment of government loans at below-market rates of interest. This amendment requires such loans to be measured at fair value in accordance with IAS 39, with market-rate interest recognized as an expense. The difference between the nominal value and the fair value of the loan represents a grant, which must be accounted for in accordance with IAS 20.

Amendment to IAS 38 (Intangible Assets) relating to advertising and promotional activities. Under this amendment, promotional expenses are recognized as an expense (i) in the case of the supply of goods, when the entity has a right to access those goods and (ii) in the case of the supply of services, when it receives those services. Advance payments are recognized as an asset until the entity obtains a right to access the goods or receives the services.

***Standards and amendments that do not apply to the consolidated financial statements of sanofi-aventis***

The IASB has also issued the following standards and amendments:

Revised version of IFRS 1 (First-Time Adoption of International Financial Reporting Standards). The structure of IFRS 1, which had become complex due to the numerous changes required as a result of amendments to other standards, has been revised and simplified, but with no change in its general principles. Because this standard applies only to first-time adopters of IFRS, it is not applicable to the Group.

Amendments to IFRS 1 and IAS 27 relating to the definition of the cost of the net investment in a subsidiary, jointly controlled entity or associate, and the accounting treatment of such investments in the separate financial statements of entities reporting under IFRS. These amendments relate solely to separate financial statements, and hence have no impact on the consolidated financial statements of sanofi-aventis.

Amendments to IAS 32 and IAS 1 relating to puttable financial instruments and obligations arising on liquidation. These specify the conditions under which an issuer must classify as equity (i) puttable financial instruments and (ii) instruments that impose obligations on the issuer in the event of its liquidation. Because sanofi-aventis has not issued any instruments of this type, these amendments have no impact on the consolidated financial statements.

All these amendments have been adopted by the European Union except for the amendment to IFRS 1.

***New interpretations***

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

The IASB has also issued the following interpretations (IFRIC 13, IFRIC 15 and IFRIC 16 are mandatorily applicable from 2009 onwards, while IFRIC 17 and IFRIC 18 are mandatorily applicable from 2010 onwards):

IFRIC 13 (Customer Loyalty Programmes), which specifies the accounting treatment applied to rewards offered by an entity to its customers when they buy goods or services. Because sanofi-aventis does not offer incentives of this kind, this interpretation is not applicable to the Group's activities.

IFRIC 15 (Agreements for the Construction of Real Estate), which clarifies which method (on completion, or by the percentage of completion method) is to be used for recognizing revenue on sales of real estate, especially off plan sales. This interpretation is not applicable to the Group's activities.

IFRIC 16 (Hedges of a Net Investment in a Foreign Operation), clarifying the risks that are eligible for this type of hedge and the applicable accounting treatment. The risk eligible for hedge accounting is the foreign currency exposure arising between the functional currency of the foreign operation and the

---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

functional currency of an intermediate or ultimate parent entity. On disposal, the effective portion of the hedge previously recognized in other components of comprehensive income is reclassified to profit or loss, as is the portion of the translation reserve relating to the entity disposed of. The Group does not anticipate any material impact from the application of IFRIC 16.

IFRIC 17 (Distributions of Non-cash Assets to Owners), which requires distributions of dividends in assets other than cash to be recognized when the declaration of dividend is authorized by the relevant authority, and measured at the fair value of the assets distributed. The fair value of those assets must be remeasured at the end of each reporting period and at the date of settlement, with adjustments to the amount of dividend payable taken to equity. On settlement, the difference between the carrying amount of the distributed assets and the amount of dividend payable is recognized in profit or loss. Because sanofi-aventis does not distribute non-cash assets, this interpretation is not applicable to the consolidated financial statements.

IFRIC 18 (Transfer of Assets from Customers), which specifies the treatment applied to property, plant and equipment received from a customer by a public service operator. This interpretation does not apply to the Group's activities.

The only one of these interpretations to have been adopted by the European Union is IFRIC 13.

***C. ALLIANCES***

**C.1. Alliance arrangements with Bristol-Myers Squibb (BMS)**

Two of the Group's leading products were jointly developed with BMS: the antihypertensive agent irbesartan (Aprovel®/Avapro®/Karvea®) and the anti-atherothrombosis treatment clopidogrel bisulfate (Plavix®/Iscover®).

As inventor of the two molecules, sanofi-aventis is paid a royalty on all sales generated by these products. This royalty is recorded in ***Other revenues***.

As co-developers of the products, sanofi-aventis and BMS each receive equal development royalties from their two licensees, which have been responsible, since 1997, for marketing the products using their local distribution networks, composed of subsidiaries of both groups. These licensees operate in two separate territories: (i) Europe, Africa and Asia, under the operational management of sanofi-aventis; and (ii) other countries (excluding Japan), under the operational management of BMS. In Japan, Aprovel® has since June 2008 been marketed jointly by Shionogi Pharmaceuticals and Dainippon Sumitomo Pharma Co. Ltd., under license and sub-license agreements contracted with BMS. The alliance with BMS does not cover the rights to Plavix® in Japan, where the product is marketed by sanofi-aventis.

The products are marketed in different ways in different countries.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Co-promotion consists of a pooling of sales resources under a single brand name, and is preferably achieved through contracts or through appropriate tax-transparent legal entities. Each partner records directly its share of taxable income.

Co-marketing consists of separate marketing of the products by each local affiliate using its own name and resources under different brand names for the product.

In certain countries of Eastern Europe, Africa, Asia, Latin America and the Middle East, the products are marketed on an exclusive basis, either by sanofi-aventis or by BMS.

F-31

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

In the territory managed by sanofi-aventis, operations are recognized by the Group as follows:

- (i) In most countries of Western Europe and Asia (excluding Japan) for clopidogrel bisulfate (Plavix®/Iscover®) only, co-promotion is used for both products. The legal entities used are partnerships (*sociétés en participation*) or other tax-transparent entities, which are majority-owned by and under the operational management of the Group. Sanofi-aventis recognizes all the revenue associated with the sale of the drugs, as well as the corresponding expenses. The share of profits reverting to BMS subsidiaries is shown in **Minority interests** in the income statement, with no tax effect (because BMS receives a pre-tax share of profits).

The presentation of **Minority interests** in the consolidated statement of cash flows takes account of the specific terms of the alliance agreement.

- (ii) In Germany, Spain and Greece, and in Italy for irbesartan (Aprovel®/Avapro®/Karvea®) only, co-marketing is used for both products, and sanofi-aventis recognizes revenues and expenses generated by its own operations.
- (iii) In those countries in Eastern Europe, Africa, the Middle East and Asia (excluding Japan) for Aprovel® only, where the products are marketed exclusively by sanofi-aventis, the Group recognizes revenues and expenses generated by its own operations. Since September 2006, sanofi-aventis has had the exclusive right to market Aprovel® in Scandinavia and in Ireland.

In the territory managed by BMS, operations are recognized by the Group as follows:

- (i) Co-promotion is used in the United States and Canada through entities that are majority-owned by and under the operational management of BMS. Sanofi-aventis does not recognize revenues; rather, it invoices the entity for its promotion expenses, records its royalty income in **Other revenues**, and records its share of profits (net of tax) in **Share of profit/loss of associates**.
- (ii) In Brazil, Mexico, Argentina and Australia for clopidogrel bisulfate (Plavix®/Iscover®) and for irbesartan (Aprovel®/Avapro®/Karvea®) and in Colombia for clopidogrel bisulfate only, co-marketing is used, and sanofi-aventis recognizes revenues and expenses generated by its own operations.
- (iii) In certain other Latin American countries, where the products are marketed exclusively by sanofi-aventis, the Group recognizes revenues and expenses generated by its own operations.

**C.2. Alliance agreements with Procter & Gamble Pharmaceuticals (P&G)**

Actonel® (risedronate sodium) is a new-generation bisphosphonate indicated for the treatment and prevention of osteoporosis. Actonel® is developed and marketed in collaboration with P&G. This alliance covers the worldwide development and marketing of the product except for Japan for which sanofi-aventis holds no rights.

Local marketing arrangements may take various forms:

Co-promotion, whereby sales resources are pooled but only one of the two partners invoices product sales. Co-promotion is carried out under contractual agreements and is not based on any specific legal entity. P&G sells the product and incurs all the related costs in the United States, Canada and France. This co-promotion scheme also included Germany, Belgium and Luxembourg until December 31, 2007, and the Netherlands until March 31, 2008. Sanofi-aventis recognizes its share of revenues under the agreement as a component of operating income on the *Other operating income* line. In the secondary co-promotion territories (the United Kingdom, Ireland, Sweden, Finland, Greece, Switzerland, Austria, Portugal and Australia) sanofi-aventis sells the product, and recognizes all the revenues from sales of the product along with the corresponding expenses.

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

F-32



**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

The product has been marketed by P&G independently in Germany, Belgium and Luxembourg since January 1, 2008, and in the Netherlands since April 1, 2008.

In all other territories, sanofi-aventis has exclusive rights to sell the product. The Group recognizes all revenue and expenses from its own operations in its income statement, but in return for these exclusive rights pays P&G a royalty based on actual sales. This royalty is recognized in *Cost of sales*.

***D. DETAILED NOTES TO THE FINANCIAL STATEMENTS***

**D.1. Acquisitions**

The principal acquisitions during 2008 were as follows:

**- Acambis**

On September 25, 2008, sanofi-aventis completed the acquisition of Acambis plc for £285 million. Acambis plc became Sanofi Pasteur Holding Ltd, a wholly-owned subsidiary of Sanofi Pasteur Holding S.A. This company develops novel vaccines that address unmet medical needs or substantially improve current standards of care. Sanofi Pasteur and Acambis plc were already developing vaccines in a successful partnership of more than a decade: Acambis plc was conducting three of its major projects under exclusive collaboration agreements with sanofi pasteur, for vaccines against dengue fever, Japanese encephalitis and West Nile virus (see Note D.4.).

**- Symbion Consumer**

On September 1, 2008, sanofi-aventis completed the acquisition of the Australian company Symbion CP Holdings Pty Ltd (Symbion Consumer) for AUD560 million. Symbion Consumer manufactures, markets and distributes nutraceuticals (vitamins and mineral supplements) and over the counter brands throughout Australia and New Zealand. Symbion Consumer has a portfolio of brands including Natures Own, Cenovis, Bio-organics, Golden Glow and Microgenics. In 2007, Symbion Consumer sales amounted to around AUD190 million. Symbion Consumer is the market leader in Australia, with an estimated 21% market share (see Note D.4.).

The principal acquisition during 2007 was as follows:

In November 2007, sanofi-aventis acquired 12 million newly-issued shares in the biopharmaceutical company Regeneron Pharmaceuticals Inc. (Regeneron) for \$312 million, raising its interest in Regeneron from approximately 4% to approximately 19%. These shares are classified as an

available-for-sale financial asset, and are included in *Financial assets non-current* (see Note D.7.).

The principal acquisition during 2006 was as follows:

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

On March 27, 2006, sanofi-aventis paid 433 million (including acquisition costs) to acquire the entire interest in Zentiva N.V. (7,487,742 shares) held by Warburg Pincus, and a further 1,998,921 shares held by certain managers and employees of Zentiva. On completion of this transaction and as of December 31, 2008, sanofi-aventis held a 24.9% interest in the capital of Zentiva. Sanofi-aventis appoints two members of Zentiva's Board of Directors.

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

In 2008, sanofi-aventis made an offer to acquire all the shares of Zentiva (see Note D.21. *Financial commitment related to the offer for Zentiva shares*).

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

**D.2. Divestments**

There were no significant divestments during 2007 and 2008.

The principal divestment in 2006 was as follows:

Transfer of rights to Exubera<sup>®</sup> and interest in Diabel

Sanofi-aventis transferred its rights to Exubera<sup>®</sup>, an inhaled human insulin, to Pfizer. The terms of the 1998 alliance between Aventis and Pfizer to jointly develop, manufacture and market Exubera<sup>®</sup> included a change of control clause, which Pfizer decided to activate following the acquisition of Aventis by Sanofi-Synthélabo.

Under the terms of the agreement signed on January 13, 2006, sanofi-aventis sold to Pfizer its share in the worldwide rights for the development, manufacturing and marketing of Exubera<sup>®</sup>, along with its interest in the Diabel joint venture (based in Frankfurt, Germany), which owns the insulin manufacturing facility used in the production of Exubera<sup>®</sup>.

In return for the transfer of these assets and rights, sanofi-aventis received a payment of \$1.3 billion.

The impact of this transaction in 2006 was a pre-tax gain of 460 million, recognized in *Gains and losses on disposals, and litigation*, and an after-tax gain of 384 million.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008****D.3. Property, plant and equipment**

Property, plant and equipment (including assets held under finance leases) comprise:

<i>( million)</i>	<b>Land</b>	<b>Buildings</b>	<b>Plant &amp; equipment</b>	<b>Fixtures, fittings &amp; other</b>	<b>Property, plant and equipment in process</b>	<b>Total</b>
Gross value at January 1, 2006	262	2,553	3,686	924	1,016	8,441
Changes in scope of consolidation			(3)	1		(2)
Acquisitions and other increases		28	77	85	1,070	1,260
Disposals and other decreases	(27)	(11)	(12)	(14)	(13)	(77)
Translation differences	(8)	(120)	(74)	(31)	(38)	(271)
Transfers	6	361	398	247	(1,024)	(12)
<b>Gross value at December 31, 2006</b>	<b>233</b>	<b>2,811</b>	<b>4,072</b>	<b>1,212</b>	<b>1,011</b>	<b>9,339</b>
Changes in scope of consolidation	(3)		1	1		(1)
Acquisitions and other increases	3	34	90	86	1,122	1,335
Disposals and other decreases	(23)	(29)	(7)	(3)	(4)	(66)
Translation differences		(94)	(67)	(27)	(34)	(222)
Transfers	3	272	409	113	(804)	(7)
<b>Gross value at December 31, 2007</b>	<b>213</b>	<b>2,994</b>	<b>4,498</b>	<b>1,382</b>	<b>1,291</b>	<b>10,378</b>
Changes in scope of consolidation	5	13	9		12	39
Acquisitions and other increases		30	55	67	1,207	1,359
Disposals and other decreases	(4)	(6)	(4)	(58)	(1)	(73)
Translation differences	(7)	(46)	(80)	(22)	13	(142)
Transfers	8	315	501	176	(1,010)	(10)
<b>Gross value at December 31, 2008</b>	<b>215</b>	<b>3,300</b>	<b>4,979</b>	<b>1,545</b>	<b>1,512</b>	<b>11,551</b>
Accumulated depreciation & impairment at January 1, 2006	(27)	(507)	(1,211)	(512)		(2,257)
Depreciation expense		(199)	(438)	(156)		(793)
Impairment losses	(3)	(66)	(113)	(6)	(21)	(209)
Disposals	13					13
Translation differences	2	53	45	19		119
Transfers		(5)	136	(124)		7
Accumulated depreciation & impairment at Dec. 31, 2006	(15)	(724)	(1,581)	(779)	(21)	(3,120)

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Depreciation expense		(192)	(469)	(158)		(819)
Impairment losses		(10)			(12)	(22)
Disposals	11					11
Translation differences		45	41	16		102
Transfers	1	(7)	33	(19)		8
<b>Accumulated depreciation &amp; impairment at Dec. 31, 2007</b>	<b>(3)</b>	<b>(888)</b>	<b>(1,976)</b>	<b>(940)</b>	<b>(33)</b>	<b>(3,840)</b>
Depreciation expense		(205)	(476)	(161)		(842)
Impairment losses	(1)	(17)	(14)	(5)	(4)	(41)
Disposals				50		50
Translation differences		11	46	13		70
Transfers		6	20	(13)		13
<b>Accumulated depreciation &amp; impairment at Dec. 31, 2008</b>	<b>(4)</b>	<b>(1,093)</b>	<b>(2,400)</b>	<b>(1,056)</b>	<b>(37)</b>	<b>(4,590)</b>
Net book value: January 1, 2006	235	2,046	2,475	412	1,016	6,184
Net book value: December 31, 2006	218	2,087	2,491	433	990	6,219
Net book value: December 31, 2007	210	2,106	2,522	442	1,258	6,538
<b>Net book value: December 31, 2008</b>	<b>211</b>	<b>2,207</b>	<b>2,579</b>	<b>489</b>	<b>1,475</b>	<b>6,961</b>

F-35

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

Property, plant and equipment pledged as security for liabilities amounted to 10 million as of December 31, 2008 ( 13 million as of December 31, 2007 and 10 million as of December 31, 2006).

Based on the results of a review of the value of property, plant and equipment conducted using the method described in Note B.6., impairment losses of 41 million were recognized in the year ended December 31, 2008, relating primarily to industrial sites in France and in the United States. In 2007, impairment losses of 22 million were recognized, mainly relating to industrial sites in Europe. In 2006, impairment losses of 209 million were recognized, the largest item being a 115 million impairment loss for industrial assets specific to Kete<sup>®</sup> in France and Germany.

Acquisitions during 2008 related to investments in the Pharmaceuticals business, primarily in industrial facilities ( 501 million in 2008, versus 536 million in 2007 and 556 million in 2006) and in the facilities and equipment of research sites ( 376 million in 2008, versus 374 million in 2007 and 289 million in 2006). Acquisitions in the Vaccines business totaled 382 million (compared with 335 million in 2007 and 296 million in 2006). Capitalized borrowing costs of 24 million were included in acquisitions of property, plant and equipment during 2008 (versus 21 million in 2007 and 14 million in 2006). Firm orders of property, plant and equipment totaled 450 million at December 31, 2008 (against 379 million at December 31, 2007 and 332 million at December 31, 2006).

The table below shows amounts for items of property, plant and equipment held under finance leases:

( million)	December 31, 2008	December 31, 2007	December 31, 2006
Land	7	7	7
Buildings	99	97	97
Other property, plant and equipment	7	6	10
<b>Total gross value</b>	<b>113</b>	<b>110</b>	<b>114</b>
Accumulated depreciation and impairment	(83)	(77)	(77)
<b>Net book value</b>	<b>30</b>	<b>33</b>	<b>37</b>

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008****D.4. Intangible assets and Goodwill**

Intangible assets and goodwill break down as follows:

( million)	Trademarks, patents, licenses and other rights	Acquired Aventis R&D	Rights to marketed Aventis products	Software	Total intangible assets	Goodwill
Gross value at January 1, 2006	1,545	3,427	32,301	554	37,827	30,261
Changes in scope of consolidation	2				2	42
Acquisitions and other increases	261			66	327	
Disposals and other decreases	(3)			(4)	(7)	(301)
Translation differences	(119)	(221)	(2,082)	(33)	(2,455)	(1,503)
Transfers	(8)	(152)	152	4	(4)	
<b>Gross value at December 31, 2006</b>	<b>1,678</b>	<b>3,054</b>	<b>30,371</b>	<b>587</b>	<b>35,690</b>	<b>28,499</b>
Changes in scope of consolidation	25				25	7
Acquisitions and other increases	312			42	354	
Disposals and other decreases	(11)			(16)	(27)	(63)
Translation differences	(114)	(175)	(1,595)	(20)	(1,904)	(1,217)
Transfers		(235)	235	(6)	(6)	
<b>Gross value at December 31, 2007</b>	<b>1,890</b>	<b>2,644</b>	<b>29,011</b>	<b>587</b>	<b>34,132</b>	<b>27,226</b>
Changes in scope of consolidation	337			2	339	403
Acquisitions and other increases	103			47	150	
Disposals and other decreases	(76)			(53)	(129)	(6)
Translation differences	81	109	1,008	1	1,199	565
Transfers	(17)	(300)	300	1	(16)	
<b>Gross value at December 31, 2008</b>	<b>2,318</b>	<b>2,453</b>	<b>30,319</b>	<b>585</b>	<b>35,675</b>	<b>28,188</b>
Accumulated amortization & impairment at January 1, 2006	(616)	(185)	(6,447)	(350)	(7,598)	(27)
Amortization expense	(153)		(3,845)	(110)	(4,108)	
Impairment losses, net of reversals	(8)	(128)	(818)	1	(953)	
Disposals						
Translation differences	48	14	620	26	708	
Transfers	5			(6)	(1)	
Accumulated amortization & impairment at Dec. 31, 2006	(724)	(299)	(10,490)	(439)	(11,952)	(27)
Amortization expense	(159)		(3,486)	(80)	(3,725)	

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Impairment losses, net of reversals		11	(69)		(58)	
Disposals	1			15	16	
Translation differences	52	21	679	15	767	
Transfers			1	1	2	
<b>Accumulated amortization &amp; impairment at Dec. 31, 2007</b>	<b>(830)</b>	<b>(267)</b>	<b>(13,365)</b>	<b>(488)</b>	<b>(14,950)</b>	<b>(27)</b>
Amortization expense	(205)		(3,277)	(52)	(3,534)	
Impairment losses, net of reversals	(68)	(1,233)	(253)		(1,554)	
Disposals	73			53	126	
Translation differences	(38)	(2)	(486)	1	(525)	2
Transfers	24	18	(18)	(2)	22	
<b>Accumulated amortization &amp; impairment at Dec. 31, 2008</b>	<b>(1,044)</b>	<b>(1,484)</b>	<b>(17,399)</b>	<b>(488)</b>	<b>(20,415)</b>	<b>(25)</b>
Net book value: January 1, 2006	929	3,242	25,854	204	30,229	30,234
Net book value: December 31, 2006	954	2,755	19,881	148	23,738	28,472
Net book value: December 31, 2007	1,060	2,377	15,646	99	19,182	27,199
<b>Net book value: December 31, 2008</b>	<b>1,274</b>	<b>969</b>	<b>12,920</b>	<b>97</b>	<b>15,260</b>	<b>28,163</b>

F-37



---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

**Aventis Acquisition**

On August 20, 2004, sanofi-aventis acquired Aventis, a global pharmaceutical group created in 1999 by the merger between Rhône-Poulenc and Hoechst.

As part of the process of creating the new Group, the two former parent companies Sanofi-Synthélabo (renamed sanofi-aventis) and Aventis were merged on December 31, 2004.

The total purchase price as measured under IFRS 3 (Business Combinations) was 52,908 million, of which 15,894 million was settled in cash.

The goodwill arising from the acquisition of Aventis amounted to 27,632 million at December 31, 2008 ( 27,034 million at December 31, 2007, 28,286 million at December 31, 2006).

Rights to marketed products and goodwill arising on the Aventis acquisition were allocated on the basis of the split of the Group's operations into business and geographical segments, and valued in the currency of the relevant geographical segment (mainly euros and U.S. dollars) with assistance from an independent valuer. The average period of amortization for marketed products was initially set at 8 years, based on cash flow forecasts which, among other factors, take account of the period of legal protection offered by the related patents.

Rights to marketed Aventis products represent a diversified portfolio of rights relating to many different products. As of December 31, 2008, 85.8% of the net book value of these rights related to the Pharmaceuticals segment, and 14.2% to the Vaccines segment. The five principal pharmaceutical products in this portfolio by net book value (Lantus®: 2,097 million, Lovenox®: 1,527 million; Taxotere®: 1,346 million; Actonel®: 952 million; Tritac®: 278 million) accounted for approximately 55.9% of the total net book value of product rights for the Pharmaceuticals business as of December 31, 2008.

During 2006, some of the acquired Aventis research and development ( 152 million) came into commercial use; it is being amortized from the date of marketing approval. The main products involved are Taxotere®, Lantus®, Apidra®, and Menactra® in Canada.

The amount shown for goodwill on the Disposals and other decreases line for 2006 corresponds to the recognition of deferred tax assets associated with the acquisition of Aventis, in accordance with the principle described in Note B.22.

During 2007, some of the acquired Aventis research and development ( 235 million) came into commercial use; it is being amortized from the date of marketing approval. The main items involved are the Lantus®-Apidra® pens, and new indications for Taxotere®.

During 2008, some of the acquired Aventis research and development ( 300 million) came into commercial use; it is being amortized from the date of marketing approval. The main products involved are Pentacel<sup>®</sup> vaccine in the United States and the once-a-month dose of Acton<sup>®</sup> in the United States.

#### **Other acquisitions**

The purchase price allocation on the Symbion Consumer acquisition (see Note D.1.) resulted in the recognition of intangible assets totaling 116 million as of December 31, 2008. Goodwill arising on this acquisition amounted to 206 million. The purchase price allocation on the Acambis acquisition (see Note D.1.) led to the recognition of intangible assets totaling 223 million (including 198 million for research projects). Goodwill arising on this acquisition amounted to 197 million.

Acquisitions of intangible assets (other than software) in 2008 were 103 million, and related mainly to license agreements, including the collaboration agreements signed with Dyax Corp. and Novozymes (see Note D.21.).

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

Acquisitions of intangible assets (other than software) in 2007 were 312 million. This amount includes payments made under collaboration agreements, including those signed during the year with Oxford BioMedica (TrovaX®) and Regeneron (see Note D.21.). It also includes the buyout of the Japanese rights for Panaldine® (Daiichi) and Myslee® (Astellas).

Acquisitions of intangible assets (other than software) in 2006 mainly comprised the buyout of the entire rights to Plavix®, Cordarone® and rimonabant in Japan, and payments made under the agreements with Taiho (S-1) and UCB (Xyzal®) (see Note D.21.).

Amortization of intangible assets is recognized in the income statement under *Amortization of intangibles* except for amortization of software, which is recognized on the relevant line of the income statement according to the purpose for which the software is used:

( million)	Year ended December 31, 2008	Year ended December 31, 2007	Year ended December 31, 2006
Cost of sales	10	18	29
Research and development expenses	14	16	26
Selling and general expenses	28	45	54
Other operating expenses		1	1
<b>Total</b>	<b>52</b>	<b>80</b>	<b>110</b>

**D.5. Impairment of property, plant and equipment, goodwill and intangibles**

The allocation of goodwill to segmental cash-generating units (CGUs) is shown below:

( million)	December 31, 2008			December 31, 2007			December 31, 2006		
	Pharma- ceuticals	Vaccines	Total	Pharma- ceuticals	Vaccines	Total	Pharma- ceuticals	Vaccines	Total
Europe	12,414		12,414	12,428		12,428	12,426		12,426
United States	10,496	693	11,189	9,917	464	10,381	11,141	519	11,660
Other countries	4,391	169	4,560	4,221	169	4,390	4,225	161	4,386
<b>Total carrying amount</b>	<b>27,301</b>	<b>862</b>	<b>28,163</b>	<b>26,566</b>	<b>633</b>	<b>27,199</b>	<b>27,792</b>	<b>680</b>	<b>28,472</b>

In testing goodwill for impairment, the recoverable amount of the segmental CGUs was determined by reference to the value in use of each CGU based on the discounted estimates of the future cash flows from the CGU, as described in Note B.6.1.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

The assumptions used in testing goodwill for impairment in 2008 were:

	<b>Pharmaceuticals</b>	<b>Vaccines</b>
Operating margin	31% - 37%	32% - 33%
Perpetual growth rate	4% - 5%	5%
After-tax discount rate	10%	11%

Some of these assumptions were determined with the assistance of an independent valuer at the time of the Aventis acquisition, and are reviewed annually by the Group.

The operating margin used is the range of values per the five-year plan for each business segment.

The perpetual growth rate is an average rate by business segment and geographical area.

The discount rate is the average for all geographical areas within a single business segment.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

No impairment losses have been recognized against goodwill.

Goodwill relating to the Pharmaceuticals segment relates primarily to Europe and the United States. The assumptions used to calculate the value in use of these two CGUs comprise an after-tax discount rate of 10% and a perpetual growth rate of 4%. A zero perpetual growth rate would not result in any impairment of the goodwill relating to these CGUs.

Similarly, no impairment would need to be recognized against the goodwill relating to these CGUs unless the discount rate were to exceed the 10% rate used by more than 2.8 percentage points.

The assumptions used for intangible assets in 2008 were:

	Pharmaceuticals	Vaccines
After-tax discount rate		
- Acquired in-process R&D	11%	12%
- Rights to marketed products	10%	11%

Certain intangible assets for which indications of potential impairment were identified in the years ended December 31, 2008, 2007 and 2006 were tested for impairment.

In 2008, impairment losses were recognized to take account of:

the discontinuation of research projects, principally larotaxel and cabazitaxel (new taxane derivatives intended as treatments for breast cancer, 1,175 million) and ilepatril (antihypertensive, 57 million), both of which were recognized as assets on the acquisition of Aventis, plus the oral anti-cancer agent S-1 following the termination of the agreement with Taiho Pharmaceutical on development and marketing of this product ( 51 million);

settlements reached with Barr in the United States relating to the marketed product Nasacort® ( 114 million), and the impact of generics on some products ( 139 million).

In 2007, impairment losses totaling 69 million were recognized based on the results of impairment tests. These losses related to Amaryl® ( 46 million) and Ketek® ( 23 million). In addition, reversals of impairment losses totaling 11 million were recognized during the year.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

In 2006, impairment losses of 1,077 million were recognized based on the results of impairment tests. These losses related mainly to Altac<sup>®</sup> ( 638 million) and Kete<sup>®</sup> ( 423 million). Also in 2006, previously-recognized impairment losses of 124 million were reversed due to favorable events occurring in that year. Consequently, net impairment losses for 2006 totaled 953 million.

Impairment losses taken against property, plant and equipment are disclosed in Note D.3.

### **D.6. Investments in associates**

Associates consist of companies over which sanofi-aventis exercises significant influence, and joint ventures. Sanofi-aventis accounts for joint ventures using the equity method (i.e. as associates), in accordance with the allowed alternative treatment specified in IAS 31 (Financial Reporting of Interests in Joint Ventures).

F-40

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

Investments in associates break down as follows:

( million)	% interest	Dec. 31, 2008	Dec. 31, 2007	Dec. 31, 2006
Sanofi Pasteur MSD	50.0	427	467	500
Merial	50.0	1,203	1,151	1,257
InfraServ Höchst	30.0	96	97	97
Entities and companies managed by Bristol-Myers Squibb <sup>(1)</sup>	49.9	196	178	120
Zentiva	24.9	332 <sup>(2)</sup>	346	453
Financière des Laboratoires de Cosmétologie Yves Rocher	39.1	119	103	92
Other investments		86	151	118
<b>Total</b>		<b>2,459</b>	<b>2,493</b>	<b>2,637</b>

(1) Under the terms of the agreements with BMS (see Note C.1.), the Group's share of the net assets of entities and companies majority-owned by BMS is recorded in *Investments in associates*.

(2) The value of the investment held by sanofi-aventis based on the quoted market price at December 31, 2008 was 380 million. On June 18, 2008, sanofi-aventis announced an improved offer for the shares of Zentiva (see Notes D.1. and D.21.). The carrying amount is net of an impairment loss of 102 million recognized in 2007.

The financial statements include commercial transactions between the Group and certain of its associates:

( million)	December 31, 2008	December 31, 2007	December 31, 2006
Sales	432	404	374
Royalties <sup>(1)</sup>	1,014	945	748
Accounts receivable <sup>(1)</sup>	354	355	243
Purchases	254	236	197
Accounts payable	30	29	17
Other liabilities <sup>(1)</sup>	242	365	104

(1) These items mainly relate to entities and companies managed by BMS.

Key financial indicators for associates, excluding the effects of purchase price allocations, are shown below:

( million)

Edgar Filing: SANOFI-AVENTIS - Form 20-F

	Principal associates <sup>(1)</sup> 100% impact			Principal joint ventures <sup>(2)</sup> Share held by sanofi-aventis		
	Dec. 31, 2008	Dec. 31, 2007	Dec. 31, 2006	Dec. 31, 2008	Dec. 31, 2007	Dec. 31, 2006
Non-current assets	1,919	1,950	1,343	354	323	285
Current assets	2,717	2,788	2,680	688	687	693
Non-current liabilities	913	1,190	599	99	104	96
Current liabilities	1,798	1,552	1,531	404	418	395
Equity attributable to equity holders of the company	1,622	1,712	1,630	536	486	485
Minority interests	303	284	263	2	2	2
Net sales	9,770	9,165	7,795	1,537	1,431	1,247
Cost of sales	2,555	2,371	1,850	433	394	295
Operating income	2,838	2,338	1,722	372	313	280
Net income	2,384	2,054	1,475	225	206	199

(1) The following associates and joint ventures are included in this table for 2008, 2007 and 2006: BMS/Sanofi Pharmaceuticals Holding Partnership, BMS/Sanofi Pharmaceuticals Partnership, BMS/Sanofi-Synthelabo Partnership, Yves Rocher, Merial, Sanofi Pasteur MSD, and Zentiva. Full-year figures are shown, before allocation of partnership profits.

(2) The principal joint ventures are:

	Partner	Business
Merial	Merck & Co., Inc.	Animal Health
Sanofi Pasteur MSD	Merck & Co., Inc.	Vaccines



**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008****D.7. Financial assets non-current**

The main items included in *Financial assets non-current* are:

( million)	December 31, 2008	December 31, 2007	December 31, 2006
Available-for-sale financial assets	491	676	525
Pre-funded pension obligations (see Note D.18.1.)	1	7	3
Long-term loans and advances	186	219	237
Assets recognized under the fair value option	72	85	75
Derivative financial instruments (see Note D.20.)	71	50	205
<b>Total</b>	<b>821</b>	<b>1,037</b>	<b>1,045</b>

Equity investments classified as available-for-sale financial assets include:

An interest in the biopharmaceuticals company Regeneron, with which sanofi-aventis has research and development collaboration agreements (see Note D.21.). This investment had a carrying amount of 195 million at December 31, 2008 ( 243 million at December 31, 2007 and 42 million at December 31, 2006). In November 2007, sanofi-aventis acquired an additional 12 million newly-issued shares in Regeneron, taking its interest in Regeneron's common stock to approximately 19%. As part of this transaction, sanofi-aventis signed an Investor Agreement which limits its ability to exercise certain voting rights. Consequently, the acquisition of this additional interest does not give sanofi-aventis significant influence over Regeneron.

A 13% interest in ProStrakan, carried at an amount of 24 million as of December 31, 2008 ( 23 million at December 31, 2007 and 43 million at December 31, 2006).

Interests in research and development companies such as Proteome Science ( 3 million at December 31, 2008, 9 million at December 31, 2007 and 14 million at December 31, 2006) and Genfit ( 4 million at December 31, 2008).

Financial assets held to match commitments ( 223 million at December 31, 2008, 306 million at December 31, 2007 and 324 million at December 31, 2006).

During 2008, the Group divested its equity interest in Millennium (carrying amount 46 million), generating a pre-tax gain of 38 million (see Note D.29.).

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

The cumulative unrealized net after-tax loss recognized directly in equity on available-for-sale financial assets at December 31, 2008 was 49 million, and related principally to the investment in Regeneron ( 49 million). The situation of Regeneron at the balance sheet date does not reflect a significant or prolonged decline in the quoted share price and does not represent objective evidence of a decrease in the intrinsic value of this asset that would require the recognition of an impairment loss in the income statement. As at December 31, 2007 and 2006, there were cumulative unrealized net after-tax gains recognized in equity for available-for-sale financial assets amounting to 48 million and 64 million respectively (see Note D.15.7.).

The impact of a 10% fall in stock prices on listed shares included in available-for-sale assets at December 31, 2008 would have been as follows:

<i>( million)</i>	<b>Sensitivity</b>
Income/(expense) recognized directly in equity, before tax	(34)
Income before tax	(3)
<b>Total</b>	<b>(37)</b>

F-42

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

A 10% fall in stock prices combined with a simultaneous 0.5% rise in the yield curve would have had the following impact at December 31, 2008:

<i>( million)</i>	<b>Sensitivity</b>
Income/(expense) recognized directly in equity, before tax	(13)
Income before tax	
<b>Total <sup>(1)</sup></b>	<b>(13)</b>

<sup>(1)</sup> This impact would represent approximately 6% of the value of the underlying assets.

Available-for-sale financial assets also include equity investments not quoted in an active market. These investments had a carrying amount of 34 million at December 31, 2008, against 36 million at December 31, 2007 and 43 million at December 31, 2006.

Loans and long-term advances are measured at amortized cost, which at the balance sheet date was not materially different from their fair value.

Assets recognized under the fair value option represent a portfolio of financial investments held to fund a deferred compensation plan offered to certain employees.

**D.8. Assets held for sale**

As of December 31, 2008, sanofi-aventis had assets held for sale relating to the ongoing divestment of a plant at Colomiers in the Haute-Garonne region of France. However, these assets were fully written down as of that date.

There were no assets held for sale as of December 31, 2007 and December 31, 2006.

**D.9. Inventories**

Inventories break down as follows:

Edgar Filing: SANOFI-AVENTIS - Form 20-F

( million)	December 31, 2008			December 31, 2007			December 31, 2006		
	Gross	Impairment	Net	Gross	Impairment	Net	Gross	Impairment	Net
Raw materials	615	(91)	524	607	(83)	524	728	(42)	686
Work in process	2,028	(226)	1,802	2,073	(230)	1,843	1,741	(200)	1,541
Finished goods	1,449	(185)	1,264	1,534	(172)	1,362	1,646	(214)	1,432
<b>Total</b>	<b>4,092</b>	<b>(502)</b>	<b>3,590</b>	<b>4,214</b>	<b>(485)</b>	<b>3,729</b>	<b>4,115</b>	<b>(456)</b>	<b>3,659</b>

The impact of changes in provisions for impairment of inventories in 2008 was a net expense of 30 million, compared with a net expense of 39 million in 2007 and a net expense of 159 million in 2006.

Impairment losses taken against inventory at December 31, 2008 relate primarily to the products Ketek® and Lovenox®.

Inventories pledged as security for liabilities amounted to 10 million at December 31, 2008.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008****D.10. Accounts receivable**

Accounts receivable break down as follows:

<i>( million)</i>	December 31, 2008	December 31, 2007	December 31, 2006
Gross value	5,391	5,034	5,208
Impairment	(88)	(130)	(176)
<b>Net value</b>	<b>5,303</b>	<b>4,904</b>	<b>5,032</b>

The impact of changes in provisions for impairment of accounts receivable in 2008 was a net expense of 7 million (against a net reversal of 17 million in 2007 and a net expense of 15 million in 2006).

The gross value of overdue receivables at December 31, 2008 was 794 million (versus 801 million at December 31, 2007 and 1,055 million at December 31, 2006).

<i>( million)</i>	Overdue accounts Gross value	Overdue < 1 month	Overdue from 1 to 3 months	Overdue from 3 to 6 months	Overdue from 6 to 12 months	Overdue > 12 months
December 31, 2008	794	267	146	121	95	165
December 31, 2007	801	218	166	130	115	172

Amounts overdue by more than one month relate mainly to public-sector customers.

Group policy is to retain receivables until maturity, and hence not to use receivables securitization programs.

**D.11. Other current assets**

Other current assets break down as follows:

Edgar Filing: SANOFI-AVENTIS - Form 20-F

<i>( million)</i>	December 31, 2008	December 31, 2007	December 31, 2006
Taxes recoverable	927	1,185	1,097
Other receivables <sup>(1)</sup>	781	754	947
Prepaid expenses	173	187	164
<b>Total</b>	<b>1,881</b>	<b>2,126</b>	<b>2,208</b>

(1) This line mainly comprises amounts due from alliance partners, advance payments to suppliers, sales commission receivable, and amounts due from employees.

**D.12. Financial assets – current**

Financial assets – current break down as follows:

<i>( million)</i>	December 31, 2008	December 31, 2007	December 31, 2006
Interest rate derivatives measured at fair value (see Note D.20.)	33		
Currency derivatives measured at fair value (see Note D.20.)	348	67	70
Other current financial assets	22	16	38
<b>Total</b>	<b>403</b>	<b>83</b>	<b>108</b>

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008****D.13. Cash and cash equivalents**

( million)	December 31, 2008	December 31, 2007	December 31, 2006
Cash	502	831	844
Cash equivalents <sup>(1)</sup>	3,724	880	309
<b>Cash and cash equivalents <sup>(2)</sup></b>	<b>4,226</b>	<b>1,711</b>	<b>1,153</b>

<sup>(1)</sup> Cash equivalents at December 31, 2008 included 2,601 million invested in collective investment schemes classified as Euro Money-Market Funds by the *Autorité des Marchés Financiers*, 481 million in certificates of deposit with a maturity of less than three months on issue, and 604 million of term deposits with a maturity of less than three months on inception.

<sup>(2)</sup> Includes cash held by captive insurance and reinsurance companies in accordance with insurance regulations amounting to 429 million at December 31, 2008, 420 million at December 31, 2007, and 427 million at December 31, 2006.

**D.14. Net deferred tax position**

The net deferred tax position breaks down as follows:

( million)	December 31, 2008	December 31, 2007	December 31, 2006
Deferred tax on:			
Consolidation adjustments (intragroup margin on inventory)	845	808	961
Provision for pensions and other employee benefits	1,070	915	1,134
Remeasurement of acquired intangible assets <sup>(1)</sup>	(4,805)	(6,123)	(8,378)
Recognition of Aventis property, plant and equipment at fair value	(65)	(77)	(89)
Tax cost of distributions made from reserves <sup>(2)</sup>	(769)	(693)	(720)
Stock options	6	48	96
Tax losses available for carry-forward (see below)	171	266	99
Other non-deductible provisions and other items	799	833	1,143
<b>Net deferred tax liability</b>	<b>(2,748)</b>	<b>(4,023)</b>	<b>(5,754)</b>

<sup>(1)</sup> Mainly arising on the remeasurement of Aventis intangible assets (see Note D.4.).

<sup>(2)</sup> In certain countries, the Group is liable to withholding taxes and other tax charges when dividends are distributed. Consequently, the Group recognizes a deferred tax liability on those reserves (approximately 8 billion) which the Group regards as likely to be distributed in the foreseeable future.

The table below shows when the tax losses available for carry-forward are due to expire:

Edgar Filing: SANOFI-AVENTIS - Form 20-F

<i>( million)</i>	Tax loss carry- forwards at December 31, 2008 <sup>(*)</sup>	Tax loss carry- forwards at December 31, 2007 <sup>(*)</sup>	Tax loss carry- forwards at December 31, 2006
2007			14
2008		63	45
2009	30	32	47
2010	50	33	43
2011	20	23	30
2012 and later	745	919	621
<b>Total</b>	<b>845</b>	<b>1,070</b>	<b>800</b>

—

<sup>(\*)</sup> Excluding tax loss carry-forwards on asset disposals. These carry-forwards amounted to 776 million at December 31, 2008 and to 653 million at December 31, 2007.

Use of these tax loss carry-forwards is limited to the entity in which they arose. In jurisdictions where tax consolidations are applied, carry-forwards can be netted against taxable income generated by the entities in the consolidated tax group.

F-45



**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

Deferred tax assets not recognized because their future recovery was not considered probable given the likely future results of the entities in question amounted to 374 million at December 31, 2008 (including 162 million on asset disposals), compared with 274 million at December 31, 2007 (including 131 million on asset disposals) and 369 million at December 31, 2006.

Deferred tax assets requiring a corresponding adjustment to goodwill amounted to 6 million at December 31, 2008, 43 million at December 31, 2007, and 301 million at December 31, 2006.

**D.15. Consolidated shareholders' equity****D.15.1. Share capital**

The share capital of 2,631,050,926 comprises 1,315,525,463 shares with a par value of 2.

Treasury shares held by the Group are as follows:

Closing	Number of shares	%
December 31, 2008	10,014,971	0.76%
December 31, 2007	37,725,706	2.76%
December 31, 2006	8,940,598	0.66%
January 1, 2006	58,211,254	4.15%

Treasury shares are deducted from shareholders' equity. Gains and losses on disposals of treasury shares are taken directly to equity and not recognized in net income for the period.

Movements in the share capital of the sanofi-aventis parent company over the last three years are presented below:

Date	Transaction	Number of shares	Share capital	( million) Additional paid-in capital
January 1, 2006		1,401,306,569	2,803	11,147

Edgar Filing: SANOFI-AVENTIS - Form 20-F

During 2006	Capital increase by exercise of stock subscription options	6,022,984	12	295
Board meeting of February 23, 2006	Capital reduction by cancellation of treasury shares	(48,013,520)	(96)	(2,308)
Shareholders meeting of May 31, 2006	Capital increase on merger of Rhône Cooper into sanofi-aventis	118,650		4
<b>December 31, 2006</b>		<b>1,359,434,683</b>	<b>2,719</b>	<b>9,138</b>
During 2007	Capital increase by exercise of stock subscription options	4,950,010	10	201
Shareholders meeting of May 31, 2007	Capital increase reserved for employees	1,531,951	3	71
<b>December 31, 2007</b>		<b>1,365,916,644</b>	<b>2,732</b>	<b>9,410</b>
During 2008	Capital increase by exercise of stock subscription options	1,046,238	2	37
Board meeting of April 29, 2008	Capital reduction by cancellation of treasury shares	(51,437,419)	(103)	(2,843)
<b>December 31, 2008</b>		<b>1,315,525,463</b>	<b>2,631</b>	<b>6,604</b>

F-46

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Year ended December 31, 2008

**D.15.2. Consolidated statements of changes in equity**

( million)	Share capital	Additional paid-in capital and retained earnings	Treasury shares	Stock options	Other items recognized directly in equity	Cumulative translation difference	Attributable to equity holders of the Company	Attributable to minority interests	Total equity
<b>Balance at January 1, 2006</b>	<b>2,803</b>	<b>44,413</b>	<b>(3,253)</b>	<b>1,248</b>	<b>(408)</b>	<b>1,325</b>	<b>46,128</b>	<b>189</b>	<b>46,317</b>
Income/(expense) recognized directly in equity					216	(3,194)	(2,978)	(3)	(2,981)
Net income for the period		4,006					4,006	393	4,399
<b>Total recognized income/(expense) for the period</b>		<b>4,006</b>			<b>216</b>	<b>(3,194)</b>	<b>1,028</b>	<b>390</b>	<b>1,418</b>
Dividend paid out of 2005 earnings ( 1.52 per share)		(2,042)					(2,042)		(2,042)
Payment of dividends and equivalents to minority shareholders								(345)	(345)
Share-based payment:									
Exercise of stock options	12	295					307		307
Proceeds from sale of treasury shares on exercise of stock options				50			50		50
Cancellation of Aventis warrants		(6)		6					
Value of services obtained from employees				149			149		149
Tax effect of exercise of stock options					(28)		(28)		(28)
Rhône Cooper merger premium		8					8		8
Reduction in share capital	(96)	(2,609)	2,705						
Buyout of minority shareholders								(8)	(8)
Other movements								(6)	(6)
<b>Balance at December 31, 2006</b>	<b>2,719</b>	<b>44,065</b>	<b>(492)</b>	<b>1,369</b>	<b>(192)</b>	<b>(1,869)</b>	<b>45,600</b>	<b>220</b>	<b>45,820</b>
Income/(expense) recognized directly in equity					165	(2,762)	(2,597)	(1)	(2,598)
Net income for the period		5,263					5,263	419	5,682
<b>Total recognized income/(expense) for the period</b>		<b>5,263</b>			<b>165</b>	<b>(2,762)</b>	<b>2,666</b>	<b>418</b>	<b>3,084</b>
Dividend paid out of 2006 earnings ( 1.75 per share)		(2,364)					(2,364)		(2,364)
Payment of dividends and equivalents to minority shareholders								(459)	(459)
Share repurchase program			(1,806)				(1,806)		(1,806)
Share-based payment:									
Exercise of stock options	10	201					211		211

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Proceeds from sale of treasury shares on exercise of stock options			23				23		23
Value of services obtained from employees			115				115		115
Tax effect of exercise of stock options			(16)				(16)		(16)
Capital increase reserved for employees (excluding stock option plans)	3	92 <sup>(1)</sup>					95		95
Buyout of minority shareholders								(2)	(2)
Other movements			18				18		18
<b>Balance at December 31, 2007</b>	<b>2,732</b>	<b>47,275</b>	<b>(2,275)</b>	<b>1,468</b>	<b>(27)</b>	<b>(4,631)</b>	<b>44,542</b>	<b>177</b>	<b>44,719</b>
Income/(expense) recognized directly in equity					(723)	962	239	(16)	223
Net income for the period		3,851					3,851	441	4,292
<b>Total recognized income/(expense) for the period</b>		<b>3,851</b>			<b>(723)</b>	<b>962</b>	<b>4,090</b>	<b>425</b>	<b>4,515</b>
Dividend paid out of 2007 earnings ( 2.07 per share)		(2,702)					(2,702)		(2,702)
Payment of dividends and equivalents to minority shareholders								(397)	(397)
Share repurchase program			(1,227)				(1,227)		(1,227)
Reduction in share capital <sup>(2)</sup>	(103)	(2,843)	2,946						
Share-based payment:									
Exercise of stock options	2	37					39		39
Proceeds from sale of treasury shares on exercise of stock options			4				4		4
Value of services obtained from employees			125				125		125
Tax effect of exercise of stock options			(12)				(12)		(12)
Other movements		7					7		7
<b>Balance at December 31, 2008</b>	<b>2,631</b>	<b>45,625</b>	<b>(552)</b>	<b>1,581</b>	<b>(750)</b>	<b>(3,669)</b>	<b>44,866</b>	<b>205</b>	<b>45,071</b>

(1) Includes discount of 21 million in 2007 (see Note D.15.3.)

(2) See Note D.15.5.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

**D.15.3. Capital increase reserved for employees (employee share ownership plan)**

At its meeting of October 30, 2007, the Board of Directors used the authorization granted by the Shareholders Annual General Meeting of May 31, 2007 to launch an employee share ownership plan by carrying out a share issue reserved for employees. The plan involved the issuance of a maximum of 6.8 million shares, ranking for dividend from January 1, 2007 and priced at 48.55 per share. The subscription period was from November 19, 2007 through November 30, 2007, and a total of 1,531,951 shares were subscribed. An expense of 21 million was recognized in respect of this share issue in the income statement for the year ended December 31, 2007.

There were no share issues reserved for employees in either 2008 or 2006.

**D.15.4. Repurchase of sanofi-aventis shares**

The Shareholders Annual General Meeting of May 31, 2007 authorized a share repurchase program for a period of 18 months. Under this program, sanofi-aventis repurchased 23,052,169 of its own shares in the period from January 1, 2008 through May 14, 2008 for a total of 1,191 million (including transaction costs). Under the same program, sanofi-aventis had previously acquired 29,366,500 of its own shares during the second half of 2007 for a total of 1,806 million (including transaction costs). The Board of Directors meeting of April 29, 2008 decided to cancel 51,407,169 shares.

The Shareholders Annual General Meeting of May 14, 2008 authorized a further share repurchase program. Under this new program, sanofi-aventis acquired 810,000 of its own shares during the period from June 6, 2008 through August 21, 2008 for a total of 36 million (including transaction costs).

During 2006, sanofi-aventis did not repurchase any of its own shares under the share repurchase programs authorized by the Shareholders Annual General Meetings of May 31, 2005 and May 31, 2006.

**D.15.5. Reduction in share capital**

The Board of Directors meeting of April 29, 2008 decided to cancel 51,437,419 treasury shares ( 2,946 million), of which 51,407,169 had been repurchased through April 14, 2008 under the share repurchase program, representing 3.77% of the share capital as of that date; see Note D.15.4.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

The Board of Directors meeting of February 23, 2006 decided to cancel 48,013,520 treasury shares representing 3.42% of the share capital as of that date. The same meeting also decided to cancel 257,248.50 warrants (acquired as part of the public offer for Aventis) giving entitlement to subscribe for 301,986 sanofi-aventis shares.

These cancellations had no effect on consolidated shareholders equity.

### D.15.6. Cumulative translation differences

Cumulative translation differences break down as follows:

<i>( million)</i>	December 31, 2008	December 31, 2007	December 31, 2006
Attributable to equity holders of the Company	(3,669)	(4,631)	(1,869)
Attributable to minority interests	(16)	(2)	
<b>Total</b>	<b>(3,685)</b>	<b>(4,633)</b>	<b>(1,869)</b>

The movement in cumulative translation differences during the period was mainly due to the effect of changes in the U.S. dollar exchange rate, primarily on goodwill, intangible assets and deferred taxes.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

In accordance with the accounting policy described in Note B.8.4., cumulative translation differences attributable to equity holders of the Company include the post-tax effect of currency hedges of net investments in foreign operations, totaling 98 million at December 31, 2008; this amount is unchanged from December 31, 2007 and December 31, 2006.

**D.15.7. Other items recognized directly in equity**

Movements in other items recognized directly in equity break down as follows:

<i>( million)</i>	Year ended December 31, 2008	Year ended December 31, 2007	Year ended December 31, 2006
<b>Balance, beginning of period</b>	<b>(26)</b>	<b>(192)</b>	<b>(408)</b>
Available-for-sale financial assets:			
Change in fair value	(132) <sup>(1)</sup>	(5)	(27)
Deferred taxes on these changes in fair value	33	(10)	(7)
Derivatives designated as hedging instruments:			
Change in fair value, other than on derivatives relating to held-for-sale assets (see Note D.20.1.b) and c))	104 <sub>(2)</sub>	8	50
Change in fair value of derivatives relating to held-for-sale assets (Exubera <sup>®</sup> )			7
Deferred taxes on these changes	(37)	(3)	(20)
Actuarial gains and losses and impact of asset ceiling:			
Asset ceiling	2	(6)	
Actuarial gains/(losses) excluding associates and joint ventures (see Note D.18.1.)	(824)	282	354
Actuarial gains/(losses) in associates and joint ventures	(7)	6	(8)
Deferred taxes on actuarial gains and losses	136	(106)	(133)
<b>Balance, end of period</b>	<b>(751)</b>	<b>(26)</b>	<b>(192)</b>

(1) Includes matching entries for changes recognized in the income statement of (11) million. (2007: 11 million; 2006: (98) million, of which (101) million relates to the gain on the sale of the investment in Rhodia).

(2) Includes matching entries for changes recognized in the income statement of (9) million in operating income and (17) million in financial income/expense. (2007: (7) million in operating income and (8) million in financial income/expense; 2006: 5 million in operating income and 3 million in financial income/expense).

**D.15.8. Share-based payment**

**Stock option plans and share warrants**

**a) Assumption by sanofi-aventis of the obligations of Aventis**

*Stock subscription option plans*

With effect from December 31, 2004, sanofi-aventis substituted for Aventis in all the rights and obligations of the issuer in respect of stock subscription options granted to employees and former corporate officers of Aventis and of related companies (as defined in article L.225-180 of the Commercial Code) and not exercised as of that date.



**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

With effect from December 31, 2004, stock subscription options granted by Aventis and not yet exercised may be exercised in sanofi-aventis shares on the same terms, subject to the adjustments described below. The number and subscription price of the optioned shares have been adjusted to reflect the share exchange ratio applicable to Aventis shareholders, subject to possible further adjustment in the event of future capital transactions. The new terms for the exercise of options, subject to future financial adjustments, are as follows:

The number of sanofi-aventis shares for which each grantee may subscribe under a given stock option plan equals the number of Aventis shares to which the grantee may subscribe under that plan multiplied by the exchange ratio applicable to the shareholders (i.e. 27/23), rounded down to the nearest whole number.

The subscription price per sanofi-aventis share equals the subscription price per Aventis share divided by the exchange ratio applicable to the shareholders (i.e. 27/23), rounded down to the nearest euro cent.

*Stock purchase option plans*

In the case of stock option plans issued by Aventis Inc. and Hoechst AG entitling the grantees to purchase Aventis shares, the plan regulations have been amended in accordance with the principles described above so as to enable the grantees to purchase sanofi-aventis shares. The other terms of exercise are unchanged.

*Share warrants*

Under two capital increases reserved for Aventis Group employees belonging to the Aventis Group employee savings plan, carried out in September 2002 ( Plan Horizon 2002 ) and December 2003 ( Plan Horizon 2003 ), Aventis issued, to certain German employees of the Aventis Group, shares accompanied by warrants giving entitlement to subscribe for Aventis shares. These shares with warrants attached were subscribed for on behalf of these employees by two dedicated mutual funds, Aventis Deutschland 2002 and Aventis Deutschland 2003 .

Sanofi-aventis acquired the share warrants issued in 2002 and 2003 as part of the public offer for Aventis.

These share warrants were cancelled in 2006 (see Note D.15.5.).

**b) Description of stock option plans**

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

### *2007 stock subscription option plan granted by sanofi-aventis*

On December 13, 2007, the Board of Directors granted 11,988,975 stock subscription options at an exercise price of 62.33 per share.

The vesting period is four years and the plan expires on December 13, 2017.

### *2006 stock subscription option plan granted by sanofi-aventis*

On December 14, 2006, the Board of Directors granted 11,772,050 stock subscription options at an exercise price of 66.91 per share.

The vesting period is four years and the plan expires on December 14, 2016.

### *Stock purchase option plans*

Sanofi and Synthelabo awarded several stock option plans which allow grantees to purchase a fixed number of shares at a pre-determined price over a specified period. Options generally vest two to five years from the date of grant and expire seven to twenty years from the date of grant. Shares acquired under these plans generally may not be disposed of prior to the fifth anniversary of the date of grant.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

The stock option plans allowing grantees to purchase shares in Aventis Inc. (formerly Rhône-Poulenc Rorer Inc.) and issued by that company were bought out or exchanged by that company for options to purchase shares in Rhône-Poulenc S.A. (subsequently Aventis) in October 1997, when the Aventis group bought out the minority shareholders of Aventis Inc.

On the formation of Aventis, grantees of 1998 Hoechst stock purchase options were offered either a cash payment or the possibility of exercising their options or converting them into options to purchase Aventis shares. Grantees of Hoechst 1999 options had their options converted into options to purchase Aventis shares, which in turn were converted into options to purchase sanofi-aventis shares on completion of the merger on December 31, 2004.

Details of the terms of exercise of stock purchase options granted under the various plans are presented below in sanofi-aventis share equivalents. The table shows all sanofi-aventis stock purchase option plans still outstanding or under which options were exercised in the year ended December 31, 2008.

<b>Origin</b>	<b>Date of grant</b>	<b>Options granted</b>	<b>Start date of exercise period</b>	<b>Expiration date</b>	<b>Exercise price ( )</b>	<b>Options outstanding at December 31, 2008</b>
Synthélabo	12/15/1993	364,000	12/15/1998	12/15/2013	6.36	8,000
Synthélabo	10/18/1994	330,200	10/18/1999	10/18/2014	6.01	17,100
Synthélabo	01/12/1996	208,000	01/12/2001	01/12/2016	8.56	19,270
Synthélabo	04/05/1996	228,800	04/05/2001	04/05/2016	10.85	37,420
Synthélabo	10/14/1997	262,080	10/14/2002	10/14/2017	19.73	30,974
Synthélabo	06/25/1998	296,400	06/26/2003	06/25/2018	28.38	30,520
Synthélabo	03/30/1999	716,040	03/31/2004	03/30/2019	38.08	334,820
Aventis (Hoechst AG)	09/07/1999	2,930,799	09/08/2002	09/07/2009	41.25	316,127
Sanofi-Synthélabo	05/24/2000	4,292,000	05/25/2004	05/24/2010	43.25	1,806,908
Sanofi-Synthélabo	05/10/2001	2,936,500	05/11/2005	05/10/2011	64.50	2,557,739
Sanofi-Synthélabo	05/22/2002	3,111,850	05/23/2006	05/22/2012	69.94	2,912,150
<b>Total</b>						<b>8,071,028</b>

Under IFRS, sanofi-aventis shares acquired to cover stock purchase options are deducted from shareholders' equity. The exercise of all outstanding stock purchase options would increase shareholders' equity by 469 million.

*Stock subscription option plans*

Details of the terms of exercise of stock subscription options granted under the various plans are presented below in sanofi-aventis share equivalents. These options have been granted to certain corporate officers and employees of Group companies.



**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

The table shows all sanofi-aventis stock subscription option plans which are still outstanding or for which exercise took place in the year ended December 31, 2008.

<b>Origin</b>	<b>Date of grant</b>	<b>Options granted</b>	<b>Start date of exercise period</b>	<b>Expiration date</b>	<b>Exercise price ( )</b>	<b>Options outstanding at December 31, 2008</b>
Aventis	12/15/1998	6,372,000	01/06/2002	12/15/2008	34.14	
Aventis	12/15/1999	5,910,658	01/06/2003	12/15/2009	50.04	2,634,784
Aventis	05/11/2000	877,766	05/11/2003	05/11/2010	49.65	254,121
Aventis	11/14/2000	13,966,871	11/15/2003	11/14/2010	67.93	10,395,431
Aventis	03/29/2001	612,196	03/30/2004	03/29/2011	68.94	546,756
Aventis	11/07/2001	13,374,051	11/08/2004	11/07/2011	71.39	9,748,054
Aventis	03/06/2002	1,173,913	03/07/2005	03/06/2012	69.82	1,173,906
Aventis	11/12/2002	11,775,414	11/13/2005	11/12/2012	51.34	5,492,136
Aventis	12/02/2003	12,012,414	12/03/2006	12/02/2013	40.48	6,519,744
Sanofi-Synthelabo	12/10/2003	4,217,700	12/11/2007	12/10/2013	55.74	3,877,720
Sanofi-aventis	05/31/2005	15,228,505	06/01/2009	05/31/2015	70.38	13,720,150
Sanofi-aventis	12/14/2006	11,772,050	12/15/2010	12/14/2016	66.91	11,195,460
Sanofi-aventis	12/13/2007	11,988,975	12/14/2011	12/13/2017	62.33	11,675,660
<b>Total</b>						<b>77,233,922</b>

The exercise of all outstanding stock subscription options would increase shareholders' equity by approximately 4,871 million. The exercise of each option results in the issuance of one share.

*Summary of stock option plans*

A summary of stock options outstanding at each balance sheet date, and of changes during the relevant periods, is presented below:

	<b>Number of options</b>	<b>Exercise price Weighted average per share ( )</b>	<b>Total ( million)</b>
Options outstanding at January 1, 2006	79,330,701	59.10	4,688
<i>Of which exercisable</i>	<i>43,860,426</i>	<i>59.60</i>	<i>2,614</i>
Options granted	11,772,050	66.91	788
Options exercised	(7,259,259)	49.56	(360)
Options cancelled <sup>(1)</sup>	(1,230,478)	62.06	(77)

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Options forfeited	(13,354)	18.23	
Options outstanding at December 31, 2006	82,599,660	61.00	5,039
<i>Of which exercisable</i>	<i>50,920,604</i>	<i>58.02</i>	<i>2,954</i>
Options granted	11,988,975	62.33	747
Options exercised	(5,530,880)	42.07	(233)
Options cancelled <sup>(1)</sup>	(712,658)	68.05	(48)
Options forfeited	(69,402)	29.14	(2)
Options outstanding at December 31, 2007	88,275,695	62.34	5,503
<i>Of which exercisable</i>	<i>50,643,150</i>	<i>59.05</i>	<i>2,991</i>
Options exercised	(1,141,554)	36.82	(42)
Options cancelled <sup>(1)</sup>	(1,682,800)	65.51	(110)
Options forfeited	(146,391)	34.14	(5)
Options outstanding at December 31, 2008	85,304,950	62.66	5,345
<i>Of which exercisable</i>	<i>48,713,680</i>	<i>59.59</i>	<i>2,903</i>

<sup>(1)</sup> Cancellations mainly due to the departure of the grantees.

Table of Contents

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## Year ended December 31, 2008

The table below provides summary information about options outstanding and exercisable as of December 31, 2008:

Range of exercise prices per share	Outstanding			Exercisable	
	Number of options	Average residual life (in years)	Weighted average exercise price per share ( )	Number of options	Weighted average exercise price per share ( )
From 1.00 to 10.00 per share	44,370	6.18	7.18	44,370	7.18
From 10.00 to 20.00 per share	68,394	7.96	14.87	68,394	14.87
From 20.00 to 30.00 per share	30,520	9.49	28.38	30,520	28.38
From 30.00 to 40.00 per share	334,820	10.25	38.08	334,820	38.08
From 40.00 to 50.00 per share	8,896,900	3.95	41.33	8,896,900	41.33
From 50.00 to 60.00 per share	12,004,640	3.58	52.48	12,004,640	52.48
From 60.00 to 70.00 per share	40,457,102	5.78	66.02	17,585,982	67.92
From 70.00 to 80.00 per share	23,468,204	4.94	70.80	9,748,054	71.39
<b>Total</b>	<b>85,304,950</b>			<b>48,713,680</b>	

*Measurement of stock option plans*

The fair value of the plan awarded in 2007 is 143 million, and the fair value of the plan awarded in 2006 is 169 million.

The following assumptions were used in determining the fair value of these plans:

Dividend yield: 3.08% (2007 plan), 2.48% (2006 plan).

Residual life: 6 years (2007 and 2006 plans).

Volatility of sanofi-aventis shares, computed on a historical basis: 19.36% (2007 plan), 19.58% (2006 plan).

Risk-free interest rate: 4.21% (2007 plan), 3.74% (2006 plan).

The fair value of the options granted in 2007 and 2006 is 11.92 and 14.35 per option, respectively.

The expense recognized for stock option plans, and the matching entry taken to shareholders' equity, amounted to 125 million in the year ended December 31, 2008 (including 13 million for the Vaccines segment); 115 million in the year ended December 31, 2007 (including 10 million for the Vaccines segment); and 149 million in the year ended December 31, 2006 (including 13 million for the Vaccines segment).

As of December 31, 2008, the total cost related to non-vested share-based compensation arrangements was 193 million, to be recognized over a weighted average period of 2.26 years. The current tax benefit related to share-based compensation arrangements in 2008 amounted to 2 million (2007: 19 million; 2006: 29 million).

**D.15.9. Number of shares used to compute diluted earnings per share**

Diluted earnings per share is computed using the number of shares outstanding plus stock options with a potentially dilutive effect.

<i>(in million)</i>	<b>December 31, 2008</b>	<b>December 31, 2007</b>	<b>December 31, 2006</b>
Average number of shares outstanding	1,309.3	1,346.9	1,346.8
Adjustment for options with potentially dilutive effect	1.6	7.0	12.0
Average number of shares used to compute diluted earnings per share	1,310.9	1,353.9	1,358.8



**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

In 2008, a total of 76.2 million stock options were not taken into account in the calculation because they did not have a potentially dilutive effect, compared with 65.4 million in 2007 and 26.1 million in 2006.

**D.16. Minority interests**

Minority interests in consolidated companies break down as follows:

<i>( million)</i>	December 31, 2008	December 31, 2007	December 31, 2006
Minority interests of ordinary shareholders:			
BMS <sup>(1)</sup>	111	80	127
Aventis Pharma Ltd India	60	64	54
Maphar	6	6	6
Sanofi-aventis Pakistan	5	6	6
Other	23	21	27
<b>Total</b>	<b>205</b>	<b>177</b>	<b>220</b>

(1) Under the terms of the agreements with BMS (see Note C.1.), the BMS share of the net assets of entities majority-owned by sanofi-aventis is recognized in *Minority interests* (refer to the statement of changes in equity in Note D.15.2.).

**D.17. Debt, cash and cash equivalents**

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

<i>( million)</i>	December 31, 2008	December 31, 2007	December 31, 2006
Long-term debt, at amortized cost	4,173	3,734	4,499
Short-term debt and current portion of long-term debt	1,833	2,207	2,445
<b>Total debt</b>	<b>6,006</b>	<b>5,941</b>	<b>6,944</b>
Cash and cash equivalents	(4,226)	(1,711)	(1,153)
<b>Debt, net of cash and cash equivalents</b>	<b>1,780</b>	<b>4,230</b>	<b>5,791</b>

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Debt, net of cash and cash equivalents is a non-GAAP financial indicator used by management and investors to measure the company's overall net indebtedness.

Trends in the gearing ratio are shown below:

( million)	December 31, 2008	December 31, 2007	December 31, 2006
Debt, net of cash and cash equivalents	1,780	4,230	5,791
Total equity	45,071	44,719	45,820
<b>Gearing ratio</b>	<b>3.9%</b>	<b>9.5%</b>	<b>12.6%</b>

A reconciliation of carrying amount to value on redemption is shown below:

( million)	Carrying amount: Dec. 31, 2008	Amortized cost	Adjustment to debt measured at fair value	Dec. 31, 2008	Value on redemption Dec. 31, 2007	Dec. 31, 2006
Long-term debt	4,173	7	(57)	4,123	3,686	4,448
Short-term debt and current portion of long-term debt	1,833		(18)	1,815	2,187	2,425
<b>Total debt</b>	<b>6,006</b>	<b>7</b>	<b>(75)</b>	<b>5,938</b>	<b>5,873</b>	<b>6,873</b>
Cash and cash equivalents	(4,226)			(4,226)	(1,711)	(1,153)
<b>Debt, net of cash and cash equivalents</b>	<b>1,780</b>	<b>7</b>	<b>(75)</b>	<b>1,712</b>	<b>4,162</b>	<b>5,720</b>

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008****a) Principal financing transactions during the year**

The following refinancing transactions took place during 2008:

CHF100 million fixed-rate bond issue, fungible with the initial issue of CHF300 million maturing December 2015, giving a total amount of CHF400 million.

¥15 billion floating-rate bond issue maturing June 2013.

150 million bank loan from the European Investment Bank, maturing February 2013.

108 million fixed-rate and 162 million floating-rate Schuldschein notes issues, both maturing May 2013.

CHF275 million fixed-rate bond issue, maturing December 2012.

One bond issue was repaid on maturity:

December 2006 bond issue with a nominal value of 1,250 million, which matured December 1, 2008.

**b) Debt, net of cash and cash equivalents by type, at value on redemption**

( million)	December 31, 2008			December 31, 2007			December 31, 2006		
	Non-current	Current	Total	Non-current	Current	Total	Non-current	Current	Total
Bond issues	2,418	488	2,906	2,390	1,390	3,780	2,350	1,089	3,439
Credit facility drawdowns	1,000	34	1,034	1,000	1	1,001	1,000	2	1,002
Other bank borrowings	670	262	932	257	266	523	1,055	356	1,411
Commercial paper		717	717		102	102		603	603
Finance lease obligations	21	4	25	25	4	29	29	4	33
Other borrowings	14	11	25	14	1	15	14	1	15
Bank credit balances		299	299		423	423		370	370
<b>Total debt</b>	<b>4,123</b>	<b>1,815</b>	<b>5,938</b>	<b>3,686</b>	<b>2,187</b>	<b>5,873</b>	<b>4,448</b>	<b>2,425</b>	<b>6,873</b>
Cash and cash equivalents		(4,226)	(4,226)		(1,711)	(1,711)		(1,153)	(1,153)

<b>Debt, net of cash and cash equivalents</b>	<b>4,123</b>	<b>(2,411)</b>	<b>1,712</b>	<b>3,686</b>	<b>476</b>	<b>4,162</b>	<b>4,448</b>	<b>1,272</b>	<b>5,720</b>
---	--------------	----------------	--------------	--------------	------------	--------------	--------------	--------------	--------------

The bond issues, quoted on the Luxembourg stock exchange under Euro Medium Term Note (EMTN) documentation, comprise:

1,500 million of bonds issued in September 2003 [ISIN: XS0176128675] and maturing 2010, bearing annual interest of 4.25%.

100 million of bonds issued in December 2006 [ISIN: XS0279336290] and maturing December 2009, bearing floating-rate interest indexed to 3-month Euribor.

£200 million of bonds issued in January 2007 [ISIN: XS0282647634] and maturing January 2010, bearing annual interest of 5.50% and swapped into euros at a floating rate indexed to 3-month Euribor.

¥19.2 billion of bonds issued in July 2007 [ISIN: XS0308471647] and maturing July 2009, bearing annual interest of 0.217% and swapped into euros at a floating rate indexed to 3-month Euribor.

200 million of bonds issued in July 2007 [ISIN: XS0309617578] and maturing July 2009, bearing interest at 3-month Euribor.

CHF200 million of bonds issued in December 2007 [ISIN: CH0035703021] and maturing January 2010, bearing annual interest of 2.75% and swapped into euros at a floating rate indexed to 6-month Euribor.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

CHF400 million of bonds issued in December 2007 and February 2008 [ISIN: CH0035703070] and maturing December 2015, bearing annual interest of 3.375% and swapped into euros at a fixed rate of 4.867%.

¥15 billion of bonds issued in June 2008 and maturing June 2013, bearing annual interest at a floating rate indexed to 3-month JPY-Libor and swapped into euros at a floating rate indexed to 3-month Euribor.

CHF275 million of bonds [ISIN: CH0048787532] issued in December 2008 and maturing December 2012, bearing annual interest of 3.25% and swapped into euros at a fixed rate of 4.894%.

Credit facility drawdowns and commercial paper relate to the following programs and agreements:

A syndicated bank facility of 8 billion, of which 0.3 billion expires in 2011 and 7.7 billion in 2012. As of December 31, 2008, drawdowns under this facility totaled 1 billion.

A syndicated 364-day bank facility, contracted in 2005 for an initial amount of 5 billion, with four 364-day extension options. The final extension option has been exercised, thereby extending the expiry of the facility from January 2009 to January 2010. With effect from January 2009, the amount of this facility will be 3.7 billion, versus 4.1 billion in 2008.

A bilateral 364-day bank facility of \$0.6 billion (0.4 billion) expiring January 2009. This facility was renewed in January 2009, and now expires in January 2010.

These short-term bank facilities, which are confirmed but have not been drawn down, are being used to back two commercial paper programs, of 6 billion in France and \$6 billion in the United States. In 2008, the average drawdown under these programs was 0.4 billion (maximum 0.8 billion). At December 31, 2008, drawdowns under these programs amounted to 0.7 billion.

The financing in place at December 31, 2008 is not subject to covenants regarding financial ratios, and contains no clauses linking credit spreads or fees to the credit rating of sanofi-aventis.

The line Other borrowings mainly includes:

Participating shares issued between 1983 and 1987, of which 96,983 remain outstanding, valued at 14.8 million.

Series A participating shares issued in 1989, of which 3,296 remain outstanding, valued at 0.2 million.

## c) Debt by maturity, at value on redemption

( million)	Total	December 31, 2008					2014 and later
		Current 2009	2010	2011	Non-current 2012 2013		
Bond issues	2,906	488	1,845		185	119	269
Credit facility drawdowns <sup>(1)</sup>	1,034	34			1,000		
Other bank borrowings	932	262	13	7	208	439	3
Commercial paper <sup>(2)</sup>	717	717					
Finance lease obligations	25	4	3	6	2	3	7
Other borrowings	25	11					14
Bank credit balances	299	299					
<b>Total debt</b>	<b>5,938</b>	<b>1,815</b>	<b>1,861</b>	<b>13</b>	<b>1,395</b>	<b>561</b>	<b>293</b>
Cash and cash equivalents	(4,226)	(4,226)					
<b>Debt, net of cash and cash equivalents</b>	<b>1,712</b>	<b>(2,411)</b>	<b>1,861</b>	<b>13</b>	<b>1,395</b>	<b>561</b>	<b>293</b>

(1) Maturities used for credit facility drawdowns are those of the facility, not the drawdown.

(2) Commercial paper had a maturity of no more than three months as of December 31, 2008.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

( million)	Total	Current 2008	December 31, 2007				2013 and later
			2009	2010	2011	2012	
Bond issues <sup>(1)</sup>	<b>3,780</b>	1,390	316	1,894			180
Credit facility drawdowns <sup>(2)</sup>	<b>1,001</b>	1				1,000	
Other bank borrowings	<b>523</b>	266	15	12	9	216	5
Commercial paper	<b>102</b>	102					
Finance lease obligations	<b>29</b>	4	4	3	6	6	6
Other borrowings	<b>15</b>	1					14
Bank credit balances	<b>423</b>	423					
<b>Total debt</b>	<b>5,873</b>	<b>2,187</b>	<b>335</b>	<b>1,909</b>	<b>15</b>	<b>1,222</b>	<b>205</b>
Cash and cash equivalents	<b>(1,711)</b>	(1,711)					
<b>Debt, net of cash and cash equivalents</b>	<b>4,162</b>	<b>476</b>	<b>335</b>	<b>1,909</b>	<b>15</b>	<b>1,222</b>	<b>205</b>

(1) The maturity used for the 100 million bond issue is the date of the bondholders' first early redemption option (June 2008).

(2) Maturities used for credit facility drawdowns are those of the facility, not the drawdown.

( million)	Total	Current 2007	December 31, 2006				2012 and later
			2008	2009	2010	2011	
Bond issues <sup>(1)</sup>	<b>3,439</b>	1,089	850		1,500		
Credit facility drawdowns <sup>(2)</sup>	<b>1,002</b>	2					1,000
Other bank borrowings	<b>1,411</b>	356	1,014	12	21	3	5
Commercial paper	<b>603</b>	603					
Finance lease obligations	<b>33</b>	4	4	4	3	6	12
Other borrowings	<b>15</b>	1					14
Bank credit balances	<b>370</b>	370					
<b>Total debt</b>	<b>6,873</b>	<b>2,425</b>	<b>1,868</b>	<b>16</b>	<b>1,524</b>	<b>9</b>	<b>1,031</b>
Cash and cash equivalents	<b>(1,153)</b>	(1,153)					
<b>Debt, net of cash and cash equivalents</b>	<b>5,720</b>	<b>1,272</b>	<b>1,868</b>	<b>16</b>	<b>1,524</b>	<b>9</b>	<b>1,031</b>

(1) The maturity used for the 100 million bond issue is the date of the bondholders' first early redemption option (June 2008).

(2) Maturities used for credit facility drawdowns are those of the facility, not the drawdown.

The main undrawn confirmed credit facilities that were not allocated to outstanding commercial paper drawdowns at December 31, 2008 break down as follows:

Year of expiry	Undrawn confirmed credit facilities available ( million)
January 2009	68
2010	3,700
2011	327
2012	6,673
<b>Total</b>	<b>10,768</b>

Confirmed credit facilities mainly include:

8 billion syndicated credit facility expiring in 2011 ( 0.3 billion, undrawn) and in 2012 ( 7.7 billion, of which 1 billion was drawn down at December 31, 2008 and 6.7 billion was undrawn).

Confirmed bank facilities available for backing commercial paper programs (of which 3.8 billion was not being used to back commercial paper programs at December 31, 2008). The Group also has 0.7 billion of undrawn confirmed bank facilities that were being used to back outstanding U.S. commercial paper programs at December 31, 2008.



**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

As of December 31, 2008, no single counterparty represented more than 11% of undrawn confirmed credit facilities.

**d) Debt by interest rate type, at value on redemption**

The tables below split total debt, net of cash and cash equivalents between fixed and floating rate, and by maturity or contractual repricing date, at December 31, 2008. The figures shown are the value on redemption, before the effects of derivative instruments:

( million)	December 31, 2008						2014 and later
	Total	2009	2010	2011	2012	2013	
Fixed-rate	2,909	152	1,845		385	258	269
<i>% fixed-rate</i>	<b>49%</b>						
Floating-rate (maturity based on contractual repricing date)	3,029	1,663	16	13	1,010	303	24
<i>% floating-rate</i>	<b>51%</b>						
<b>Debt</b>	<b>5,938</b>	<b>1,815</b>	<b>1,861</b>	<b>13</b>	<b>1,395</b>	<b>561</b>	<b>293</b>
Cash and cash equivalents	(4,226)	(4,226)					
<i>% floating-rate</i>	<b>100%</b>						
<b>Debt, net of cash and cash equivalents</b>	<b>1,712</b>	<b>(2,411)</b>	<b>1,861</b>	<b>13</b>	<b>1,395</b>	<b>561</b>	<b>293</b>

Floating-rate interest on debt is usually indexed to the euro zone interbank offered rate (Euribor). Floating-rate interest on cash and cash equivalents is usually indexed to the EONIA rate.

In order to reduce the amount and volatility of the cost of debt, sanofi-aventis has contracted derivative instruments (swaps, and in some cases caps or combinations of purchases of caps and sales of floors). This has the effect of altering the fixed/floating split and the maturity based on contractual repricing dates:

( million)	December 31, 2008						2014 and later
	Total	2009	2010	2011	2012	2013	
Fixed-rate	3,412		1,500		1,385	258	269
<i>% fixed-rate</i>	<b>57%</b>						
Floating-rate	2,526	1,815	361	13	10	303	24
<i>% floating-rate</i>	<b>43%</b>						

Edgar Filing: SANOFI-AVENTIS - Form 20-F

<b>Debt</b>	<b>5,938</b>	<b>1,815</b>	<b>1,861</b>	<b>13</b>	<b>1,395</b>	<b>561</b>	<b>293</b>
Cash and cash equivalents	(4,226)	(4,226)					
<i>% floating-rate</i>	<i>100%</i>						
<b>Debt, net of cash and cash equivalents</b>	<b>1,712</b>	<b>(2,411)</b>	<b>1,861</b>	<b>13</b>	<b>1,395</b>	<b>561</b>	<b>293</b>

The table below shows the fixed/floating rate split at redemption value after taking account of derivative instruments at December 31, 2007 and December 31, 2006:

<i>( million)</i>	<b>2007</b>	<i>%</i>	<b>2006</b>	<i>%</i>
Fixed-rate	2,892	49%	2,500	36%
Capped-rate			750	11%
Floating-rate	2,981	51%	3,623	53%
<b>Debt</b>	<b>5,873</b>	<b>100%</b>	<b>6,873</b>	<b>100%</b>
Cash and cash equivalents	(1,711)		(1,153)	
<b>Debt, net of cash and cash equivalents</b>	<b>4,162</b>		<b>5,720</b>	

F-58

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

The weighted average interest rate on debt at December 31, 2008 was 4.33% before derivative instruments and 4.46% after derivative instruments. All cash and cash equivalents were invested at an average rate of 3.28% at December 31, 2008.

Based on the Group's level of debt, and taking account of derivative instruments in place at December 31, 2008, the sensitivity of pre-tax net income and equity in 2009 to movements in market interest rates (mostly 3-month Euribor) affecting the entire year is as follows:

Change in 3-month Euribor interest rate assumptions	Impact on pre-tax net income ( million)	Impact on income/(expense) recognized directly in equity, before tax ( million)
+ 100 bp	(17)	14
+ 25 bp	(4)	4
- 25 bp	4	(4)
- 100 bp	17	(15)

**e) Debt, net of cash and cash equivalents by currency, at value on redemption**

The table below shows debt, net of cash and cash equivalents by currency at December 31, 2008, before and after taking account of derivative instruments contracted to convert third-party debt into the functional currency of the borrower entity:

( million)	December 31, 2008	
	Before derivative instruments	After derivative instruments
EUR	(184)	1,603
CHF	587	(2)
GBP	146	(64)
USD	698	(19)
JPY	273	2
Other currencies	192	192
<b>Debt, net of cash and cash equivalents</b>	<b>1,712</b>	<b>1,712</b>

The table below shows debt, net of cash and cash equivalents by currency at December 31, 2007 and 2006, after taking account of derivative instruments contracted to convert third-party debt into the functional currency of the borrower entity:

( million)	2007	2006
------------	------	------

EUR	4,192	5,563
USD	78	17
Other currencies	(108)	140
<b>Debt, net of cash and cash equivalents</b>	<b>4,162</b>	<b>5,720</b>

**f) Market value of debt, net of cash and cash equivalents**

The market value of debt, net of cash and cash equivalents (excluding derivative instruments) at December 31, 2008 was 1,779 million (December 31, 2007: 4,162 million; December 31, 2006: 5,741 million), versus a value on redemption of 1,712 million (December 31, 2007: 4,162 million; December 31, 2006: 5,720 million).

Derivative instruments contracted for debt management purposes had a positive fair value of 18 million at December 31, 2008, compared with a positive fair value of 29 million at December 31, 2007 and 40 million at December 31, 2006 (see Note D.20.).

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008****g) Future contractual cash flows relating to debt and debt hedging instruments**

The table below shows the amount of future contractual undiscounted cash flows (principal and interest) relating to debt and to derivative instruments designated as hedges of debt as at December 31, 2008:

( million)	December 31, 2008						
	Contractual cash flows by maturity						
	Total	2009	2010	2011	2012	2013	2014 and later
<b>Debt</b>	<b>6,468</b>	<b>1,957</b>	<b>2,004</b>	<b>88</b>	<b>1,470</b>	<b>591</b>	<b>358</b>
principal	5,921	1,784	1,851	6	1,407	562	311
interest <sup>(1)</sup>	547	173	153	82	63	29	47
<b>Net cash flows related to derivative instruments</b>	<b>16</b>	<b>17</b>	<b>77</b>	<b>7</b>	<b>(9)</b>	<b>(35)</b>	<b>(41)</b>
<b>Total</b>	<b>6,484</b>	<b>1,974</b>	<b>2,081</b>	<b>95</b>	<b>1,461</b>	<b>556</b>	<b>317</b>

(1) Interest cash flows are estimated on the basis of forward interest rates applicable as of December 31, 2008.

Future contractual cash flows are shown on the basis of the carrying amount in the balance sheet at the reporting date, without reference to any subsequent management decision that might materially alter the structure of the Group's debt or its hedging policy.

Maturities used for credit facility drawdowns are those of the facility, not the drawdown.

The table below shows the amount of future contractual undiscounted cash flows (principal and interest) relating to debt and to derivative instruments designated as hedges of debt as at December 31, 2007 and 2006:

( million)	December 31, 2007						
	Contractual cash flows by maturity						
	Total	2008	2009	2010	2011	2012	2013 and later
<b>Debt</b>	<b>6,509</b>	<b>2,376</b>	<b>488</b>	<b>2,056</b>	<b>80</b>	<b>1,252</b>	<b>257</b>
principal	5,831	2,145	335	1,909	15	1,222	205
interest	678	231	153	147	65	30	52
<b>Net cash flows related to derivative instruments</b>	<b>(4)</b>	<b>(5)</b>	<b>(3)</b>	<b>5</b>	<b>(11)</b>	<b>(1)</b>	<b>11</b>
<b>Total</b>	<b>6,505</b>	<b>2,371</b>	<b>485</b>	<b>2,061</b>	<b>69</b>	<b>1,251</b>	<b>268</b>

<i>( million)</i>	December 31, 2006						
	Contractual cash flows by maturity						
	Total	2007	2008	2009	2010	2011	2012 and later
<b>Debt</b>	<b>7,528</b>	<b>2,615</b>	<b>2,023</b>	<b>126</b>	<b>1,633</b>	<b>54</b>	<b>1,077</b>
principal	6,849	2,399	1,868	16	1,524	10	1,032
interest	679	216	155	110	109	44	45
<b>Net cash flows related to derivative instruments</b>	<b>(45)</b>	<b>(6)</b>	<b>(10)</b>	<b>(9)</b>	<b>(9)</b>	<b>(9)</b>	<b>(2)</b>
<b>Total</b>	<b>7,483</b>	<b>2,609</b>	<b>2,013</b>	<b>117</b>	<b>1,624</b>	<b>45</b>	<b>1,075</b>

F-60

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Year ended December 31, 2008

**D.18. Provisions and other non-current liabilities**

Provisions and other non-current liabilities break down as follows:

( million)	Provisions for pensions and other long-term benefits (D.18.1.)	Restructuring provisions (D.18.2.)	Other provisions (D.18.3.)	Other non-current liabilities	Total
<b>January 1, 2006</b>	<b>4,259</b>	<b>151</b>	<b>3,426</b>	<b>414</b>	<b>8,250</b>
Changes in scope of consolidation	(2)		1		(1)
Charged during the period	348	98	931	22	1,399
Provisions utilized	(414)	(54)	(240)	(53)	(761)
Reversals of unutilized provisions <sup>(3)</sup>	(27)	(11)	(440)		(478)
Transfers <sup>(1)</sup>	94	35	(46)	(47)	36
Unwinding of discount		1	31	6	38
Unrealized gains and losses				(6)	(6)
Translation differences	(66)	(2)	(109)	(27)	(204)
Actuarial gains/losses on defined-benefit plans	(353)				(353)
<b>December 31, 2006</b>	<b>3,839</b>	<b>218</b>	<b>3,554</b>	<b>309</b>	<b>7,920</b>
Changes in scope of consolidation			1		1
Charged during the period	346	64	670		1,080
Provisions utilized <sup>(4)</sup>	(401)	(26)	(171)	(186)	(784)
Reversals of unutilized provisions <sup>(3)</sup>	(14)	(12)	(614)		(640)
Transfers <sup>(1)</sup>	(1)	(54)	(285)	35	(305)
Unwinding of discount			35	4	39
Unrealized gains and losses				(6)	(6)
Translation differences	(94)	(2)	(64)	(11)	(171)
Actuarial gains/losses on defined-benefit plans	(277)				(277)
<b>December 31, 2007</b>	<b>3,398</b>	<b>188</b>	<b>3,126</b>	<b>145</b>	<b>6,857</b>
Changes in scope of consolidation			33		33
Charged during the period	334	290	828 <sup>(2)</sup>		1,452
Provisions utilized	(365)	(33)	(223)	(3)	(624)
Reversals of unutilized provisions <sup>(3)</sup>	(65)		(531)		(596)
Transfers <sup>(1)</sup>	1	(84)	(176)	51	(208)
Unwinding of discount		5	31	1	37
Unrealized gains and losses				14 <sup>(5)</sup>	14
Translation differences	(59)		(4)	4	(59)
Actuarial gains/losses on defined-benefit plans	824				824

Edgar Filing: SANOFI-AVENTIS - Form 20-F

<b>December 31, 2008</b>	<b>4,068</b>	<b>366</b>	<b>3,084</b>	<b>212</b>	<b>7,730</b>
--------------------------	--------------	------------	--------------	------------	--------------

- (1) This line includes transfers between current and non-current provisions.
- (2) Amounts charged during the period mainly comprise provisions to cover tax exposures in various countries and changes to estimates of future expenditure on environmental risks, including risks relating to sites formerly operated by sanofi-aventis or sold to third parties (see Note D.26.).
- (3) Reversals of unutilized provisions:  
  - Reversals of unutilized provisions for pensions and other long-term benefits are due to the effect of plan curtailments (see Note D.18.1.). In both 2008 and 2007, plan curtailments related mainly to early retirement programs in France.
  - Reversals of other provisions relate mainly to provisions for tax exposures, reversed either because (i) the risk exposure became time-barred during the reporting period or (ii) the tax dispute was settled during the period and the outcome proved more favorable than expected for sanofi-aventis.
- (4) Provisions utilized:  
  - In other non-current liabilities for 2007, this relates to settlement of the Carderm liability for 184 million. On June 28, 2001, a financial investor paid \$250 million to acquire preferred shares in Carderm Capital LP (Carderm), which owned certain assets of Aventis Pharma U.S. Sanofi-aventis had an option to repurchase these preferred shares on or after March 10, 2007. In accordance with the terms of the agreement, the preferred shares were repurchased in June 2007 for \$250 million.
- (5) Remeasurement of interest rate derivatives recognized in equity.

F-61



**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008****D.18.1. Provisions for pensions and other benefits**

The Group and its subsidiaries have a significant number of pension plans covering the majority of their employees. The specific features (benefit formulas, funding policies and types of assets held) of the plans vary depending on laws and regulations in the particular country in which the employees work. Several of these plans are defined benefit plans and cover certain members of the Board of Directors as well as employees.

Actuarial valuations of the Group's benefit obligations were computed by external actuaries as of December 31, 2008, 2007 and 2006. The calculations incorporate the following:

Assumptions on staff turnover and life expectancy, specific to each country.

A retirement age of 60 to 65 for a total working life allowing for full rate retirement rights for employees of French companies, and retirement assumptions reflecting local economic and demographic factors specific to employees of foreign companies.

A salary inflation rate for the principal countries ranging from 3% to 5% at December 31, 2008, from 2.75% to 5% at December 31, 2007, and from 2.75% to 5.6% at December 31, 2006.

An annuity inflation rate for the principal countries ranging from 2% to 3% at December 31, 2008, from 2% to 4% at December 31, 2007, and from 2% to 3% at December 31, 2006.

A weighted average long-term healthcare cost inflation rate of 4.53% at December 31, 2008, 4.49% at December 31, 2007, and 4.82% at December 31, 2006, applied to post-employment benefits.

Discount rates used to determine the present value of defined benefit obligations at the balance sheet date, as shown in the table below:

Discount rate	Pensions and other long-term benefits			Other post-employment benefits		
	2008	Year ended December 31, 2007	2006	2008	Year ended December 31, 2007	2006
Weighted average for all regions:	5.98%	5.42%	4.80%	6.01%	5.93%	5.62%
- Euro zone	5.75% or 6% <sup>(1)</sup>	5% or 5.25%	4.25% or 4.50%	6%	5.25%	4.50%
- United States	6%	6%	5.75%	6%	6%	5.75%
- United Kingdom	6.5%	5.75%	5%	6.5%	5.75%	5%

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

<sup>(1)</sup> Depends on the term of the plan: 5.75% medium-term, 6% long-term.

The discount rates used are based on market rates for high quality corporate bonds (AA) the term of which approximates that of the expected benefit payments of the plans. The principal benchmark indices used are the Iboxx Corporate index for the euro zone, the Iboxx Corporate £ index for the United Kingdom, and the Citigroup Pension Liability Index for the United States. Rates fluctuated significantly during 2008. Sanofi-aventis restated the Iboxx rates as of December 31, 2008 to adjust for the overweighting of financial sector issuers in these indices and thereby approximate the effect of the corrections made to exclude some financial sector issuers from the benchmark index at the start of 2009. In the case of the United States, the composition of the benchmark index (the Citigroup Pension Liability Index) was corrected during December 2008, so sanofi-aventis was able to use the benchmark without adjustment.

F-62

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

Sensitivity analysis of pension plans and other post-employment benefits in the principal countries shows that a 0.5% reduction in the discount rate would increase the Group's obligation by approximately 400 million, of which approximately 110 million would relate to the United Kingdom and 80 million to the United States.

Expected long-term rates of return for plan assets which (depending on the company) range from 2.5% to 13.5% for the year to December 31, 2008, 2.5% to 12% for the year to December 31, 2007, and 2% to 11.5% for the year to December 31, 2006. The majority of fund assets are invested in Germany, the United States and the United Kingdom. The long-term rates of return used are as follows:

Expected long-term rate of return on plan assets	Pensions and other long-term benefits			Other post-employment benefits		
	Year ended December 31,			Year ended December 31,		
	2008	2007	2006	2008	2007	2006
Weighted average for all regions	6.97%	7.01%	6.67%	8%	8%	7.75%
- Germany	6.75%	7%	6.50%			
- United States	8%	8%	7.75%	8%	8%	7.75%
- United Kingdom	7%	6.75%	6.55%			

The average long-term rate of return on plan assets was determined on the basis of actual long-term rates of return in the financial markets. These returns vary according to the asset category (equities, bonds, real estate, other). As a general rule, sanofi-aventis applies the risk premium concept in assessing the return on equities relative to bond yields.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

The table below reconciles the net obligation in respect of the Group's pension plans and other employee benefits with the amounts recognized in the consolidated financial statements:

( million)	Pensions and other long-term benefits			Other post-employment benefits (healthcare cover)		
	2008	2007	2006	2008	2007	2006
<b>Valuation of obligation:</b>						
Beginning of period	8,481	9,187	9,425	339	321	224
Service cost	228	236	276	12	13	16
Contributions from plan members	4	6	9			
Interest cost	435	414	407	19	18	17
Actuarial (gain)/loss	(579)	(437)	(172)	5	(12)	(2)
Plan amendments	71	(24)	(11)		45	(2)
Translation differences	(336)	(326)	(179)	8	(29)	(34)
Plan curtailments/settlements	(68)	(51)	(23)			
Changes in scope of consolidation, transfers	34	(5)	(44)	2		122
Benefits paid	(528)	(519)	(501)	(17)	(17)	(20)
<b>Obligation at end of period</b>	<b>7,742</b>	<b>8,481</b>	<b>9,187</b>	<b>368</b>	<b>339</b>	<b>321</b>
<b>Fair value of plan assets:</b>						
Beginning of period	5,362	5,575	5,350	51	56	
Expected return on plan assets <sup>(1)</sup>	362	366	343	4	4	4
Difference between actual and expected return on plan assets	(1,348)	(161)	189	(12)	1	2
Translation differences	(270)	(257)	(129)	2	(6)	(6)
Contributions from plan members	4	6	9			
Employer's contributions	175	146	274			
Plan settlements	(2)	(39)				
Changes in scope of consolidation, transfers	25		(83)			60
Benefits paid	(351)	(274)	(378)	(4)	(4)	(4)
<b>Fair value of plan assets at end of period</b>	<b>3,957</b>	<b>5,362</b>	<b>5,575</b>	<b>41</b>	<b>51</b>	<b>56</b>
<b>Net amount shown in the balance sheet:</b>						
Net obligation	3,785	3,119	3,612	327	288	265
Unrecognized past service cost	(55)	(28)	(60)	6	6	19
Effect of asset ceiling	4	6				
<b>Net amount shown in the balance sheet</b>	<b>3,734</b>	<b>3,097</b>	<b>3,552</b>	<b>333</b>	<b>294</b>	<b>284</b>
<b>Amounts recognized in the balance sheet:</b>						
Pre-funded obligations (see Note D.7.)	(1)	(7)	(3)			
Obligations provided for <sup>(2)</sup>	3,735	3,104	3,555	333	294	284
<b>Net amount recognized</b>	<b>3,734</b>	<b>3,097</b>	<b>3,552</b>	<b>333</b>	<b>294</b>	<b>284</b>
<b>Benefit cost for the period:</b>						
Service cost	228	236	276	12	13	16

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Interest cost	435	414	407	19	18	17
Expected return on plan assets	(362)	(366)	(343)	(4)	(4)	(4)
Amortization of past service cost	42	9	(10)		34	(2)
Recognition of actuarial (gains)/losses	(38)	(8)	(9)			
Effect of plan settlements	(38)	(9)				
Effect of plan curtailments	(27)	(3)	(27)			
<b>Benefit cost for the period</b>	<b>240</b>	<b>273</b>	<b>294</b>	<b>27</b>	<b>61</b>	<b>27</b>

- (1) Given the fall in the market value of plan assets at the end of 2008, the expected return on plan assets for 2009 is estimated at 272 million.
- (2) Long-term benefits awarded to employees prior to retirement (mainly discretionary bonuses, long service awards and deferred compensation plans) accounted for 346 million of these obligations at December 31, 2008, 367 million at December 31, 2007, and 379 million at December 31, 2006 (including 101 million transferred from other current liabilities to long-term benefits in 2006). The expense associated with these obligations totaled 31 million in 2008, 44 million in 2007 and 52 million in 2006.

F-64

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

Actuarial gains and losses on pensions and other post-employment benefits break down as follows:

( million)	2008	2007	2006
Actuarial gain/(loss) arising during the period	(786) <sup>(1)</sup>	289	359
Comprising:			
gain/(loss) on experience adjustments	(1,326)	(135)	126
gain/(loss) on changes in assumptions <sup>(2)</sup>	540	424	233
Breakdown of experience adjustments:			
gain/(loss) on plan assets <sup>(3)</sup>	(1,360)	(160)	191
gain/(loss) on obligations	34	25	(65)
Amount of obligations at the balance sheet date	8,110	8,820	9,508
Fair value of plan assets at the balance sheet date	3,998	5,413	5,631

(1) Comprises a loss of 824 million recognized in equity (see Note D.15.7.) and a gain of 38 million taken directly to the income statement.

(2) Changes in assumptions mainly relate to changes in the discount rate.

(3) The negative experience adjustments of 1,360 million arising in 2008 are due to trends in the financial markets (especially equity markets) during the year.

The net actuarial loss before tax (and excluding associates) recognized directly in equity was 974 million as of December 31, 2008 and 150 million at December 31, 2007.

As of December 31, 2008, the present value of obligations in respect of pensions and similar benefits under wholly or partially funded plans was 5,924 million, and the present value of unfunded obligations was 1,817 million (compared with, respectively, 6,557 million and 1,924 million at December 31, 2007 and with 7,252 million and 1,935 million at December 31, 2006).

In Germany, sanofi-aventis is a member of a *Pensionskasse* multi-employer plan. This is a defined contribution plan which covers the current level of annuities. However, the obligation arising from future increases in annuity rates is recognized as part of the overall pension obligation; it amounted to 393 million at December 31, 2008, 428 million at December 31, 2007 and 465 million at December 31, 2006.

The table below shows the sensitivity of (i) the benefit cost recognized in the consolidated income statement, and (ii) the obligation in the consolidated balance sheet, to changes in healthcare costs associated with post-employment benefits.

( million)

**Sensitivity of assumptions**

	2008
1% increase in healthcare costs	
Impact on benefit cost for the period	4
Impact on obligation in the balance sheet	65
1% reduction in healthcare costs	
Impact on benefit cost for the period	(4)
Impact on obligation in the balance sheet	(55)

The total cost relating to pensions and other benefits (excluding the effect of plan curtailments and settlements) for 2008 was 332 million, compared with 346 million in 2007 and 348 million in 2006, split as follows:

***Selling and general expenses:*** 180 million in 2008, 200 million in 2007, and 201 million in 2006

***Cost of sales:*** 91 million in 2008, 87 million in 2007 and 2006

***Research and development expenses:*** 61 million in 2008, 59 million in 2007, and 60 million in 2006

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

The weighted average allocation of funds invested in Group pension plans is shown below:

Asset category (percentage)	Funds invested		
	2008	2007	2006
Equities	46%	51%	54%
Bonds	49%	47%	43%
Real estate	2%	{ 2%	{ 3%
Cash	3%		
<b>Total</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

The target allocation of investments at December 31, 2008 was not materially different from the actual allocation at December 31, 2007 and December 31, 2006.

The table below shows the expected cash outflows on pensions and other post-employment benefits over the next ten years:

( million)	Pensions and similar benefits
<b>Estimated employer's contribution in 2009</b>	<b>310</b>
<b>Estimated benefit payments:</b>	
2009	538
2010	553
2011	555
2012	533
2013	555
2014 through 2018	3,170

**D.18.2. Restructuring provisions**

The table below shows movements in restructuring provisions classified in *Other non-current liabilities* and *Other current liabilities*:

( million)	Year ended December 31, 2008	Year ended December 31, 2007	Year ended December 31, 2006
<b>Balance, beginning of period</b>	<b>395</b>	<b>496</b>	<b>562</b>



Edgar Filing: SANOFI-AVENTIS - Form 20-F

of which:

Classified in	Other non-current liabilities	188	218	151
Classified in	Other current liabilities	207	278	411
Change in provisions recognized in profit or loss for the period		510	180	231
Provisions utilized		(228)	(273)	(319)
Transfers		(3)		36
Unwinding of discount		5		1
Translation differences		(1)	(8)	(15)
<b>Balance, end of period</b>		<b>678</b>	<b>395</b>	<b>496</b>

of which:

Classified in	Other non-current liabilities	366	188	218
Classified in	Other current liabilities	312	207	278

Charges to restructuring provisions mainly relate to reorganization plans initiated further to measures taken by sanofi-aventis in response to the changing economic environment in Europe, primarily France, Spain and Italy. For a breakdown of restructuring costs for the period by type, see Note D.27.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008****D.18.3. Other provisions**

Other provisions include provisions for environmental, tax, commercial and product liability risks, and for litigation.

<i>( million)</i>	December 31, 2008	December 31, 2007	December 31, 2006
Tax exposures	1,770	1,645	1,858
Environmental risks and remediation	589	494	528
Product liability risks, litigation and other	725	987	1,168
<b>Total</b>	<b>3,084</b>	<b>3,126</b>	<b>3,554</b>

Provisions for tax exposures are recorded if the Group is exposed to a probable risk resulting from a tax position adopted by the Group or a subsidiary, and the risk has been quantified at the balance sheet date.

Provisions for environmental risks and remediation mainly relate to contingencies arising from business divestments.

Identified environmental risks are covered by provisions estimated on the basis of the costs sanofi-aventis believes it will be obliged to meet over a period not exceeding (other than in exceptional cases) 30 years. Sanofi-aventis expects that 88 million of these provisions will be utilized in 2009 and 291 million over the period from 2010 through 2013.

Product liability risks, litigation and other mainly comprises provisions for risks relating to product liability, government investigations, regulatory or competition law claims or contingencies arising from business divestments (other than environmental risks).

The main pending legal and arbitral proceedings and government investigations are described in Note D.22.

A full risk and litigation assessment is performed with the assistance of the Group's legal advisers, and provisions are recorded as required by circumstances in accordance with the principles described in Note B.12.

**D.19. Other current liabilities**

Other current liabilities break down as follows:

<i>( million)</i>	<b>December 31, 2008</b>	<b>December 31, 2007</b>	<b>December 31, 2006</b>
Taxes payable	664	797	956
Employee-related liabilities	1,366	1,337	1,298
Restructuring provisions (see Note D.18.2.)	312	207	278
Interest rate derivatives (see Note D.20.)			2
Currency derivatives (see Note D.20.)	249	187	20
Amounts payable for acquisitions of non-current assets	292	429	275
Other liabilities	1,838	1,756	1,996
<b>Total</b>	<b>4,721</b>	<b>4,713</b>	<b>4,825</b>

This item includes the current portion of provisions for litigation, product returns and other risks; amounts due to associates (see Note D.6.); and amounts due to governmental agencies and the healthcare authorities (see Note D.23.).

F-67

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008****D.20. Derivative financial instruments and market risks**

The table below shows the fair value of derivative instruments as of December 31, 2008:

( million)	Non-current assets	Current assets	Total assets	Non-current liabilities	Current liabilities	Total liabilities	Fair value at Dec. 31, 2008 (net)	Fair value at Dec. 31, 2007 (net)	Fair value at Dec. 31, 2006 (net)
<b>Currency derivatives</b>		348	348		(249)	(249)	99	(120)	50
<i>operational</i>		243	243		(42)	(42)	201	33	6
<i>financial</i>		105	105		(207)	(207)	(102)	(153)	44
<i>net investment hedges</i>									
<b>Interest rate derivatives</b>	71	33	104	(86)		(86)	18	29	40
<b>Equity derivatives</b>									163
<b>Total</b>	<b>71</b>	<b>381</b>	<b>452</b>	<b>(86)</b>	<b>(249)</b>	<b>(335)</b>	<b>117</b>	<b>(91)</b>	<b>253</b>

**Objectives of the use of derivative financial instruments**

Sanofi-aventis uses derivative instruments primarily to manage operational exposure to movements in exchange rates, and financial exposure to movements in interest rates and exchange rates (where debt is not contracted in the functional currency of the borrower or lender entity). Less frequently, sanofi-aventis uses equity derivatives in connection with asset divestments.

Sanofi-aventis performs periodic reviews of its transactions and contractual agreements in order to identify any embedded derivatives, which are accounted for separately from the host contract in accordance with IAS 39. As of December 31, 2008, sanofi-aventis had no material embedded derivatives.

**Counterparty risk**

As of December 31, 2008, all currency and interest rate hedges were contracted with leading banks, and no single counterparty accounted for more than 17% of the Group's overall currency or interest rate positions.

**D.20.1. Currency and interest rate derivatives**

**a) Valuation methods**

Sanofi-aventis estimates the fair value of financial instruments using methods and data based on financial market sources, as described below:

**Currency forward and options contracts:**

**Market data**

Spot price  
Interest rates: less than 1 year  
Interest rates: more than 1 year  
Volatility

**Source**

ECB Fixing  
Mid Money Market  
Mid Zero Coupon  
Reuters Mid ATM

**Instrument to be assessed**

Forward contracts: less than 1 year  
Forward contracts: more than 1 year  
Plain vanilla options

**Model used**

Proportional formula  
Actuarial formula  
Black-Scholes

F-68

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008****Interest rate forward and options contracts:**

<b>Market data</b>	<b>Source</b>
Interest rates: less than 1 year	LIFFE Mid Money Market and interest rate futures
Interest rates: more than 1 year	Mid Zero Coupon
Cap/Floor volatility	Bloomberg volatility matrix, per strike
<b>Instrument to be assessed</b>	<b>Model used</b>
Swap	NPV/cash flow projection
Cross currency	As for swap + ECB fixing for conversion
Plain vanilla options	Black-Scholes

**b) Currency derivatives used to manage operational risk exposures**

Sanofi-aventis operates a foreign exchange risk hedging policy to reduce the exposure of operating income to fluctuations in foreign currencies, in particular the U.S. dollar. This policy involves regular assessments of the Group's worldwide foreign currency exposure, based on budget estimates of foreign-currency transactions to be carried out by the parent company and its subsidiaries. These transactions mainly comprise sales, purchases, research costs, co-marketing and co-promotion expenses, and royalties. To reduce the exposure of these transactions to exchange rate movements, sanofi-aventis contracts economic hedges using liquid financial instruments such as forward purchases and sales of currency, call and put options, and combinations of currency options (collars).

<i>December 31, 2008</i>	Notional amount	Fair value	Of which derivatives designated as cash flow hedges			Of which derivatives not eligible for hedge accounting	
			Notional amount	Fair value	Of which recognized in equity	Notional amount	Fair value
( million)							
<b>Forward currency sales</b>	<b>3,305</b>	<b>219</b>	<b>1,562</b>	<b>121</b>	<b>123</b>	<b>1,743</b>	<b>98</b>
of which U.S. dollar	2,461	182	1,358	108	111	1,103	74
of which Japanese yen	191	(5)	95	3	2	96	(8)
of which Russian rouble	134	15				134	15
of which Pound sterling	104	6				104	6
of which Saudi Arabian riyal	58	5	4			54	5
of which Polish zloty	53	6	33	5	6	20	1
<b>Forward currency purchases</b>	<b>601</b>	<b>(11)</b>				<b>601</b>	<b>(11)</b>
of which Hungarian forint	175	(1)				175	(1)
of which U.S. dollar	140	3				140	3
of which Pound sterling	75	(6)				75	(6)
of which Russian rouble	72	(6)				72	(6)
of which Canadian dollar	51	(1)				51	(1)
<b>Put options purchased</b>	<b>24</b>		<b>2</b>			<b>22</b>	
<b>Call options written</b>	<b>48</b>	<b>(7)</b>	<b>2</b>			<b>46</b>	<b>(7)</b>
<b>Total</b>	<b>3,978</b>	<b>201</b>	<b>1,566</b>	<b>121</b>	<b>123</b>	<b>2,412</b>	<b>80</b>

As of December 31, 2008, none of these instruments had an expiry date after December 31, 2009.

These positions hedge:

All material future foreign-currency cash flows arising after the balance sheet date in relation to transactions carried out during the year ended December 31, 2008 and recognized in the balance sheet at that date. Gains and losses on hedging instruments (forward contracts) have been and will continue to be calculated and recognized in parallel with the recognition of gains and losses on the hedged items. Consequently, the commercial foreign exchange gain or loss to be recognized on these items (hedges and hedged instruments) in 2009 is not expected to be material.

F-69

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

Forecast foreign-currency cash flows relating to commercial transactions to be carried out in 2009. These hedges (forward contracts and options) cover approximately 20% to 40% of the expected net cash flows for 2009 in currencies subject to budgetary hedging. The portfolio of derivatives contracted to cover 2009 U.S. dollar cash flows consists solely of forward contracts, and represents approximately one-third of the forecast net cash flows for 2009. Given the designation of these forward sales as cash flow hedges, the estimated sensitivity of these positions in terms of foreign exchange gains/losses and equity impact for 2009 is as follows:

	Foreign exchange gain/(loss) on U.S. dollar hedges ( million)	Impact on equity at December 31, 2008 ( million)
<b>Assumes a constant /\$ exchange rate over the year ending December 31, 2009</b>		
Depreciation of 10% in the U.S. dollar ( 1 = \$1.5309)	234.1	123.5
Exchange rate maintained at the December 31, 2008 rate ( 1 = \$1.3917)	110.7	
Appreciation of 10% in the U.S. dollar ( 1 = \$1.2525)	(40.2)	(150.9)

The table below shows operational currency hedging instruments in place as of December 31, 2007, with the notional amount translated into euros at the relevant closing exchange rate.

<i>December 31, 2007</i>			Of which derivatives designated as cash flow hedges			Of which derivatives not eligible for hedge accounting	
	Notional amount	Fair value	Notional amount	Fair value	Of which recognized in equity	Notional amount	Fair value
( million)							
<b>Forward currency sales</b>	<b>2,205</b>	<b>30</b>	<b>486</b>	<b>8</b>	<b>8</b>	<b>1,719</b>	<b>22</b>
of which U.S. dollar	1,288	20	239	3	3	1,049	17
of which Russian rouble	224					224	
of which Japanese yen	132	4	77	4	3	55	1
of which Pound sterling	119	3				119	3
of which Polish zloty	62	(2)	33	(1)	(1)	29	
of which Australian dollar	45	2	36	2	2	9	
of which Mexican peso	43	1	19			24	1
of which Turkish lira	39					39	
of which Korean won	33	1				33	1
of which Slovakian koruna	33		10			23	
<b>Forward currency purchases</b>	<b>464</b>					<b>464</b>	
of which Hungarian forint	214	1				214	1
of which Swiss franc	54					54	
of which U.S. dollar	48	(1)				48	(1)
of which Canadian dollar	47					47	
<b>Put options purchased</b>	<b>409</b>	<b>4</b>	<b>15</b>	<b>1</b>	<b>1</b>	<b>394</b>	<b>3</b>
of which U.S. dollar knock-out options <sup>(1)</sup>	326	3				326	3
<b>Call options written</b>	<b>741</b>	<b>(1)</b>	<b>15</b>			<b>726</b>	<b>(1)</b>
of which U.S. dollar knock-out options <sup>(1)</sup>	652	(2)				652	(2)
<b>Put options written</b>	<b>12</b>					<b>12</b>	
<b>Total</b>	<b>3,831</b>	<b>33</b>	<b>516</b>	<b>9</b>	<b>9</b>	<b>3,315</b>	<b>24</b>



- (1) Knock-out options expire worthless once a specified level of gain is reached.

F-70

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

The table below shows operational currency hedging instruments in place as of December 31, 2006:

<i>December 31, 2006</i>			Of which derivatives designated as cash flow hedges			Of which derivatives not eligible for hedge accounting	
	Notional amount	Fair value	Notional amount	Fair value	Of which recognized in equity	Notional amount	Fair value
( million)							
<b>Forward currency sales</b>	<b>1,615</b>	<b>7</b>	<b>352</b>	<b>6</b>	<b>7</b>	<b>1,263</b>	<b>1</b>
of which U.S. dollar	800	10	114	7	7	686	3
of which Russian rouble	126					126	
of which Australian dollar	86		66			20	
of which Singapore dollar	73					73	
of which Japanese yen	66	1				66	1
of which Polish zloty	66		47			19	
of which Mexican peso	65	1	42	1	2	23	
of which Korean won	52					52	
of which Slovakian koruna	49	(2)	18	(1)	(1)	31	(1)
of which Czech koruna	40	(1)	22	(1)	(1)	18	(1)
<b>Forward currency purchases</b>	<b>351</b>	<b>(1)</b>				<b>351</b>	<b>(1)</b>
of which Swiss franc	92	(1)				92	(1)
of which Pound sterling	81					81	
of which Canadian dollar	71	(1)				71	(1)
of which Hungarian forint	33					33	
<b>Put options purchased</b>	<b>18</b>		<b>18</b>				
<b>Call options written</b>	<b>36</b>		<b>18</b>			<b>18</b>	
<b>Total</b>	<b>2,020</b>	<b>6</b>	<b>388</b>	<b>6</b>	<b>7</b>	<b>1,632</b>	

**c) Currency and interest rate derivatives used to manage financial risk exposures**

Cash pooling arrangements for foreign subsidiaries outside the euro zone, and some of the Group's financing activities such as U.S. commercial paper issues (equivalent to 0.7 billion as of December 31, 2008), expose certain entities—in particular the sanofi-aventis parent company—to financial foreign exchange risk. This is the risk of changes in the value of borrowings and loans denominated in a currency (mainly the U.S. dollar) other than the functional currency of the borrower or lender. The Group's net foreign exchange exposure is hedged by firm financial instruments (usually currency swaps).

The table below shows instruments used to manage financial risk exposures as of December 31, 2008, with the notional amount translated into euros at the relevant closing exchange rate.

December 31, 2008

December 31, 2007

December 31, 2006

Edgar Filing: SANOFI-AVENTIS - Form 20-F

<i>( million)</i>	Notional amount	Fair value	Expiry	Notional amount	Fair value	Expiry	Notional amount	Fair value	Expiry
<b>Forward currency purchases</b>	<b>9,210</b>	<b>(80)</b>		<b>8,261</b>	<b>(179)</b>		<b>5,708</b>		
<i>of which U.S. dollar <sup>(1)</sup></i>	8,256	(66)	2009	7,348	(167)	2008	4,984	2	2007
<i>of which Pound sterling</i>	235	(4)	2009	442	(11)	2008	146		2007
<i>of which Canadian dollar</i>	189	(13)	2009				1		2007
<b>Forward currency sales</b>	<b>1,954</b>	<b>(22)</b>		<b>1,563</b>	<b>26</b>		<b>1,470</b>	<b>44</b>	
<i>of which U.S. dollar</i>	1,043	(23)	2009	936	20	2008	1,032	44	2007
<i>of which Japanese yen</i>	695	(7)	2009	206	3	2008	83	2	2007
<i>of which Hungarian forint</i>	95	1	2009	246	(1)	2008	176	(1)	2007
<b>Total</b>	<b>11,164</b>	<b>(102)</b>		<b>9,824</b>	<b>(153)</b>		<b>7,178</b>	<b>44</b>	

(1) Includes 7,537 million used to hedge U.S. dollar intragroup deposits placed with the sanofi-aventis parent company as of December 31, 2008.

F-71

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

These currency swaps generate a net financial foreign exchange gain or loss arising from the interest rate differential between the hedged currency and the euro, the change in the value of the foreign-currency payables and receivables caused by interest rate movements being offset by the change in the intrinsic value of the hedging instruments. As regards the main currency hedged (the U.S. dollar), the interest rate differential on forward purchase contracts, which had been favorable in 2007, became unfavorable in 2008, leading to a negative movement of 119 million in the net foreign exchange gain/loss. In addition, the Group may hedge some future foreign-currency cash flows relating to investment or divestment transactions.

The Group's exposure to interest rate risk arises from the floating-rate component of its debt (credit facilities, commercial paper and floating rate notes), which is primarily indexed to EONIA, U.S. Libor and Euribor. To reduce the amount and volatility of the cost of short-term and medium-term debt, sanofi-aventis uses interest rate swaps, cross-currency swaps and interest rate options (purchases of caps, or combined purchases of caps and sales of floors) that alter the structure of its debt. The table below shows instruments of this type in place at December 31, 2008:

( million)	Notional amounts by expiry date as of December 31, 2008						Fair value	Of which derivatives designated as fair value hedges		Of which derivatives designated as cash flow hedges		Of which recognized in equity
	2009	2010	2012	2013	2015	Total		Notional amount	Fair value	Notional amount	Fair value	
Interest rate swap, pay 3.69% / receive floating <sup>(1)</sup>		1,000				1,000	(12)			1,000	(12)	(14)
Cross currency swaps												
- pay floating <sup>(1)</sup> / receive £ 5.50%		299				299	(74)	299	(74)			
- pay floating <sup>(1)</sup> / receive ¥ 0.22%	116					116	33	116	33			
- pay floating <sup>(1)</sup> / receive ¥ floating <sup>(2)</sup>				92		92	27					
- pay floating <sup>(3)</sup> / receive CHF 2.75%		122				122	16	122	16			
- pay 4.89% / receive CHF 3.26%			180			180	5			180	5	
- pay 4.87% / receive CHF 3.38%					244	244	23			244	23	(1)
<b>Total</b>	<b>116</b>	<b>1,421</b>	<b>180</b>	<b>92</b>	<b>244</b>	<b>2,053</b>	<b>18</b>	<b>537</b>	<b>(25)</b>	<b>1,424</b>	<b>16</b>	<b>(15)</b>

(1) Floating: benchmark rate 3-month Euribor

(2) Floating: benchmark rate 3-month Libor JPY

(3) Floating: benchmark rate 6-month Euribor

For details of how these financial instruments change the structure of the Group's debt and for details of the Group's overall sensitivity to interest rates, see Note D.17.

The table below shows the portfolio of interest rate derivative instruments at December 31, 2007:

Edgar Filing: SANOFI-AVENTIS - Form 20-F

	Notional amounts by expiry date as of December 31, 2007						Of which derivatives designated as fair value hedges			Of which derivatives designated as cash flow hedges		
	2008	2009	2010	2012	2015	Total	Fair value	Notional amount	Fair value	Notional amount	Fair value	Of which recognized in equity
( million)												
Interest rate swap, pay 3.11% / receive floating (1)				1,000		1,000	50			1,000	50	50
Interest rate swap, pay floating ( ) EONIA + 0.59%	250					250						
Cross currency swaps												
- pay floating <sup>(1)</sup> / receive £ 5.50%			299			299	(14)	299	(14)			
- pay floating <sup>(1)</sup> / receive ¥ 0.22%		116				116	(2)	116	(2)			
- pay floating <sup>(2)</sup> / receive CHF 2.75%			122			122	(2)	122	(2)			
- pay 4.87% / receive CHF 3.38%					183	183	(3)			183	(3)	
<b>Total</b>	<b>250</b>	<b>116</b>	<b>421</b>	<b>1,000</b>	<b>183</b>	<b>1,970</b>	<b>29</b>	<b>537</b>	<b>(18)</b>	<b>1,183</b>	<b>47</b>	<b>50</b>

(1) Floating: benchmark rate 3-month Euribor

(2) Floating: benchmark rate 6-month Euribor

F-72

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

The table below shows the portfolio of interest rate derivative instruments at December 31, 2006:

( million)	Average rate	Notional amounts by expiry date as of December 31, 2006			Fair value	Of which derivatives designated as fair value hedges		Of which derivatives designated as cash flow hedges		Of which recognized in equity
		2007	2012	Total		Notional amount	Fair value	Notional amount	Fair value	
Interest rate swap, pay fixed ( )	3.11%		1,000	1,000	42			1,000	42	42
Purchases of caps ( )	4.00%	250		250				250		
Collars ( )	(3.68%-4.00%)	500		500				200		
Cross currency swaps - pay floating <sup>(1)</sup> / receive	CHF 1.98%	65		65	(2)					
<b>Total</b>		<b>815</b>	<b>1,000</b>	<b>1,815</b>	<b>40</b>			<b>1,450</b>	<b>42</b>	<b>42</b>

(1) Floating: benchmark rate 3-month Euribor

**D.20.2. Equity derivatives**

The Group did not hold any equity derivatives in 2008.

Aventis sold Aventis Behring to the Australian company CSL Ltd on March 31, 2004. The sale price included additional payments contingent upon the performance of CSL shares. Sanofi-aventis was entitled to receive \$125 million if the CSL share price (calculated on the basis of an average price weighted for trading volumes) was greater than AUD28 during a period from October 1, 2007 through March 31, 2008. Sanofi-aventis was entitled to receive a further \$125 million if the CSL share price (calculated on the same basis and over the same period) was greater than AUD35. CSL Ltd could opt to settle these amounts in shares. At December 31, 2006, based on a CSL share price of AUD65.37, the fair value of this instrument was \$214 million.

A new agreement between sanofi-aventis and CSL Ltd was signed with effect from January 31, 2007 under the terms of which it was agreed that CSL Ltd would pay the contingent consideration of \$250 million early. Sanofi-aventis received payment of this amount on February 5, 2007.

**D.21. Contractual obligations and other commitments**

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

The Group's contractual obligations and other commitments break down as follows:

December 31, 2008	Payments due by period				
( million)	Total	Under 1 year	From 1 to 3 years	From 3 to 5 years	Over 5 years
Debt <sup>(1)</sup> :					
- principal	5,921	1,784	1,857	1,969	311
- interest	547	173	235	92	47
- net cash flows related to derivative instruments	16	17	84	(44)	(41)
Operating lease obligations	1,192	265	353	185	389
Irrevocable purchase commitment <sup>(2)</sup> :					
- given	2,575	1,666	390	131	388
- received	(278)	(126)	(64)	(27)	(61)
Other commercial commitments	2,624	128	424	323	1,749
Commitment related to Zentiva offer	1,226	1,226			
<b>Total contractual obligations and other commitments</b>	<b>13,823</b>	<b>5,133</b>	<b>3,279</b>	<b>2,629</b>	<b>2,782</b>
<b>Undrawn credit facilities<sup>(3)</sup></b>	<b>10,768</b>	<b>68</b>	<b>4,027</b>	<b>6,673</b>	

(1) A breakdown of debt is provided in Note D.17.g), and a breakdown of obligations under finance leases is provided below.

(2) These comprise irrevocable commitments to suppliers of (i) property, plant and equipment, net of down payments (see Note D.3) and (ii) goods and services.

(3) For details of confirmed credit facilities, see Note D.17.c).

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008****Leases****Finance leases**

Future minimum lease payments due under finance leases at December 31, 2008 were 31 million ( 35 million at December 31, 2007 and 38 million at December 31, 2006), including interest of 5 million ( 6 million at December 31, 2007 and 5 million at December 31, 2006). The payment schedule is as follows:

December 31, 2008 ( million)	Total	Payments due by period			
		Under 1 year	From 1 to 3 years	From 3 to 5 years	Over 5 years
Finance lease obligations:					
- principal	25	4	9	5	7
- interest	5	1	2	1	1
<b>Total</b>	<b>30</b>	<b>5</b>	<b>11</b>	<b>6</b>	<b>8</b>

**Operating leases**

Sanofi-aventis leases certain of its properties and equipment used in the ordinary course of business under operating leases. Future minimum lease payments due under non-cancelable operating leases at December 31, 2008 amounted to 1,192 million ( 1,283 million at December 31, 2007, 1,462 million at December 31, 2006).

Total rental expense recognized in the year ended December 31, 2008 was 282 million ( 292 million in the year ended December 31, 2007, 322 million in the year ended December 31, 2006).

**Guarantees**

Guarantees given and received (mainly surety bonds) are as follows:

( million)	2008	2007	2006
------------	------	------	------



Guarantees given	1,524	1,895	2,223
Guarantees received	(218)	(195)	(215)

***Commercial commitments***

This includes commitments to third parties under collaboration agreements. In pursuance of its strategy, sanofi-aventis acquires technologies and rights to products. Such acquisitions may be made in various contractual forms: acquisitions of shares, loans, license agreements, joint development and co-marketing. These contracts usually involve upfront payments on signature of the agreement, and development milestone payments. Some of these complex agreements include undertakings to finance research programs in future years, and payments contingent upon completion of development milestones, or upon the granting of approvals or licenses, or upon the attainment of sales targets once a product is on the market.

The main collaboration agreements in the Pharmaceuticals segment are described below:

In December 2008, sanofi-aventis announced the signature of a global licensing and collaboration agreement with Novozymes for the development and commercialization of a new antibiotic, plectasin NZ2114, for the treatment of severe infections such as pneumonia and septicemia. Under the terms of the agreement, sanofi-aventis was granted an exclusive worldwide license for the development, registration and commercialization of the drug. The two companies will work jointly to develop and implement industrial-scale manufacturing of the plectasin NZ2114 drug substance, using a recombinant process that builds on Novozymes' proprietary expression technology. Future milestone payments under the agreement could reach 64 million.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

In February 2008, sanofi-aventis and Dyax Corp. entered into agreements that granted sanofi-aventis an exclusive worldwide license for the development and commercialization of Dyax's fully human monoclonal antibody DX-2240, as well as a worldwide non-exclusive license to use Dyax's proprietary Phage Display technology (phage expression and antibody banks). Under the terms of the two agreements, Dyax could receive up to \$270 million in license fees and milestone payments in the event of commercial success in three indications for the DX-2240 project currently under development and in one indication for the first antibody candidates developed by sanofi-aventis alone using the Phage Display technology. In addition, Dyax will receive royalties on sales of the antibody candidates.

In March 2007, sanofi-aventis and Oxford BioMedica announced that they had entered into an exclusive global license agreement to develop and commercialize TroVax<sup>®</sup> for the treatment and prevention of cancers. Future milestone payments could reach up to 450 million. Oxford BioMedica will be entitled to escalating royalties on global sales of TroVax<sup>®</sup>, and to sales milestones payments if and when net sales of TroVax<sup>®</sup> reach certain levels.

In September 2003, sanofi-aventis signed a collaboration agreement with Regeneron in oncology to develop the Vascular Endothelial Growth Factor (VEGF) Trap program. Development milestone payments and royalties on VEGF Trap sales are payable under the contract. Total milestone payments could reach \$400 million if all indications specified in the contract obtain approval in the United States, Europe and Japan. Sanofi-aventis will pay 100% of the development costs of the VEGF Trap. Once a VEGF Trap product starts to be marketed, Regeneron will repay 50% of the development costs (originally paid by sanofi-aventis) in accordance with a formula based on Regeneron's share of the profits, including royalties received in Japan. In 2005, the VEGF Trap program was extended to Japan, and the treatment of ocular pathologies was excluded from the scope of the collaboration agreement.

In November 2007, sanofi-aventis signed a further collaboration agreement with Regeneron to discover, develop and commercialize fully-human therapeutic antibodies.

Under the terms of the research agreement, the Group will fund up to \$416 million of research over the next five years. Sanofi-aventis will have an option to extend the research agreement for an additional three years. Under the terms of the development agreement, sanofi-aventis will fund 100% of the development costs. Once a product begins to be marketed, Regeneron will repay out of its profits (provided they are sufficient) half of the development costs borne by sanofi-aventis.

In addition, Regeneron will be entitled to receive up to a total of \$250 million of sales milestone payments when the collaboration achieves certain aggregate annual excluding U.S. sales levels.

A collaboration agreement with IDM was signed in 2001. Under this agreement, IDM granted sanofi-aventis 20 development options on current and future research and development programs. For each option that leads to a commercially marketed product, IDM could receive between 17 million and 32 million depending on the potential of the market, plus reimbursement of the development costs. Contractually, sanofi-aventis may suspend the development program for each option exercised at any time and without penalty. In 2007, sanofi-aventis decided to suspend the development program for the treatment of melanoma, the only program for which it has exercised its option since the collaboration agreement with IDM was signed. At December 31, 2008, sanofi-aventis still had an option on 6 programs.

Under a collaboration agreement with Zealand Pharma signed in June 2003, sanofi-aventis obtained rights relating to the development and worldwide marketing of ZP10, an agent used in the treatment of type 2 diabetes. Under this agreement, sanofi-aventis is

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

responsible for the development of this compound. Payments to Zealand Pharma could reach a total of \$85 million, contingent upon marketing approvals being obtained.

Under a co-promotion agreement with UCB, signed in September 2006, sanofi-aventis co-promotes Xyzal® in the United States jointly with UCB. Xyzal® is a prescription antihistamine. The agreement requires payments to be made on attainment of development and marketing milestones, based on regulatory approvals and sales targets. Total future payments under the agreement could reach \$130 million. The agreement also specifies how profits are split between sanofi-aventis and UCB.

F-75

---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

Sanofi-aventis has entered into various other collaboration agreements with partners including Immunogen, Coley, Wayne State University, Innogenetics and Inserm, under which sanofi-aventis may be required to make total contingent payments of approximately 31 million over the next five years.

In 2008, sanofi-aventis returned its territory rights for the development and commercialization of the oral anti-cancer agent S-1 to Taiho Pharmaceutical Co., Ltd. As from the termination date, the milestone payments specified in this agreement no longer constitute commercial commitments. As of December 31, 2007, they represented a commitment of \$295 million.

The main collaboration agreements in the Vaccines segment are described below:

Following the acquisition of Acambis plc by sanofi pasteur during 2008, the agreements previously signed with Acambis (vaccines against Japanese encephalitis, West Nile virus and dengue fever) have been integrated into the Group's pipeline. These agreements represented future milestone payments of 57 million as of December 31, 2007.

In December 2007, sanofi pasteur signed an exclusive collaboration and commercialization agreement with Crucell N.V. for Crucell's rabies monoclonal antibodies. Under the terms of the agreement, Crucell will continue to develop and manufacture the product. The contract includes milestone payments that could reach \$53 million.

Sanofi Pasteur has entered into a number of other collaboration agreements with partners including Becton Dickinson, Crucell, Intercell, Vactech, Maxigen and SSI, under which sanofi pasteur may be required to make total contingent payments of around 52 million over the next five years.

***Financial commitment related to the offer for Zentiva shares***

As of December 31, 2008 sanofi-aventis held 9.5 million shares (see Note D.1.) representing around 24.9% of the share capital of Zentiva, which is accounted for as an associate (see Note D.6.).

On June 18, 2008 sanofi-aventis made an offer to acquire all the issued ordinary shares including shares held in the form of Global Depositary Receipts (GDRs) that make up Zentiva's share capital, at a price of CZK1,050 per share payable in cash.

On September 22, 2008 sanofi-aventis raised its cash offer price to CZK1,150 per share. This improved offer was recommended by the Board of Directors of Zentiva, and represents a 25.5% premium to Zentiva's April 30, 2008 closing share price.

The offer was opened by sanofi-aventis Europe on July 11, 2008 for an initial period of 10 weeks, closing on September 19, 2008. On September 18, 2008 sanofi-aventis announced a 10-week extension in the offer period until November 28, 2008, with the agreement of the

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Czech National Bank and as set out in the Offer Memorandum published July 11, 2008, additional time being required to meet the offer conditions. The Czech National Bank subsequently issued a decision authorizing sanofi-aventis Europe to extend the offer period beyond November 28, 2008 for an additional-12 week period ending February 20, 2009.

As of December 31, 2008 this offer was subject to two conditions: (i) obtaining the required clearances from the antitrust authorities, and (ii) meeting the minimum tender condition of 10.3 million shares (including shares held in the form of GDRs), which is designed to ensure that on the closing date of the Offer sanofi-aventis would hold directly or indirectly over 50.0% of Zentiva's share capital and voting rights.

On February 4, 2009 the European Commission cleared the acquisition of Zentiva by sanofi-aventis Europe.

As of December 31, 2008, sanofi-aventis had a financial commitment of 1,226 million relating to the acquisition of the 28.6 million Zentiva shares not yet held by the Group.

F-76

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

**D.22. Legal and Arbitral Proceedings**

Sanofi-aventis and its affiliates are involved in litigation, arbitration and other legal proceedings. These proceedings typically are related to product liability claims, intellectual property rights (particularly claims against generic companies seeking to limit the patent protection of sanofi-aventis products), compliance and trade practices, commercial claims, employment and wrongful discharge claims, tax assessment claims, waste disposal and pollution claims, and claims under warranties or indemnification arrangements relating to business divestitures. Provisions related to legal and arbitral proceedings are recorded in accordance with the principles described in Note B.12.

Most of these claims involve highly complex issues, actual damages and other matters. Often these issues are subject to substantial uncertainties, and, therefore, the probability of loss and an estimation of damages are difficult to ascertain. Consequently, for a majority of these claims, we are unable to make a reasonable estimate of the expected financial effect that will result from ultimate resolution of the proceeding. In those cases, we have not accrued a reserve for the potential outcome, but disclose information with respect to the nature of the contingency.

In the cases that have been settled or adjudicated, or where quantifiable fines and penalties have been assessed, we have indicated our losses or the amount of provision accrued that is the estimate of the probable loss.

In a limited number of ongoing cases, while we are able to make a reasonable estimate of the expected loss or range of the possible loss and have accrued a provision for such loss, we believe that publication of this information on a case-by-case basis or by class would seriously prejudice the Company's position in the ongoing legal proceedings or in any related settlement discussions. Accordingly, in those cases, we have disclosed information with respect to the nature of the contingency but have not disclosed our estimate of the range of potential loss, in accordance with paragraph 92 of IAS 37.

These assessments can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions. Our assessments are based on estimates and assumptions that have been deemed reasonable by management. We believe that the aggregate provisions recorded for the above matters are adequate based upon currently available information. However, given the inherent uncertainties related to these cases and involved in estimating contingent liabilities, we could in the future incur judgments that could have a material adverse effect on our net income in any particular period.

Long term provisions other than provisions for pensions and other long-term benefits and restructuring provisions are disclosed in Note D.18.3.

Provisions for product liability risks, litigation and other amount to 725 million in 2008. These provisions are mainly related to product liabilities, government investigations, competition law, regulatory claims, contingencies that have arisen from business divestitures other than environmental matters and other claims.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Provisions for environmental risks and remediation amount to 589 million in 2008, the majority of which are related to contingencies that have arisen from business divestitures.

When a legal claim involves a challenge to the patent protection of a pharmaceutical product, the principal risk to sanofi-aventis is that the sales of the product might decline following the introduction of a competing generic product in the relevant market. In cases where the product rights have been capitalized as an asset on the balance sheet (*i.e.*, assets acquired through a separate acquisition or through a business combination see Note B.4.), such a decline in sales could negatively affect the value of the intangible asset. In those cases, the Company performs impairment tests in accordance with the principles disclosed in Note B.6.1., based upon the best available information and, where appropriate, records an impairment loss to reduce the carrying amount of the related intangible asset to its estimated fair value. The amounts of such impairments are disclosed in Note D.5.

F-77

---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

The principal ongoing legal and arbitral proceedings are described below.

**a) Products**

*Sabril® Litigation (anti-epilepsy)*

Aventis Pharma Ltd, UK, has settled a group litigation consisting of 166 active claimants in the United Kingdom relating to the anti-epilepsy drug Sabril®. The action alleged that patients have suffered irreversible visual field constriction as a result of taking Sabril®. In November 2008 the court validated full and final settlement by Aventis Pharma Ltd, with no admission of liability, for a global settlement sum of around £18 million (more than half of which consists of claimants' recoverable costs and interest). A small number of individual claims remain pending in the United Kingdom and other jurisdictions.

*Sanofi Pasteur Hepatitis B Vaccine Litigation*

More than 180 lawsuits have been filed in various French civil courts against Sanofi Pasteur S.A. or Sanofi Pasteur MSD, two French subsidiaries of sanofi-aventis, in which the plaintiffs allege that they suffer from a variety of neurological disorders and autoimmune diseases, including multiple sclerosis or Guillain-Barré syndrome as a result of receiving the hepatitis B vaccine. More than 50 judgments in France have rejected claims alleging a causal link between the hepatitis B vaccine and the claimants' alleged injuries. On May 22, 2008 the *Cour de cassation* (the French Supreme Court) rendered two decisions with Sanofi Pasteur S.A. as defendant. In one case, it decided to reject the claims relating to hepatitis B vaccination, ending this case. In the second case, it overruled a Court of Appeals decision in favor of sanofi pasteur, holding that the lower court's decision did not contain sufficient grounds to reject plaintiffs claims. This case has been remanded back to the Court of Appeal of Paris.

Since January 31, 2008, both the legal entity Sanofi-Pasteur MSD and a corporate officer are under investigation in an ongoing criminal inquiry in France relating to alleged side effects caused by the hepatitis B vaccine.

*Sanofi Pasteur Inc. Thimerosal Litigation*

Since early 2001, Sanofi Pasteur Inc. has been a defendant in lawsuits filed in several federal and state courts in the United States alleging that serious personal injuries resulted from the presence of mercury in the preservative thimerosal, trace amounts of which are contained in vaccines manufactured by Sanofi Pasteur Inc.



## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Currently, there are 285 such cases pending. Several of the cases seek certification to proceed as class actions.

Sanofi Pasteur Inc. believes that under U.S. law, all of these claims must first be filed in the U.S. Court of Federal Claims to determine whether the claim qualifies for compensation by the National Vaccine Injury Compensation Program (VICP) before the claimants may bring direct actions against the company. The U.S. Court of Federal Claims (Claims Court) has established a process designed to facilitate the handling of the almost 5000 thimerosal claims within the VICP. The process involves a committee of petitioners' representatives and representatives of the U.S. Department of Justice, who represent the government in the VICP. As originally planned, the process called for petitioners' representatives to designate three test cases in each of the three different theories of general causation advanced by the petitioners. Hearings on two of the theories were completed in 2007. No time frame for the decisions has been specified.

Currently, all of the 285 cases are either in the preliminary response stage, in the discovery process, have been stayed pending adjudication by the U.S. Court of Federal Claims, or have pending plaintiffs' requests for reconsideration of preliminary determinations to stay proceedings pending such adjudication by the U.S. Court of Federal Claims.

F-78

---

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008***Sanofi Pasteur Blood Products Litigation*

Sanofi pasteur S.A. and/or its subsidiaries have been named in civil claims in Argentina and France on behalf of individuals with hemophilia, alleging that they became infected with the Human Immunodeficiency Virus (HIV) or hepatitis C virus (HCV) as a result of the administration of non-heat-treated antihemophilic factor (AHF) manufactured in France in the early 1980s by a predecessor company.

*Other Blood Products Litigation*

On June 2, 2003 a purported worldwide class action was filed against current and former Group affiliates Armour Pharmaceutical Company, Aventis Behring, Aventis Inc. and against three other U.S. plasma fractionators, on behalf of a purported class of foreign and domestic plaintiffs alleging infection with HIV and/or hepatitis C from 1978-1990. This action is pending before the U.S. District Court for the Northern District of Illinois. On March 3, 2005, the U.S. District Court for the Northern District of Illinois denied plaintiffs' requests to certify class actions with respect to the cases before it. Many plaintiffs chose not to proceed with individual claims, and most of the approximately 2,650 remaining plaintiffs' cases have remained before the U.S. District Court for the Northern District of Illinois because of shared questions of fact.

All of the United Kingdom claimants have been dismissed from the U.S. litigation on jurisdictional grounds. Since that decision, approximately 160 HIV/HCV claims have been filed in the United Kingdom, presumably by some of the same claimants. In 2008, the U.S. District Court also dismissed plaintiffs from Argentina and Israel on similar jurisdictional grounds. At present there are a number of additional motions pending with the Court to dismiss plaintiffs from Germany and Taiwan on the same basis.

*Agreal<sup>®</sup> Product Litigation*

The Group faces civil, criminal or administrative claims chiefly in Spain from women alleging that the menopause treatment Agreal<sup>®</sup> (veralipride) has caused a range of neurological and psychological harm. In 2007, decisions in suits involving several hundred claimants were handed down by civil tribunals in Spain. In the majority of cases to date, the decisions have been favorable to the Group, generally on the basis of a finding that causation was not proven by the claimants and/or that the leaflet gave adequate notice of potential side effects. A small number of the civil cases have been decided adversely to sanofi-aventis and sanofi-aventis has appealed each of these. On November 27, 2007 the Appeal Court of Barcelona confirmed a decision holding that the product is defective due to insufficient information in the leaflet on side effect. Sanofi-aventis has appealed against this decision before the *Tribunal Superior de Justicia de Catalonia*. Any amounts awarded to date have not been material. A substantial number of claims remain to be adjudicated, and new civil, criminal and administrative claims have been recently filed. There can be no assurance that cases decided to date will be representative of future decisions and that additional claims will not be filed in Spain or other countries.

*Plavix<sup>®</sup> Product Litigation*

Affiliates of the Group and Bristol-Myers Squibb are named in a number of individual actions seeking recovery under state law for personal injuries allegedly sustained in connection with the use of Plavix<sup>®</sup>. The actions are primarily venued in the U.S. District Court for the District of New Jersey, which has administratively stayed the proceedings pending a U.S. Supreme Court decision in the Levine case, which presents issues of federal preemption relevant to state law claims. The parties have also entered into a tolling agreement relating to the unfiled claims of a number of additional potential plaintiffs.

**b) Patents**

*Plavix<sup>®</sup> Patent Litigation*

*United States.* On March 21, 2002, sanofi-aventis, Sanofi-Synthélabo Inc. and Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership (or BMS Sanofi Holding, our partnership with Bristol-Myers Squibb)

---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

filed suit in the U.S. District Court for the Southern District of New York against Apotex Inc. and Apotex Corp. (hereinafter Apotex) for the infringement of U.S. patent rights relating to Plavix® as a result of an ANDA filed by Apotex including a paragraph IV challenge to U.S. Patent No. 4,847,265 (the 265 patent), expiring in 2011, which discloses and claims *inter alia* the clopidogrel bisulfate compound, the active ingredient in Plavix®. Apotex asserted antitrust counterclaims.

On January 24, 2006, sanofi-aventis learned that the FDA had granted final approval to the Apotex ANDA. This FDA approval allowed Apotex to manufacture a generic version of clopidogrel bisulfate, but it did not resolve the outstanding patent claims against Apotex.

On March 21, 2006, sanofi-aventis and BMS announced that they had reached an agreement subject to certain conditions (including antitrust review and clearance by the Federal Trade Commission (FTC) and state attorneys general) with Apotex to settle the patent infringement lawsuit pending among the parties. On June 25, 2006, sanofi-aventis, BMS and Apotex announced that, in response to concerns to the settlement as initially proposed raised by the FTC and certain state attorneys general, the companies had entered into a revised agreement.

On July 28, 2006, sanofi-aventis learned that the revised agreement had failed to receive required antitrust clearance. On August 8, 2006, Apotex announced the launch at risk of its generic product in the United States. On August 31, 2006, the District Court granted sanofi-aventis motion for a preliminary injunction ordering Apotex to halt its sales of a generic version of clopidogrel bisulfate product that competes with Plavix® until the pending patent infringement lawsuit was resolved.

On June 19, 2007, the U.S. District Court issued a decision upholding the validity and enforceability of the principal Plavix® patent, and permanently enjoined Apotex from further sale of generic clopidogrel bisulfate. On December 12, 2008 the U.S. Court of Appeals for the Federal Circuit upheld this decision. Apotex has petitioned the Court of Appeals for a rehearing by the original judges that decided the case and an en-banc review of such decision by all of the judges on the Court.

Sanofi-aventis and Bristol-Myers Squibb are seeking damages from Apotex, in reparation of harm caused by that company's marketing and sale of an infringing generic version of Plavix® in 2006. Trial on damage claims against Apotex will be held on a schedule to be determined by the District Court.

The same plaintiffs filed suit on May 14, 2002 in the U.S. District Court for the Southern District of New York against Dr. Reddy's Laboratories for infringement of these same patent rights in an ANDA. Although it was filed in the same court, this suit was not tried concurrently with the Apotex suit. In January 2008, FDA granted final approval to Dr. Reddy's ANDA. This FDA approval does not resolve the outstanding patent claims, and the litigation against Dr. Reddy's remains pending before the same judge that ruled against Apotex. On January 23, 2008, the District Court entered an order requiring Dr. Reddy's provide notice 10 business days before selling or marketing a generic version of clopidogrel bisulfate or committing most other acts of infringement of the 265 patent, so as to permit sanofi-aventis and BMS to seek injunctive relief prior to the infringing act.

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Subsequent to the Apotex and Dr Reddy's cases, each of Cobalt, Ivax, Mylan, Roxane Laboratories, Sandoz, Sun and Teva notified sanofi-aventis that it had filed an ANDA with the FDA with regard to purported generic versions of form 1 of clopidogrel bisulfate in the United States. Only the Teva, Cobalt and Sun ANDAs contains a paragraph IV certification contesting the 265 patent claiming form 1. Teva and Cobalt's respective ANDAs claim the purported form 1 generics do not infringe patents related to a second crystalline form of clopidogrel bisulfate known as form 2. Form 2 is claimed by separate patents. Sanofi-aventis has filed suit against Teva and Cobalt for infringement of the 265 patent and against Sun for infringement of both form 1 and form 2 patents. In separate stipulations approved by the U.S. District Court for the Southern District of New York on April 15, 2005, all parties to each of the Teva and Cobalt patent infringement suits agreed to be bound by the outcome of the litigation in the District Court against Apotex or Dr. Reddy's. Teva and Cobalt are now bound by the Court of Appeals decision against Apotex and in January 2009, Sun agreed also to be bound by it.

F-80

---

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

Certain more significant Plavix<sup>®</sup>-related patent suits outside of the United States are described below.

*Korea.* A number of companies have received marketing authorizations in Korea for generic forms of clopidogrel bisulfate and other salts of clopidogrel. Sanofi-aventis has asserted the Korean patent for Plavix<sup>®</sup> (Korean Patent No. 103094) in patent infringement actions against a number of companies. On June 28, 2006, in a nullity action filed by several companies against Korean Patent No. 103094, the Korean Intellectual Property Tribunal issued a decision holding that this patent's claims were not patentable under Korean law. On January 18, 2008 this Intellectual Property Tribunal decision was upheld on appeal. Sanofi-aventis appealed to the Supreme Court on February 15, 2008 and the Supreme Court accepted the appeal.

*Canada.* In March 2005 the Canadian Federal Court of Ottawa issued an order of prohibition against the Minister of Health and Apotex Inc. in relation to Apotex's 2003 application in Canada to market a generic version of clopidogrel bisulfate tablets. In its order, the Canadian Federal Court held that the asserted claims of Canadian Patent No. 1,336,777 (which corresponds to the U.S. form 1 patent) are novel, not obvious and infringed. Attempts by Apotex to overturn the decision were dismissed on December 22, 2006, by the Canadian Federal Court of Appeals and on November 6, 2008, by the Supreme Court of Canada.

In similar litigation relating to their respective Canadian applications for a proposed generic clopidogrel bisulfate product, each of Pharmascience, Novopharm and Cobalt have agreed with sanofi-aventis that they will be bound by the final outcome of the Apotex case described above. Those proceedings are now being terminated given the decision of the Canadian Supreme Court.

*Australia.* On August 17, 2007, GenRX, a subsidiary of Apotex obtained registration of a generic clopidogrel bisulfate product on the Australian Register of Therapeutic Goods and sent notice to sanofi-aventis that it had in parallel applied to the Federal Court of Australia for an order revoking the Australian enantiomer patent claiming clopidogrel salts. On September 21, 2007, sanofi-aventis obtained a preliminary injunction from the Federal Court preventing commercial launch of this generic clopidogrel bisulfate product until judgment on the substantive issues of patent validity and infringement. In February 2008 Spirit also introduced a nullity action against the enantiomer patent. Spirit Proceeding was consolidated with the Apotex Proceeding.

On August 12, 2008 the Federal Court confirmed that the claim directed to clopidogrel bisulfate was valid and infringed. Claims covering the hydrochloride, hydrobromide and taurocholate salts also were found valid. However claim 1 of the patent directed to clopidogrel base and its unspecified salts has been found to be invalid. All parties have appealed. The Apotex and Spirit appeals are expected to be heard during the first quarter of 2009.

*Germany.* On May 28, 2008, sanofi-aventis became aware that the German federal drug agency (BfArM) had reviewed and approved three applications for marketing approval relating to clopidogrel besylate in Germany, ahead of the expiry date of the data exclusivity period for clopidogrel in the European Union (July 15, 2008). Clopidogrel besylate is a different pharmaceutical salt of clopidogrel from the one used in Plavix<sup>®</sup>, and the approvals granted cover only some of the indications of Plavix<sup>®</sup>. Sanofi-aventis believes that these applications—which rely on data from sanofi-aventis and Bristol-Myers Squibb, who developed Plavix<sup>®</sup>/ Iscover<sup>®</sup> (clopidogrel bisulfate)—should not have been accepted by a regulatory body within the European Union before July 15, 2008. Starting in May 2008, sanofi-aventis therefore instigated a number of civil, administrative and regulatory actions, which initially led to the suspension of the marketing authorizations pending further review by the

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

BfArM. On July 29, 2008, the German Administrative Court in Cologne issued an order ending the suspension of these marketing authorizations. This order was later confirmed in appeal. On November 17, 2008 BfArM dismissed the third party objection filed by sanofi-aventis. Further to this BfArM decision, sanofi-aventis and Bristol-Myers Squibb filed administrative actions for the annulment of the marketing authorizations before the Administrative Court of Cologne. These clopidogrel besylate products remain authorized for sale on the German market, and there can be no assurance that generics of Plavix® will not be authorized in other European markets.

F-81

---

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008***Allegra® Patent Litigation*

*United States.* Sanofi-aventis has been engaged in patent infringement actions concerning Allegra® since the first ANDA referring to this product was submitted to the FDA in 2001. In 2005, Barr Laboratories Inc. and Teva launched a generic version of Allegra® at risk, despite the patent infringement litigation pending against them and other ANDA filers. In November 2008, sanofi-aventis U.S. entered into agreements to settle the U.S. patent infringement suits related to Barr and Teva's generic version of Allegra® (fexofenadine hydrochloride), as well as the U.S. patent infringement suit related to Barr's proposed generic version of Allegra® D-12 Hour (fexofenadine hydrochloride; pseudoephedrine hydrochloride). The respective settlements each took effect on January 2, 2009.

Under the settlement agreements, the U.S. patent suits, including any damage claims, against Barr and Teva related to sanofi-aventis U.S. Allegra® patent and against Barr related to its U.S. Allegra® D-12 Hour patent were dismissed without prejudice; the Barr/Teva generic version of Allegra® product remains on the market under a non-exclusive license and Barr has been granted a non-exclusive license starting in November 2009 for the commercialization of Allegra® D-12 Hour in the United States (this date may be accelerated under certain circumstances), in each case with royalties paid to sanofi-aventis.

Sanofi-aventis U.S. continues to be involved in ongoing U.S. patent litigation against other parties in relation to the Allegra® single entity formulation (Mylan, Dr. Reddy's, Sandoz), Allegra® D-12 Hour (Impax, Mylan, Dr. Reddy's, Sandoz and Sun Pharma Global) as well as Allegra® D-24 Hour (Dr. Reddy's). These other suits were not settled by the agreements described above. The previously disclosed Israeli litigation against Teva has been resolved favorably for the Group.

*Actonel® Patent Litigation*

Actonel® is marketed by the Alliance for Better Bone Health, an alliance between Procter & Gamble Company and P&G Pharmaceuticals (together P&G) and Aventis Pharmaceuticals Inc. (API). P&G filed patent infringement litigation in 2004 against Teva Pharmaceuticals USA in the U.S. District Court for the District of Delaware in response to Teva's application to market a generic version of Actonel® (risedronate sodium) tablets in the United States. Sanofi-aventis is not a party to this action. On February 28, 2008 the United District Court for the District of Delaware held U.S. Patent 5,538,122 owned by P&G and claiming the active ingredient of Actonel® to be valid and enforceable.

P&G filed additional patent infringement actions against Teva in 2008 in response to Teva's applications to market a generic version of Actonel® 75mg tablets and Actonel® plus Calcium. In May 2008, the District Court judge entered an order of final judgment in favor of P&G in both cases and Teva has appealed all three final judgments. The three appeals have been consolidated by the Federal Circuit and a Hearing was held December 2, 2008.

In September 2008 and January 2009, P&G and Roche brought suit in the U.S. District Court of Delaware in response to respectively Teva's and Sun Pharma Global applications to market a generic version of the 150mg Actonel® tablets. These cases remain pending.



*Lovenox® Patent Litigation (enoxaparin sodium)*

*United States.* In June 2003, Aventis Pharmaceuticals Inc. (API) received notice that both Amphastar Pharmaceuticals and Teva Pharmaceuticals were seeking approval from the FDA for purportedly generic versions of Lovenox® (pre-filled syringes) and were challenging U.S. Patent No. 5,389,618 (the 618 patent ) listed in the Orange Book for Lovenox®. API brought a patent infringement suit against both Amphastar and Teva in U.S. District Court (Central District of California) on the 618 patent.

On February 8, 2007, the U.S. District Court for the Central District of California issued a decision in the sanofi-aventis Lovenox® patent infringement suit against Amphastar and Teva holding the 618 patent

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

unenforceable. The defendant's antitrust counterclaims have not been resolved by this decision and remain pending before the district court. On May 14, 2008, the Federal Circuit Court of Appeals denied sanofi-aventis' appeal of the District Court's decision and subsequently refused sanofi-aventis' petition to rehear the appeal en banc. In January 2009 Sanofi-aventis has petitioned the U.S. Supreme Court to hear the case.

Further to the Federal Circuit Amphastar decision of May 14, 2008, the U.S. District Court for the Central District of California has entered judgment against sanofi-aventis in two patent infringement suits brought against Sandoz and Hospira as a result of these companies' respective ANDAs relating to pre-filled syringe and multidose presentations of Lovenox®.

*Italy.* The company Opocrin has filed suit in Italy before the Tribunale di Milano (civil section) seeking a declaratory judgment of invalidity and of non-infringement with respect to the Italian patent covering Clexane® (enoxaparin sodium) which is the Italian counterpart to the U.S. patent number 5,389,618. The suit remains pending. Biofer and Chemi had also filed a similar suit in 2001. A judgment against these companies upholding the validity of the patent, within certain limitations, is under appeal.

*Germany.* The companies Hexal, Ratiopharm, Chemi and Opocrin have filed opposition proceedings with the German Federal Patent Court, requesting the revocation of the German patent DE 41 21 115 which claims the active ingredient of Clexane® (enoxaparin sodium) and is the German counterpart to the U.S. patent number 5,389,618. Following a hearing held in January 2009, judgment is awaited in the first quarter of 2009.

*Ramipril Canada Patent Litigation*

Sanofi-aventis is involved in a number of legal proceedings involving companies which market generic Altace® (ramipril) in Canada. Notwithstanding proceedings initiated by sanofi-aventis, the following eight manufacturers, Apotex (in 2006), Novopharm, Sandoz and Cobalt (in 2007), Riva, Genpharm, Ranbaxy and Pro Doc (in 2008), have now obtained marketing authorizations from the Canadian Minister of Health for generic versions of ramipril in Canada. Following the marketing of these products, sanofi-aventis filed patent infringement actions against all eight companies. Trial for patent infringement actions involving Apotex and Novopharm has been underway since January 2009. Each of Novopharm and Riva subsequently initiated damages claims against sanofi-aventis, seeking compensation for their alleged inability to market a generic ramipril during the time taken to resolve the proceedings against the Canadian Ministry of Health. The Novopharm claim has been stayed pending outcome of the infringement trial and the Riva proceeding is in an early stage.

*Taxotere® Patent Litigation*

*United States.* Sanofi-aventis has received notification from Hospira and Apotex who have filed (505(b)(2)) applications with the U.S. Food and Drug Administration (FDA) respectively in 2007 and 2008 seeking to market generic versions of Taxotere®. In response to these notifications, sanofi-aventis has filed patent infringement lawsuits against each applicant in 2007 and 2008. Presently, the lawsuits are pending in the U.S. District Court for the District of Delaware. Neither application contests U.S. patent 4,814,470 claiming the active ingredient, which expires in May 2010.

*Canada.* In October 2007, sanofi-aventis learned that Hospira Healthcare Corporation had filed an application with Canadian authorities for a marketing authorization for a proposed docetaxel product which is the active ingredient of Taxotere<sup>®</sup>, alleging that Aventis Pharma S.A.'s Canadian Patent Nos. 2,102,777 and 2,102,778 for docetaxel were invalid and not infringed. On November 29, 2007, sanofi-aventis Canadian subsidiary and Aventis Pharma S.A. commenced an application for judicial review in the Federal Court of Canada. In Canada, the compound patent relating to this product has expired.

*Eloxatin<sup>®</sup> (oxaliplatin) Patent Litigation*

*Europe.* Sanofi-aventis is no longer pursuing infringement suits or defending nullity actions relating to Eloxatine<sup>®</sup> in Europe (cases were previously pending in Germany, France and Austria).

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

*United States.* Starting in February 2007, sanofi-aventis has received several ANDA certifications relating to Eloxatine<sup>®</sup> (oxaliplatin) solution and/or lyophilized products in the United States contesting part or all of the Orange Book patents under paragraph IV. Each of the generic manufacturers has been sued for infringement of one or more of the Orange-Book listed patents before the U.S. District Court for the District of New Jersey. U.S. regulatory data exclusivity expired in February 2008.

Discovery is underway and the New Jersey court has permitted several generic filers to submit motions for a summary judgment. The first such motions, filed by Mayne Pharma Limited with respect to the U.S. Patent No. 5,338,874 ( 874) and by Sandoz concerning allegations of invalidity and non-infringement of the 874 patent and U.S. Patent No. 5,716,988, are expected to be decided in the first half of 2009. Summary judgment against sanofi-aventis on one or more of these motions could permit generic market entry, assuming FDA approval of the generic product has been obtained.

*Ambien<sup>®</sup> CR Patent Litigation*

Starting in 2007, sanofi-aventis filed suits for infringement of U.S. patent 6,514,531 in the U.S. District Court for the District of New Jersey based on ANDAs for a generic version of Ambien<sup>®</sup> CR filed by Synthon, Barr, Mutual and Sandoz.

Sanofi-aventis has not brought suit against Anchen, which was the first to notify sanofi-aventis of its paragraph-IV ANDA, or against Abrika, Lupin, Andrx and PTS Consulting. In addition to its Orange-Book listed patent 6,514,531 expiring in 2019, Ambien<sup>®</sup> CR benefits from an FDA marketing exclusivity in the United States expiring in March 2009.

*Nasacort<sup>®</sup> AQ Patent Litigation*

In March 2006, sanofi-aventis was notified that Barr Laboratories had submitted an ANDA to the FDA containing a paragraph IV patent certification relating to triamcinolone acetonide 55 microgram nasal spray (Nasacort<sup>®</sup> AQ). Further to this notification, sanofi-aventis filed a patent infringement lawsuit in the U.S. District Court of Delaware against Barr Laboratories, Inc. regarding two Nasacort<sup>®</sup> AQ patents (U.S. Patent nos. 5,976,573 and 6,143,329). In November 2008, sanofi-aventis U.S. and Barr entered into an agreement to settle the U.S. patent infringement suits related to Barr's proposed generic version of Nasacort<sup>®</sup> (triamcinolone acetonide) AQ. This settlement took effect on January 2, 2009.

Under the settlement agreement, the U.S. patent suit has been dismissed without prejudice and Barr has been granted a license authorizing production and marketing of a generic of this product for the United States market no earlier than June 2011 and at the latest December 2013; this date may be accelerated under certain conditions.

*SoloSTAR® Patent Litigation*

On July 10, 2007, Novo Nordisk filed complaints in the Courts of Düsseldorf and Mannheim in Germany, and in the U.S. district Court for the District of New Jersey, alleging the Group's new Lantus® SoloSTAR® disposable insulin pen infringes various Novo Nordisk patent and intellectual property rights. For the New Jersey action Novo Nordisk also served a motion for a preliminary injunction for the court to enjoin the selling of the SoloSTAR® device in the United States. On February 19, 2008 the United States District Court for the District of New Jersey denied Novo Nordisk's request for a preliminary injunction against sanofi-aventis. On July 30, 2008, this ruling was confirmed on appeal. In September 2008, Novo Nordisk filed a motion for summary judgment for alleged infringement of its patent rights. No hearing date has been set.

On May 20, 2008, the Court of Mannheim dismissed Novo Nordisk's suit based on infringement of its German Utility Model by the Lantus® SoloSTAR® disposable insulin pen. On August 8, 2008 the court of Düsseldorf dismissed Novo Nordisk's suit based on infringement of its German patent by the Lantus® SoloSTAR® insulin pen. Novo Nordisk has appealed in each case.

---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

Sanofi-aventis has also been involved in related patent litigation with a subsidiary of Ypsomed, the supplier of OptiPen<sup>®</sup>, OptiSet<sup>®</sup>, and OptiClik<sup>®</sup> to Sanofi-Aventis Deutschland GmbH. On April 18, 2008 sanofi-aventis and Ypsomed agreed to settle all currently pending patent disputes and other litigations in Germany and Switzerland between these companies regarding the new Lantus<sup>®</sup> SoloSTAR<sup>®</sup> and Apidra<sup>®</sup> SoloSTAR<sup>®</sup> disposable insulin pens. Those cases were withdrawn in May 2008.

*Xatral<sup>®</sup> Patent Litigation*

Starting in August 2007, sanofi-aventis has received several ANDA certifications relating to Xatral<sup>®</sup> in the United States under paragraph IV. Each of the generic manufacturers has been sued for infringement of one or both of the Orange-Book listed patents before the U.S. District Court, District of Delaware. Trial has been scheduled for March 2010.

*Xyzal<sup>®</sup> Tablets ANDA*

Sanofi-aventis has a co-commercialization agreement with UCB Inc. with respect to Xyzal<sup>®</sup> in the United States. Sanofi-aventis is aware that UCB has received four paragraph IV certifications since February 2008 from Synthon Pharma. Inc., Sun Pharmaceuticals, Sandoz Inc., and Barr Laboratories. All the generic manufacturers have been sued by UCB for patent infringement in cases pending before the U.S. District Court of North Carolina.

***Glossary of Patent Terminology***

A number of technical terms used above in Note D.22.b are defined below for the convenience of the reader.

*ANDA or Abbreviated New Drug Application (United States):* An application by a drug manufacturer to receive authority from the U.S. FDA to market a generic version of another company's approved product, by demonstrating that the purportedly generic version has the same properties (bioequivalence) as the original approved product. As a result of data exclusivity, the ANDA may be filed only several years after the initial market authorization of the original product.

*Paragraph III and Paragraph IV Certifications:* ANDAs relating to approved products for which a patent has been listed in the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book, must specify whether final FDA approval of the ANDA is sought only *after* expiration of the listed patent(s) (this is known as a paragraph III certification under the Hatch-Waxman Act) or whether final FDA approval is sought *prior* to expiration of one or more listed patents (a paragraph IV certification). ANDAs including a paragraph IV certification may be subject to the 30-Month Stay defined below.

*Section 505(b)(2) application:* A section 505(b)(2) application may be used to seek FDA approval for, among other things, combination products, different salts of listed drugs, products that do not demonstrate bioequivalence to a listed drug and over-the-counter versions of prescription drugs.

*Summary judgment:* A judgment granted on a claim or defense about which there is no genuine issue of material fact and upon which the movant is entitled to prevail as a matter of law. This procedural device allows the speedy disposition of a controversy without the need for trial.

*30-Month Stay (United States):* If patent claims cover a product listed in the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book, and are owned by or licensed to the manufacturer of the original version, the FDA is barred from granting a final approval to an ANDA during the 30 months following the patent challenge, unless, before the end of the 30 months, a court decision or settlement has determined either that the ANDA does not infringe the listed patent or that the listed patent is invalid and/or unenforceable. FDA approval of an ANDA after this 30 month period does not resolve outstanding patent disputes, which may continue to be litigated in the courts.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008****c) Government Investigations, Competition Law and Regulatory Claims***Government Investigations Plavix® Settlement*

The Antitrust Division of the United States Department of Justice is conducting a criminal investigation regarding the proposed settlement described at Patents Plavix® Patent Litigation United States above, and sanofi-aventis U.S. has received grand jury subpoenas seeking the production of documents. In addition, in 2006 the U.S. Federal Trade Commission and the State of New York's Attorney General served subpoenas on sanofi-aventis U.S. subsidiary requesting production of certain documents and information relating to the proposed settlement of the U.S. Plavix® patent litigation against Apotex. Sanofi-aventis U.S. has provided all information required in response to these investigations. It is not possible at this time reasonably to assess the outcome of these investigations or their potential impact on the group.

*Government Investigations Pricing and Marketing Practices*

*Private Label.* The U.S. Attorney's Office in Boston had conducted a civil and criminal investigation into whether sales by Aventis Pharmaceuticals Inc. (API) of certain products to a managed care organization for resale under that organization's own label should have been included in the "best price" calculations that are used to compute the Medicaid rebates for API products. Medicaid is a public medical insurance program jointly financed by the U.S. state and federal governments. It is alleged that not including these sales in the calculation resulted in incorrect Medicaid rebates. API has responded to all requests for information in this matter. Although the Group believes that API acted in accordance with the law as it and other pharmaceutical companies interpreted it, the Group is progressing significantly in settlement talks with the Department of Justice, as a result of which the Group has aligned the level of its reserves.

*Massachusetts Physician.* The U.S. Attorney's Office in Boston is also conducting a civil and criminal investigation with regard to interactions API had with a Massachusetts physician, and affiliated managed care entities. Sanofi-aventis has responded to all subpoenas related to this investigation.

*Managed Care Investigation.* The U.S. Attorney's Office in Boston is conducting an investigation related to managed care entities which includes allegations that API directly or indirectly made payments to customers or to those in a position to influence sales of API pharmaceuticals in order to obtain or keep drug business and to evade Medicaid best price reporting requirements. As part of the investigation the government served API with a subpoena investigating criminal federal health care violations related to health care benefit programs. The subpoena asked for documents related to API interactions with, and payments to, managed care customers, formulary placement, sales and marketing of specific products to those managed care customers, as well as contracts with wholesalers and distributors and payments to non-Aventis employees. Sanofi-aventis has responded to this subpoena.

*Lahey Clinic.* In 2004, API and Aventis Behring received subpoenas issued by the U.S. Attorney's office in Boston requesting documents concerning payments and contacts between these companies and the Lahey Clinic, a Massachusetts healthcare facility, or certain of its employees, relating to various periods between January 1995 and October 2004. API and Aventis Behring have provided documents in response



to these subpoenas.

*Lovenox® Marketing.* The U.S. Attorney's Office in Chicago, Illinois has conducted a civil and criminal investigation with regard to Lovenox® sales and marketing practices for a period starting January 1, 1999. Without prejudice to its right to pursue any further investigation in the future, the U.S. government has declined to intervene in a Federal False Claims Act case related to the facts under investigation brought by two former employees, and the matter is proceeding against the Company as civil litigation in Illinois federal court under federal and Illinois whistleblower statutes.

*Ambien® and Ambien® CR Marketing.* On 11 August 2008, sanofi-aventis U.S. received subpoena issued by the Office of Inspector General. The subpoena requested information regarding Ambien® and Ambien® CR in

---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

connection with an investigation of possible false or otherwise improper claims for payment under Medicare and Medicaid. Sanofi-aventis U.S. is providing documents in response to these subpoenas.

*Civil Suits Pricing and Marketing Practices*

*Average Wholesale Prices (AWP). Class Actions.* Aventis Pharmaceuticals Inc. (API) is a defendant in several U.S. lawsuits seeking damages on behalf of multiple putative classes of individuals and entities that allegedly overpaid for certain pharmaceuticals as a result of the AWP pricing which were used to set Medicare and Medicaid reimbursement levels. Aventis Behring and Sanofi-Synthelabo, Inc. were also defendants in some of these cases. These suits allege violations of various statutes, including state unfair trade, unfair competition, consumer protection and false claim statutes.

A group of eleven defendants, including API, reached a tentative global settlement of the claims of the insurers and consumers, for a total of \$125 million. This settlement was granted preliminary approval by the U.S. District Court in Boston in early July, 2008. Subject to the final approval hearing set for April 27, 2009, all the class actions suits against API before the U.S. District Court in Boston will be ended consistent with this settlement. Two additional purported class actions remain in two distinct states.

*AWP Public Entity Suits.* U.S. subsidiaries of the Group together with several dozen other pharmaceutical companies are defendants in lawsuits brought starting in 2002 by the states of Alabama, Alaska, Hawaii, Idaho, Iowa, Illinois, Kansas, Kentucky, Mississippi, Pennsylvania Utah, and Wisconsin for AWP pricing issues described above. These suits alleged violations of state unfair trade, consumer protection and false claims statutes, breach of contract, and Medicaid fraud. The Iowa and Utah cases are before the federal district court in Boston. All of the other state suits are pending before other federal courts or in the state courts in which they were filed. Arizona, Montana and Nevada suits were settled in 2008.

Aventis Pharmaceuticals Inc., Sanofi-Synthelabo Inc. and other pharmaceutical companies had also been sued by the state of New York, several individual New York State counties and the City of New York, in suits alleging similar violations of state laws concerning pricing and marketing practices. A settlement of all these claims was completed in April 2008.

*§ 340B Suits.* On August 18, 2005, the County of Santa Clara, California filed a suit against Aventis Pharmaceuticals Inc. and fourteen other pharmaceutical companies in the Superior Court of the State of California, County of Alameda alleging that the defendants had overcharged Public Health Service entities for their pharmaceutical products. Plaintiff seeks to proceed on behalf of a California-wide class of similarly situated cities and counties in California. On September 15, 2005, the case was removed from Alameda Superior Court to the U.S. District Court. On July 28, 2006 the defendants were successful in dismissing plaintiffs' complaint in its entirety, with prejudice, for failure to state a claim. In August 2008, the Court of Appeals reversed the district court's decision with respect to one cause of action, specifically breach of contract, and remanded the case back to the District Court. In December 2008, Plaintiffs formally amended the complaint to assert this breach of contract claim.

*Pharmaceutical Industry Antitrust Litigation*

Approximately 135 cases remain pending of the numerous complaints that were filed in the mid-1990 s by retail pharmacies in both federal and state court. These complaints shared the same basic allegations: that the defendant pharmaceutical manufacturers and wholesalers, including sanofi-aventis predecessor companies, violated the Sherman Act, the Robinson Patman Act, and various state antitrust and unfair competition laws by conspiring to deny all pharmacies, including chains and buying groups, discounts off the list prices of brand-name drugs. Shortly before a November 2004 trial in the U.S. District Court for the Eastern District of New York, sanofi-aventis and the remaining manufacturer defendants settled the Sherman Act claims of the majority of the remaining plaintiffs. These settlements did not dispose of the remaining plaintiffs Robinson Patman Act claims.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

*Vitamin Antitrust Litigation*

Since 1999, sanofi-aventis, some of its subsidiaries in its former animal nutrition business, and other vitamin manufacturers have been defendants in a number of class actions and individual lawsuits in U.S. courts relating to alleged anticompetitive practices in the market for bulk vitamins. Sanofi-aventis has settled all claims brought by direct purchasers of the relevant vitamin products and the majority of actions brought on behalf of indirect purchasers.

In February 2006, sanofi-aventis and Aventis Pharmaceuticals Inc. learned that they had been named together with several other companies in a complaint filed by the Attorney General of Mississippi on the grounds of state antitrust law.

Regarding the same matter, all but one of the UK claimants have agreed to settle the civil litigation against sanofi-aventis and some of its subsidiaries for an amount not material in amount to the Group. The settlement agreement, if approved by the court, is expected to take effect in 2009.

In connection with the sale of its animal nutrition business to CVC Capital Partners, sanofi-aventis retains liability arising out of these antitrust issues.

*Methionine Antitrust Litigation*

Sanofi-aventis has settled all direct purchaser civil claims brought in the United States against sanofi-aventis and its subsidiaries relating to methionine sales and has settled the majority of claims brought by indirect purchasers starting in 2002. In connection with the sale of its animal nutrition business to CVC Capital Partners, sanofi-aventis retains liability arising out of these antitrust issues.

*European Commission Fines*

On June 18, 2008, the European Court of First Instance, reduced from 99 million to 74.25 million the fine imposed against Hoechst GmbH in 2003 by the European Commission in connection with Hoechst's involvement in anti-competitive activity in the Sorbates sector. Pursuant to the 1999 Demerger Agreement between Hoechst and Celanese, all fines, costs, and expenses relating to Sorbates cartel matters have been shared in a 80/20 ratio between Hoechst and Celanese.

The appeal regarding the MCAA market fine ( 74 million) filed by Hoechst GmbH remains pending.

*European Commission proceeding in connection with the pharmaceuticals Sector Inquiry*

In January 2008, the European Commission's Directorate General for Competition opened a sector inquiry into the functioning of the market to investigate what it considered to be a low level of competition in the pharmaceuticals industry in the European Union. The inquiry commenced with unannounced information-gathering inspections at a number of companies including sanofi-aventis. According to the Commission, the sector inquiry ultimately involved information gathering from 43 originator companies and 27 generic companies. The sector inquiry continues, with an interim report published on November 28, 2008, and a final report and possible subsequent legislative and other actions in 2009.

On May 15, 2008, the European Commission opened a formal investigation into whether sanofi-aventis had illegally obstructed the inspection of its premises. The controversy with the Commission centered on a question of procedure concerning the handing over of a single document requested by the European Commission and in fact delivered by sanofi-aventis during the inspection. In October 2008, that investigation was closed with no action taken by the Commission.

*Cipro® Antitrust Litigation*

Since August 2000, Aventis Pharmaceuticals Inc. (API) has been a defendant in several related cases in U.S. state and federal courts alleging that API and certain other pharmaceutical manufacturers violated U.S. antitrust

---

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

laws and various state laws by settling a patent dispute regarding the brand-name prescription drug Cipro<sup>®</sup> in a manner which allegedly delayed the arrival of generic competition. In March 2005, the U.S. District Court for the Eastern District of New York granted sanofi-aventis' summary judgment motions, and issued a judgment in favor of API and the other defendants in this litigation. By order entered October 15, 2008, the United States Court of Appeals for the Federal Circuit affirmed the District Court's ruling in the appeal by indirect purchaser plaintiffs; the direct purchaser plaintiffs' appeal has yet to be heard by the United States Court of Appeals for the Second Circuit.

*DDAVP<sup>®</sup> Antitrust Litigation*

Subsequent to the decision of the U.S. District Court for the Southern District of New York in February 2005 holding the patent rights at issue in the DDAVP<sup>®</sup> tablet litigation to be unenforceable as a result of inequitable conduct, eight putative class actions have been filed claiming injury as a result of Ferring B.V. and Aventis Pharmaceuticals Inc.'s alleged scheme to monopolize the market for DDAVP<sup>®</sup> tablets in violation of the Sherman Act and the antitrust and deceptive trade practices statutes of several states. On November 6, 2006, the District Court dismissed these claims. Plaintiffs have appealed the decision to dismiss.

*Plavix<sup>®</sup> Antitrust Claim*

On March 23, 2006, the U.S. retailer The Kroger Co. filed an antitrust complaint in the District Court for the Southern District of Ohio against sanofi-aventis, Bristol-Myers Squibb Co. and Apotex Corp alleging antitrust violations by the defendants in relation to their tentative agreement to settle the U.S. Plavix<sup>®</sup> patent litigation (see *Plavix<sup>®</sup> Patent Litigation - United States*, above, for a description of the transaction). 17 other complaints have since been filed by direct and indirect purchasers of Plavix<sup>®</sup> on the same or similar grounds. Plaintiffs seek relief including injunctive relief and monetary damages.

*Arava<sup>®</sup> Antitrust Litigation*

Sanofi-aventis and certain U.S. subsidiaries of the Group were defendants in a lawsuit brought in the U.S District Court for the Southern District of New York in August, 2007 by Louisiana Wholesale Drug Co. on behalf of itself and a proposed class of all direct purchasers of Arava<sup>®</sup>. Under the federal antitrust laws plaintiffs alleged that the Group had misused the Citizen Petition process in an attempt to delay approval of generic leflunomide by the U.S Food and Drug Administration, thereby injuring the class. On November 20, 2008 a jury rejected plaintiffs' allegations that sanofi-aventis had inappropriately filed the Citizen Petition. The plaintiffs have requested the judge to reconsider the jury's verdict.

*Lovenox<sup>®</sup> Antitrust Litigation*

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

On August 2008, Eisai Inc. ( Eisai ) brought suit against sanofi-aventis U.S., LLC and sanofi-aventis U.S., Inc. in the United States District Court for the District of New Jersey (Newark) alleging that certain contracting practices for Lovenox<sup>®</sup> violate federal and state antitrust laws. In October 2008, the defendants filed a motion to dismiss Eisai s complaint.

### **d) Other litigation and arbitration**

#### *Hoechst Shareholder Litigation*

On December 21, 2004 the extraordinary General Meeting of sanofi-aventis German subsidiary Hoechst AG (now Hoechst GmbH) approved a resolution transferring the shares held by minority shareholders to sanofi-aventis for compensation of 56.50 per share. Certain minority shareholders filed claims contesting the validity of the resolution, preventing its registration with the commercial register of Frankfurt and entry into effect.

On July 12, 2005, this litigation was settled. As a consequence, the squeeze out has been registered in the commercial register making sanofi-aventis the sole shareholder of Hoechst AG.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

According to the settlement agreement the cash compensation has been increased to 63.80 per share. The cash compensation was further increased by another 1.20 per share for those outstanding shareholders who inter alia waived in advance any increase of the cash compensation obtained through a judicial appraisal proceeding (*Spruchverfahren*) brought by former minority shareholders. Subsequently, a number of former minority shareholders of Hoechst initiated a judicial appraisal proceeding with the local Frankfurt court *Landgericht Frankfurt am Main* contesting the amount of the cash compensation paid in the squeeze out. The amount sought has not been specified. The proceedings are ongoing.

*Apotex Settlement Claim*

*Canada* On April 18, 2007, Apotex Inc. and Apotex Corporation filed a claim before Ontario Court of Justice against sanofi-aventis, sanofi-aventis Inc, Bristol-Myers Squibb Company and Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership, claiming the payment of \$60 million, allegedly pursuant to the terms of the initial settlement agreement of March 2006 relating to the U.S. Plavix® patent litigation (described at Patents Plavix® Patent Litigation United States ). Sanofi-aventis and BMS contested both the substance and the admissibility of this claim. In January 2008, the Court determined that Apotex's claim was non-admissible on the basis of the jurisdiction/forum non conveniens. Apotex's appeal was denied in the last quarter of 2008.

*United States* On November 13, 2008 Apotex filed a complaint before a state court in New Jersey against sanofi-aventis and BMS claiming the payment of a \$60 million as break-up fee, pursuant to the terms of the initial settlement agreement of March 2006 relating to the U.S. Plavix® patent litigation (see Patents Plavix® Patent Litigation United States ). Sanofi-aventis and BMS have removed the case to the U.S. District Court for the District of New Jersey, and Apotex subsequently filed a motion to remand the case back to New Jersey state court.

*Zimulti® /Acompli® (rimonabant) class action*

In November 2007 a purported class action was filed in the United States District Court for the Southern District of New York on behalf of purchasers of sanofi-aventis shares. The complaint charges sanofi-aventis and certain of its current and former officers and directors with violations of the Securities Exchange Act of 1934. The complaint alleges that defendants' statements regarding rimonabant were materially false and misleading when made because defendants allegedly concealed data concerning rimonabant's propensity to cause depression. An amended complaint was filed by the plaintiffs on April 29, 2008. On June 30, 2008 sanofi-aventis filed a response including a motion to dismiss the amended complaint, and hearings will be held in the first part of 2009.

*U.S. Gender discrimination*

Certain female U.S. pharmaceutical sales representatives of sanofi-aventis brought a putative class action lawsuit against sanofi-aventis U.S. LLC in the United States District Court for the Southern District of New York alleging gender discrimination. The parties are currently engaged in discovery regarding the individual claims of the named plaintiffs and the question of whether the case can be properly certified as a class action.



**e) Contingencies arising from certain Business Divestitures**

Sanofi-aventis and its subsidiaries, Hoechst and Aventis Agriculture, divested a variety of mostly chemical, including agro-chemical, businesses as well as certain health product businesses in previous years. As a result of these divestitures, the Group is subject to a number of ongoing contractual and legal obligations regarding the state of the sold businesses, their assets, and their liabilities.

F-90

---

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008***Aventis Behring*

The divestment of Aventis Behring and related protein therapies assets became effective on March 31, 2004. The purchase agreement contained customary representations and warranties running from sanofi-aventis as seller to CSL Limited as purchaser. Sanofi-aventis has indemnification obligations that generally expired on March 31, 2006 (the second anniversary of the Closing Date). However, some indemnification obligations having a longer duration, remain in effect, for example: indemnification obligations relating to the due organization, capital stock and ownership of Aventis Behring Companies runs through March 31, 2014, environmental indemnification through March 31, 2009, and product liability indemnification through March 31, 2019, subject to extension for claims related to types of product liability notified before such date. Furthermore, for tax related issues, sanofi-aventis indemnification obligation covers all taxable periods that end on or before the Closing Date and expires thirty days after the expiration of the applicable statute of limitations. In addition, the indemnification obligations relating to certain specified liabilities, including HIV liability, survive indefinitely.

Under the indemnification agreement, sanofi-aventis is generally obligated to indemnify, only to the extent indemnifiable, losses exceeding \$10 million and up to a maximum aggregate amount of \$300 million. For environmental claims, the indemnification due by sanofi-aventis equals 90% of the indemnifiable losses. Product liability claims are generally treated separately, and the aggregate indemnification is capped at \$500 million. Certain indemnification obligations, including those related to HIV liability, as well as tax claims, are not capped in amount.

*Aventis CropScience*

The sale by Aventis Agriculture and Hoechst (both predecessor companies of sanofi-aventis) of their aggregate 76% participation in Aventis CropScience Holding (ACS) to Bayer and Bayer CropScience AG (BCS), the wholly owned subsidiary of Bayer which holds the ACS shares, was effective on June 3, 2002. The Stock Purchase Agreement dated October 2, 2001 contained customary representations and warranties with respect to the sold business as well as a number of indemnifications, in particular with respect to: environmental liabilities (the representations and warranties and the environmental indemnification are subject to a cap of \$836 million, except for certain legal representations and warranties and specific environmental liabilities notably third-party site claims (i) such as the natural resources damages (NRD) claim filed by the state of New Jersey against BCS in 2007 in relation to the Factory Lane site and (ii) a remediation and NRD project underway in Portland, Oregon); taxes; certain legal proceedings; claims related to StarLink<sup>®</sup> corn; and certain pre-closing liabilities, in particular, product liability cases (which are subject to a cap of \$418 million). There are various periods of limitation depending upon the nature or subject of the indemnification claim. Further, Bayer and Bayer CropScience are subject to a number of obligations regarding mitigation and cooperation.

Starting with a first settlement agreement signed in December 2005, Aventis Agriculture and Hoechst have resolved a substantial number of disputes with Bayer and Bayer CropScience AG, including the termination of arbitration proceedings, for an alleged breach of a financial statement-related representation contained in the Stock Purchase Agreement, and numerous other warranty and indemnification claims asserted under the Stock Purchase Agreement, including claims relating to certain environmental liabilities. A number of other outstanding claims remain unresolved.

*LLRICE601 and LLRICE604 U.S. Litigation:* Bayer CropScience has sent sanofi-aventis notice of potential claims for indemnification under various provisions of the Stock Purchase Agreement. These potential claims relate to several class-action and individual complaints that have

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

been filed since August 2006 by rice growers, millers, and distributors in U.S. state and federal courts against a number of current and former subsidiaries (collectively the CropScience Companies ) which were part of the Aventis CropScience group prior to Bayer's acquisition of the ACS shares. Plaintiffs in these cases seek to recover damages, of an unspecified amount, in connection with the detection of trace amounts of the genetically modified rice called Liberty Link Rice 601 (also known as LLRICE601 ) or LibertyLink 604 (also known as LLRICE604 ) in samples of commercial long-grain rice. LLRICE601 and LLRICE604, each a variety of long grain rice

F-91

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

genetically altered to resist Liberty® Herbicide, were grown in field tests in the United States from the years 1998 to 2001. Plaintiffs assert a number of causes of action, alleging that the CropScience Companies failed to take adequate measures to prevent cross-pollination or commingling of LLRICE601 and/or LLRICE604 with conventional rice.

Sanofi-aventis denies direct or indirect liability for these cases, and has so notified Bayer CropScience.

In a related development, the FDA has concluded that the presence of LLRICE601 in the food and feed supply poses no safety concerns and on November 24, 2006, the United States Department of Agriculture (USDA) announced it would deregulate LLRICE601. With respect to LLRICE 604, the USDA announced in March 2007 that the PAT protein contained in LLRICE604 has a long history of safe use and is present in many deregulated products. Further to an investigation regarding the causation chain that led to contamination, in October 2007 the USDA declined to pursue enforcement against Bayer CropScience.

*Aventis Animal Nutrition*

Aventis Animal Nutrition S.A. and Aventis (both predecessor companies of sanofi-aventis) signed an agreement for the sale to Drakkar Holdings SA of the Aventis Animal Nutrition business effective in April 2002. The sale agreement contained customary representations and warranties. Sanofi-aventis indemnification obligations ran through April 2004, except for environmental indemnification obligations (which run through April 2012), tax indemnification obligations (which run through the expiration of the applicable statutory limitation period), and antitrust indemnification obligations (which extend indefinitely). The indemnification undertakings are subject to an overall cap of 223 million, with a lower cap for certain environmental claims. Indemnification obligations for antitrust and tax claims are not capped.

*Messer Griesheim GmbH*

Pursuant to an agreement dated December 30/31, 2000, Hoechst sold its 66.7% participation in the industrial gasses company Messer Griesheim GmbH. All purchaser claims under the representations and warranties of the agreement except those relating to tax and environmental matters were settled under an agreement entered into in July 2003. Tax and environmental claims are handled on an ongoing case by case basis.

*Celanese AG*

The demerger of the specialty chemicals business to Celanese AG became effective on October 22, 1999. Under the demerger agreement between Hoechst and Celanese, Hoechst expressly excluded any representations and warranties regarding the shares and assets demerged to Celanese. However, the following obligations of Hoechst are ongoing:

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

While all obligations of Hoechst (i) resulting from public law or (ii) pursuant to current or future environmental laws or (iii) vis-à-vis third parties pursuant to private or public law related to contamination (as defined) have been transferred to Celanese in full, Hoechst split with Celanese any such cost incurred under these obligations applying a 2:1 ratio.

To the extent Hoechst is liable to purchasers of certain of its divested businesses (as listed in the demerger agreement), Celanese must indemnify Hoechst, as far as environmental damages are concerned, for aggregate liabilities up to 250 million, liabilities exceeding such amount will be borne by Hoechst alone up to 750 million, and amounts exceeding 750 million will be borne 2/3 by Hoechst and 1/3 by Celanese without any further caps.

Compensation paid to third parties by Celanese under the aforementioned clause, through December 31, 2008 was significantly below the first threshold of 250 million.

---

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008***Rhodia*

In connection with the initial public offering of Rhodia in 1998, Rhône-Poulenc (later named Aventis, to which sanofi-aventis is the legal successor in interest) entered into an Environmental Indemnification Agreement with Rhodia on May 26, 1998 under which, subject to certain conditions, Rhodia was entitled to claim indemnification from Aventis with respect to direct losses resulting from third party claims or public authority injunctions for environmental damages. Aventis and Rhodia entered into a settlement agreement on March 27, 2003 under the terms of which the parties settled all environmental claims in connection with the Environmental Indemnification Agreement. Notwithstanding this settlement agreement, Rhodia and certain of its subsidiaries have unsuccessfully sought indemnification for environmental costs in the United States and Brazil. In both instances, the suits were decided in sanofi-aventis' favor with the court holding that the settlement precluded the indemnification claims. The decision in Brazil is currently under appeal by Rhodia.

On April 13, 2005 Rhodia initiated an *ad hoc* arbitration procedure seeking indemnification from sanofi-aventis for the financial consequences of the environmental liabilities and pension obligations that were allocated to Rhodia through the various operations leading to the formation of Rhodia in 1997, amounting respectively to 125 million and 531 million. Rhodia additionally sought indemnification for future costs related to transferred environmental liabilities and coverage of all costs necessary to fully fund the transfer of pension liabilities out of Rhodia's accounts. The arbitral tribunal has determined that it has no jurisdiction to rule on pension claims and that Rhodia's environmental claims are without merit. In May 2008, the Paris Court of Appeals rejected the action initiated by Rhodia to nullify the 2006 arbitral award in favor of sanofi-aventis.

On July 10, 2007 sanofi-aventis was served with a civil suit brought by Rhodia before the Paris Commercial Courts seeking indemnification on the same grounds as described above. The relief sought in the Paris Commercial Court is identical to the relief claimed in Rhodia's arbitration demand. The procedure is still pending.

*Rhodia Shareholder Litigation*

In January 2004, two minority shareholders of Rhodia and their respective investment vehicles filed two claims before the Commercial Court of Paris (*Tribunal de Commerce de Paris*) against Aventis, to which sanofi-aventis is successor in interest, together with other defendants including former directors and statutory auditors of Rhodia from the time of the alleged events. The claimants seek a judgment holding the defendants collectively liable for alleged management errors and for alleged publication of misstatements between 1999 and 2002 and *inter alia* regarding Rhodia's acquisition of the companies Albright & Wilson and ChiRex. These shareholders seek a finding of joint and several liability for damages to be awarded to Rhodia in an amount of 925 million for alleged harm to the Company (a derivative action), as well as personal claims of 4.3 million and 125.4 million for their own alleged individual losses. Sanofi-aventis contests both the substance and the admissibility of these claims.

Sanofi-aventis is also aware of three criminal complaints filed in France by the same plaintiffs and of a criminal investigation order issued by the Paris public prosecutor following the submission of the report issued by the *Autorité des marchés financiers* regarding Rhodia's financial communications. In 2006, the Commercial Court of Paris accepted sanofi-aventis and the other defendants' motion to stay the civil litigation pending the conclusion of the criminal proceedings. The plaintiffs' appeals against this decision, first before the Court of Appeals, and then

before the *Cour de cassation* (the French Supreme Court), were both rejected.

*Clariant Specialty Chemicals Business*

Hoechst conveyed its specialty chemicals business to Clariant AG pursuant to a 1997 agreement. While Clariant has undertaken to indemnify Hoechst for all costs incurred for environmental matters relating to purchased sites, certain ongoing indemnification obligations of Hoechst for environmental matters in favor of Clariant can be summarized as follows:

Costs for environmental matters at the sites taken over directly or indirectly by Clariant and not attributable to a specific activity of Hoechst or of a third party not related to the business transferred to

---

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

Clariant are to be borne by Clariant to the extent the accumulated costs since the closing in any year do not exceed a threshold amount for the then current year. The threshold increases annually from approximately 102 million in 1997/98 to approximately 816 million in the fifteenth year after the closing. Only the amount by which Clariant's accumulated costs exceed the then-current year's threshold must be compensated by Hoechst. No payments have yet become due under this rule.

Hoechst must indemnify Clariant indefinitely (i) for costs attributable to four defined waste deposit sites in Germany which are located outside the sites taken over by Clariant (to the extent exceeding an indexed amount of approximately 20.5 million), (ii) for costs from certain locally concentrated pollutions in the sites taken over by Clariant but not caused by specialty chemicals activities in the past, and (iii) for 75% of the costs relating to a specific waste deposit site in Frankfurt, Germany.

*InfraServ Höchst*

By the Asset Contribution Agreement dated December 19/20, 1996 as amended in 1997, Hoechst contributed all land, buildings, and related assets of the Hoechst site at Frankfurt-Höchst to InfraServ Höchst GmbH & Co KG. InfraServ Höchst undertook to indemnify Hoechst against environmental liabilities at the Höchst site and with respect to certain landfills. As consideration for the indemnification undertaking, Hoechst transferred to InfraServ approximately 57 million to fund reserves. In 1997, Hoechst also agreed it would reimburse current and future InfraServ Höchst environmental expenses up to 143 million. As a former owner of the land and as a former user of the landfills Hoechst may ultimately be liable for costs of remedial action in excess of this amount.

*DyStar*

Hoechst held a 35% interest in the DyStar group of companies, whose business is the manufacturing and marketing of textile dyestuffs. The other shareholders were Bayer Chemicals AG (35%) and BASF AG (30%). Hoechst, as well as Bayer and BASF, sold their interests to an investment vehicle of Platinum Equities LLP in August 2004. In addition to customary representations and warranties, the selling shareholders agreed to a guarantee on certain minimum purchases by the sellers from the DyStar group (including a certain minimum return to DyStar) within a period of four years following the closing. Various purchasers have submitted claims related to environmental and tax matters, as well as under the minimum purchase guarantee are handled on an ongoing case by case basis.

*Albemarle Arbitration*

In 1992, Rhône-Poulenc S.A. (a predecessor company of sanofi-aventis) signed with Ethyl Overseas Development, now known as Albemarle, a Stock Purchase Agreement by which Rhône-Poulenc sold 100% of the share capital of Potasse et Produits Chimiques S.A. (PPC) to Ethyl. Under the terms of the Stock Purchase Agreement, Rhône-Poulenc agreed to indemnify Albemarle for and to hold it harmless from any claims, losses, damages, costs or any other present and prospective liabilities arising out of soil and/or groundwater contamination at the site of the Thann facility. Albemarle sought indemnification by sanofi-aventis for environmental expenses incurred, citing the Stock Purchase Agreement. Following a dispute concerning its claims to indemnification, Albemarle initiated arbitration proceedings in the International Chamber of Commerce in Paris against sanofi-aventis.



## Edgar Filing: SANOFI-AVENTIS - Form 20-F

In August 2006, Albemarle Corporation sold Albemarle France (the party to the above mentioned arbitration) to the German company, International Chemical Investors. In April 2008, sanofi-aventis and International Chemical Investors agreed to settle the ongoing dispute for an amount of 19 million to be paid by sanofi-aventis. This settlement was approved by the arbitral tribunal on June 4, 2008 and the corresponding amount was paid by sanofi-aventis to International Chemical Investors on June 12, 2008. This dispute is now considered as closed.

F-94

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008****D.23. Provisions for discounts, rebates and sales returns**

The adjustments between gross sales and net sales, as described in Note B.14., are recognized either as provisions or as reductions in accounts receivable, depending on their nature.

The table below shows movements in these items:

( million)	Government and State programs <sup>(1)</sup>	Managed Care and GPO programs <sup>(2)</sup>	Charge- back incentives	Rebates and discounts	Sales returns	Other deductions	Total
<b>January 1, 2006</b>	<b>260</b>	<b>165</b>	<b>58</b>	<b>147</b>	<b>164</b>	<b>63</b>	<b>857</b>
Current provision related to current period sales	438	304	647	727	201	108	2,425
Net change in provision related to prior period sales	2	(14)	6		10	(34)	(30)
Payments made	(355)	(302)	(644)	(722)	(167)	(84)	(2,274)
Translation differences	(27)	(17)	(6)	(8)	(18)	(6)	(82)
<b>December 31, 2006</b>	<b>318</b>	<b>136</b>	<b>61</b>	<b>144</b>	<b>190</b>	<b>47</b>	<b>896</b>
Current provision related to current period sales	453	329	692	1,195	201	174	3,044
Net change in provision related to prior period sales	(6)	5	(7)	12	5	3	12
Payments made	(502)	(319)	(679)	(906)	(182)	(153)	(2,741)
Translation differences	(21)	(15)	(7)	(8)	(18)	(2)	(71)
<b>December 31, 2007</b>	<b>242</b>	<b>136</b>	<b>60</b>	<b>437</b>	<b>196</b>	<b>69</b>	<b>1,140</b>
Current provision related to current period sales	466	366	751	1,516	173	135	3,407
Net change in provision related to prior period sales	10	(3)	(8)	5	4	(3)	5
Payments made	(442)	(324)	(725)	(1,678)	(193)	(146)	(3,508)
Translation differences	10	10	4	(19)	3	(3)	5
<b>December 31, 2008</b>	<b>286</b>	<b>185</b>	<b>82</b>	<b>261</b>	<b>183</b>	<b>52</b>	<b>1,049</b>

(1) Primarily the U.S. government's Medicare and Medicaid programs.

(2) Rebates and other price reductions, primarily granted to healthcare authorities in the United States.

**D.24. Personnel costs**

Total personnel costs break down as follows:

<i>( million)</i>	Year ended December 31, 2008	Year ended December 31, 2007	Year ended December 31, 2006
Salaries	(4,774)	(4,891)	(4,832)
Social security charges (including defined-contribution pension plans)	(1,451)	(1,462)	(1,253)
Share-based payment	(125)	(115)	(149)
Employee share ownership plan		(21)	
Defined-benefit pension plans	(305)	(346)	(348)
Other employee benefits	(259)	(197)	(370)
<b>Total</b>	<b>(6,914)</b>	<b>(7,032)</b>	<b>(6,952)</b>

The total number of employees at December 31, 2008 was 98,213, compared with 99,495 at December 31, 2007 and 100,289 at December 31, 2006.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

Employee numbers by function at December 31, 2008, 2007 and 2006 were as follows:

	December 31, 2008	December 31, 2007	December 31, 2006
Production	31,903	31,292	31,735
Research and development	18,976	19,310	18,981
Sales force	33,507	35,115	35,902
Marketing and support functions	13,827	13,778	13,671
<b>Total</b>	<b>98,213</b>	<b>99,495</b>	<b>100,289</b>

**D.25. Other operating income**

Other operating income totaled 556 million in 2008, against 522 million in 2007 and 391 million in 2006. This item includes income arising from alliance agreements in pharmaceuticals (472 million in 2008, versus 323 million in 2007 and 382 million in 2006), in particular the alliance with Procter & Gamble Pharmaceuticals for the development and marketing of Actonel® on a worldwide basis, and the Group's share of profits from Copaxone® from April 1, 2008, the date on which the marketing of this product in the United States and Canada reverted to Teva Pharmaceutical Industries. It also includes net foreign exchange losses on operating items of 94 million in 2008, 33 million in 2007 and 13 million in 2006. Finally, it includes 24 million of proceeds from disposals related to ongoing operations (versus 60 million in 2007).

**D.26. Other operating expenses**

Other operating expenses were 353 million in 2008, compared with 307 million in 2007 and 116 million in 2006. This item includes shares of profits due to alliance partners (other than BMS and Procter & Gamble) under product marketing agreements, primarily in Europe, Japan, the United States and Canada (178 million in 2008, versus 136 million in 2007 and 116 million in 2006). The 2007 figure also includes an expense of 61 million arising from the signature of agreements on welfare and healthcare obligations in France for retirees and their beneficiaries.

In 2008, this item includes an expense of 113 million arising from changes to estimates of future expenditure on environmental risks at sites formerly operated by sanofi-aventis or sold to third parties (see note D.22. (e), *Contingencies arising from certain Business Divestitures*). Reversals of these provisions are classified in **Other operating income** (see Note D.25.).

**D.27. Restructuring costs**

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Restructuring costs recognized in 2008 amounted to 585 million ( 137 million in 2007 and 274 million in 2006), and break down as follows:

<i>( million)</i>	<b>Year ended December 31, 2008</b>	<b>Year ended December 31, 2007</b>	<b>Year ended December 31, 2006</b>
Employee-related expenses	498	137	219
Compensation for early termination of contracts (other than contracts of employment)			16
Abandonment of software			3
Other restructuring costs	87		36
<b>Total</b>	<b>585</b>	<b>137</b>	<b>274</b>

In 2008, restructuring costs related primarily to adaptation of industrial facilities in France and to measures taken by sanofi-aventis to adjust its sales force to reflect changing pharmaceutical market conditions in various European countries mainly France, Italy, Spain and Portugal and in the United States.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

In 2007, restructuring costs related to the cost of measures taken by sanofi-aventis in response to changes in the economic and regulatory environment in France and Germany.

In 2006, the principal item recorded on this line was the cost of measures taken by sanofi-aventis in response to the changing economic environment in Europe, mainly France and Germany ( 176 million). In addition, 98 million of restructuring costs associated with the acquisition of Aventis were recognized in 2006.

**D.28. Gains and losses on disposals, and litigation**

In 2008, this item includes 76 million of reversals of provisions in respect of litigation in the United States on pricing and market practices (see Note D.22. (c), *Government Investigations, Competition Law and Regulatory Claims* ).

Sanofi-aventis made no major divestments in the years ended December 31, 2008 or 2007.

In 2006, this line mainly comprised the 460 million gain on the sale of the Exuber<sup>®</sup> brand, and the 45 million gain on the sale of the residual interest in the Drakkar animal nutrition business.

**D.29. Financial income and expenses**

Financial income and expenses break down as follows:

( million)	Year ended December 31, 2008	Year ended December 31, 2007	Year ended December 31, 2006
Cost of debt <sup>(1)</sup>	(315)	(297)	(356)
Interest income	132	88	81
<b>Cost of debt, net of cash and cash equivalents</b>	<b>(183)</b>	<b>(209)</b>	<b>(275)</b>
Foreign exchange gains (non-operating)	(74)	87	68
Fair value gains/(losses) on other derivatives		4	68
Unwinding of discounting of provisions <sup>(2)</sup>	(37)	(38)	(35)

Edgar Filing: SANOFI-AVENTIS - Form 20-F

Net gains/(losses) on disposals of financial assets <sup>(3)</sup>	41	7	108
Impairment losses on financial assets, net of reversals <sup>(4)</sup>	(8)	(14)	(38)
Other items	29	24	24
<b>Net financial income/(expenses)</b>	<b>(232)</b>	<b>(139)</b>	<b>(80)</b>
<i>comprising: Financial expenses</i>	<i>(335)</i>	<i>(329)</i>	<i>(455)</i>
<i>Financial income</i>	<i>103</i>	<i>190</i>	<i>375</i>

(1) Includes gains/losses on interest rate derivatives used to hedge debt: 2 million loss in 2008, 13 million gain in 2007, 35 million gain in 2006.

(2) Excluding provisions for pensions and similar obligations.

(3) Includes 38 million from the sale of the investment in Millennium in 2008, and 101 million from the sale of the investment in Rhodia in 2006 (see Note D.7.).

(4) Primarily available-for-sale financial assets.

The impact of the ineffective portion of hedging relationships was not material in 2008, 2007 or 2006.

F-97

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008****D.30. Income tax expense**

The Group has opted for tax consolidations in a number of countries, principally France, Germany, the United Kingdom and the United States.

The table below shows the split of income tax expense between current and deferred taxes:

<i>( million)</i>	Year ended December 31, 2008	Year ended December 31, 2007	Year ended December 31, 2006
Current taxes	(2,140)	(2,162)	(3,276)
Deferred taxes	1,458	1,475	2,476
<b>Total</b>	<b>(682)</b>	<b>(687)</b>	<b>(800)</b>

The difference between the effective tax rate and the standard corporate income tax rate applicable in France is explained as follows:

<i>(as a percentage)</i>	Year ended December 31, 2008	Year ended December 31, 2007	Year ended December 31, 2006
Standard tax rate applicable in France	34	34	34
Impact of reduced-rate income tax on royalties in France	(12)	(8)	(10)
Impact of changes in tax rates in France (including reduced rate on capital gains)			(2)
Impact of the reduction in net deferred tax liabilities as a result of changes in tax rates <sup>(1)</sup>		(9)	(1)
Impact of tax borne by BMS for the territory managed by sanofi-aventis (see Note D.32.)	(4)	(3)	(3)
Other	(2)	(2)	(1)
<b>Effective tax rate</b>	<b>16</b>	<b>12</b>	<b>17</b>

<sup>(1)</sup> Primarily Germany in 2007: reduction from 40% to 31.3%

Because the tax impact of royalties has remained relatively static since 2006, the change in the Impact of reduced-rate income tax on royalties in France line is due mainly to the significant fall in pre-tax profits in 2008 relative to 2007, and conversely the rise in pre-tax profits in 2007 relative to 2006.



The Other line includes (i) the difference between the tax rate applicable in France and tax rates applicable in other countries, (ii) the impact of reassessing certain of the Group's tax exposures and (iii) the impact on the effective tax rate of amortization and impairment charged against intangibles.

#### **D.31. Share of profit/loss of associates**

This item mainly comprises the share of co-promotion profits attributable to sanofi-aventis for territories covered by entities majority-owned by BMS (see Note C.1.). The impact of the BMS alliance in 2008 was 984 million, before deducting the tax effect of 361 million (2007:

816 million, tax effect 290 million; 2006: 498 million, tax effect 178 million). The reduction in the share of profits recognized in 2006 was directly related to the at risk launch by Apotex of a generic of Plavix in the United States (see Note D.22.b).

It also includes the share of profits from other associates ( 189 million in 2008, 71 million in 2007 and 131 million in 2006). These figures include the effect of the Aventis acquisition (workdown of acquired inventories, amortization and impairment of intangible assets). The 2007 figure includes an impairment loss of 102 million on the equity-accounted investment in Zentiva (see Note D.6.).

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008****D.32. Net income attributable to minority interests**

This line includes the share of co-promotion profits attributable to BMS for territories covered by entities majority-owned by sanofi-aventis (see Note C.1.). The amount involved was 422 million in 2008, 403 million in 2007 and 375 million in 2006. There is no tax effect, because BMS receives its share before tax.

It also includes the share of net income attributable to the other minority shareholders ( 19 million in 2008, 16 million in 2007 and 18 million in 2006).

**D.33. Related party transactions**

The principal related parties of sanofi-aventis are companies over which the Group has significant influence, as well as joint ventures, key management personnel, and principal shareholders.

The Group has not entered into any transactions with any key management personnel. Financial relations with the Group's principal shareholders, in particular the Total group, fall within the ordinary course of business and were immaterial as of December 31, 2008, December 31, 2007 and December 31, 2006.

Details of transactions with related companies are disclosed in Note D.6.

Key management personnel comprise corporate officers (including 4 directors covered by supplementary pension plans, see Item 6.B.) and the members of the Management Committee (22 members during 2008, 21 members during 2007 and 23 members during 2006).

The table below shows, by type, the compensation paid to key management personnel:

<i>( million)</i>	<b>Year ended December 31, 2008</b>	<b>Year ended December 31, 2007</b>	<b>Year ended December 31, 2006</b>
Short-term benefits <sup>(1)</sup>	37	30	27
Post-employment benefits <sup>(2)</sup>	16	14	13
Share-based payment <sup>(3)</sup>	11	12	12

<b>Total recognized in the income statement</b>	<b>64</b>	<b>56</b>	<b>52</b>
---	-----------	-----------	-----------

—

- (1) Compensation, employer's social security contributions, directors' attendance fees, and any termination benefits.
- (2) Estimated pension cost, calculated in accordance with IAS 19.
- (3) Stock option expense computed using the Black-Scholes model, plus expense relating to the discount arising under the 2007 and 2005 employee share ownership plans

The aggregate amount of supplementary pension obligations to corporate officers and key management personnel was 183 million at December 31, 2008, versus 163 million at December 31, 2007 and 172 million at December 31, 2006. The aggregate amount of lump-sum retirement benefits payable to corporate officers and key management personnel was 10 million at December 31, 2008, versus 12 million euros at December 31, 2007 and December 31, 2006.

#### D.34. Split of net sales

Credit risk is the risk that customers (wholesalers, distributors, pharmacies, hospitals, clinics or government agencies) may fail to pay their debts. The Group manages credit risk by pre-vetting customers in order to set credit limits and risk levels and asking for guarantees where necessary, performing controls, and monitoring qualitative and quantitative indicators of accounts receivable balances such as the period of credit taken and overdue payments.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Year ended December 31, 2008**

Customer credit risk also arises as a result of the concentration of the Group's sales with its largest customers, in particular certain wholesalers in the United States. The Group's three largest customers accounted respectively for 8.7%, 8.3% and 7.7% of gross sales in 2008.

**D.35. Segment information**

**D.35.1. Business segments**

The Group has two business segments: Pharmaceuticals and Vaccines. Investments in all associates and joint ventures are included in the Pharmaceuticals segment with one principal exception: the Sanofi Pasteur MSD joint venture, which is included in the Vaccines segment.

***Adjusted net income***

Adjusted net income, reported in segment information, is an internal performance indicator defined as net income attributable to equity holders of the Company, adjusted for the material impacts of the application of purchase accounting to acquisitions (primarily the acquisition of Aventis) and for certain restructuring costs associated with acquisitions.

Management uses adjusted net income as an internal performance indicator, as a significant factor in determining variable compensation, and as a basis for determining dividend policy.

The main adjustments between net income attributable to equity holders of the Company and adjusted net income are:

elimination of expenses arising on the workdown of acquired inventories remeasured at fair value, net of tax;

elimination of expenses arising on amortization and impairment of intangible assets acquired in business combinations (acquired in-process R&D and acquired product rights), net of tax (portion attributable to equity holders of the Company);

elimination of expenses arising from the impact of acquisitions on associates (workdown of acquired inventories, amortization and impairment of intangible assets, and impairment of goodwill);

Edgar Filing: SANOFI-AVENTIS - Form 20-F

elimination of any impairment of goodwill.

Sanofi-aventis also excludes from adjusted net income integration and restructuring costs (net of tax) incurred specifically in connection with acquisitions.

F-100

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

Adjusted net income breaks down as follows:

<i>( million)</i>	Year ended December 31, 2008	Year ended December 31, 2007	Year ended December 31, 2006
<b>Net income attributable to equity holders of the Company</b>	<b>3,851</b>	<b>5,263</b>	<b>4,006</b>
<b>Material accounting adjustments related to business combinations:</b>	<b>3,217</b>	<b>1,847</b>	<b>2,969</b>
elimination of expenses arising on the workdown of acquired inventories remeasured at fair value, net of tax	2 <sup>(1)</sup>		21
elimination of expenses arising on amortization and impairment of intangible assets, net of tax (portion attributable to equity holders of the company)	3,137 <sup>(2)</sup>	1,684 <sup>(3)</sup>	2,935
elimination of expenses arising from the impact of acquisitions on associates (workdown of acquired inventories, amortization and impairment of intangible assets, and impairment of goodwill)	78 <sup>(4)</sup>	163 <sup>(4)</sup>	13 <sup>(5)</sup>
elimination of impairment of goodwill			
<b>Elimination of acquisition-related integration and restructuring charges, net of tax</b>			<b>65</b>
<b>Adjusted net income</b>	<b>7,068</b>	<b>7,110</b>	<b>7,040</b>
of which Pharmaceuticals	6,455	6,501	6,479
of which Vaccines	613	609	561

<sup>(1)</sup> Impact of the acquisition of Symbion Consumer (see Note D.1.).<sup>(2)</sup> Includes 1,485 million (see Note D.5.) of impairment losses on Aventis intangible assets ( 972 million after tax).<sup>(3)</sup> Includes a gain of 566 million due to the effect of tax rate reductions, primarily in Germany, on deferred tax liabilities recognized in 2004 on the remeasurement of acquired intangible assets of Aventis.<sup>(4)</sup> Includes the impact of the Zentiva acquisition: 3 million in 2008, and 108 million in 2007 (including an impairment loss of 102 million).<sup>(5)</sup> Includes the impact of the acquisition of Zentiva ( 11 million); amortization and impairment, net of tax, associated with the acquisition of Aventis ( 97 million); and reversal of a deferred tax liability relating to the investment in Merial ( 95 million).

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008****Income statement information by business segment**

Net sales of sanofi-aventis comprise net sales generated by the Pharmaceuticals segment and net sales generated by the Vaccines segment. The table below shows net sales of the top 15 products of the Pharmaceuticals segment:

<i>( million)</i> Product	Indication	Year ended December 31,		
		2008	2007	2006
Lovenox <sup>®</sup>	Thrombosis	2,738	2,612	2,435
Plavix <sup>®</sup>	Atherothrombosis	2,616	2,424	2,229
Lantus <sup>®</sup>	Diabetes	2,450	2,031	1,666
Taxotere <sup>®</sup>	Breast cancer, lung cancer, prostate cancer, stomach cancer, head & neck cancer	2,033	1,874	1,752
Eloxatine <sup>®</sup>	Colorectal cancer	1,348	1,521	1,693
Aprovel <sup>®</sup> /CoAprovel <sup>®</sup>	Hypertension	1,202	1,080	1,015
Stilnox <sup>®</sup> /Ambien <sup>®</sup> /Myslee <sup>®</sup>	Insomnia	829	1,250	2,026
Allegra <sup>®</sup>	Allergic rhinitis, urticaria	688	706	688
Copaxone <sup>®</sup>	Multiple sclerosis	622	1,177	1,069
Tritace <sup>®</sup>	Hypertension, congestive heart failure after myocardial infarction	513	741	977
Amaryl <sup>®</sup>	Diabetes	387	392	451
Xatral <sup>®</sup>	Benign prostatic hyperplasia	331	333	353
Actonel <sup>®</sup>	Osteoporosis	330	320	351
Depakine <sup>®</sup>	Epilepsy	329	316	301
Nasacort <sup>®</sup>	Allergic rhinitis	241	294	283
<b>Sub-total: top 15 products</b>		<b>16,657</b>	<b>17,071</b>	<b>17,289</b>
Other products		8,050	8,203	8,551
<b>Total: Pharmaceuticals segment</b>		<b>24,707</b>	<b>25,274</b>	<b>25,840</b>

Net sales by range of products recorded for the Vaccines segment are shown below:

<i>( million)</i>	Year ended December 31,		
	2008	2007	2006
Pediatric Combination and Poliomyelitis Vaccines	768	660	633
Influenza Vaccines*	736	766	835
Meningitis/Pneumonia Vaccines	472	482	310
Adult and Adolescent Booster Vaccines	399	402	337
Travel and Endemic Vaccines	309	327	284
Other Vaccines	177	141	134

<b>Total: Vaccines segment</b>	<b>2,861</b>	<b>2,778</b>	<b>2,533</b>
--------------------------------	--------------	--------------	--------------

\* Seasonal and pandemic influenza vaccines.

F-102



**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

The table below shows the principal income statement indicators by business segment:

( million)	Year ended December 31, 2008			Year ended December 31, 2007			Year ended December 31, 2006		
	Pharma- ceuticals	Vaccines	Sanofi- aventis consolidated	Pharma- ceuticals	Vaccines	Sanofi- aventis consolidated	Pharma- ceuticals	Vaccines	Sanofi- aventis consolidated
Net sales	24,707	2,861	27,568	25,274	2,778	28,052	25,840	2,533	28,373
Other revenues	1,208	41	1,249	1,085	70	1,155	1,045	71	1,116
Research and development expenses	(4,150)	(425)	(4,575)	(4,108)	(429)	(4,537)	(4,035)	(395)	(4,430)
Selling and general expenses	(6,648)	(520)	(7,168)	(7,032)	(522)	(7,554)	(7,515)	(505)	(8,020)
Amortization of intangibles	(3,222)	(261)	(3,483)	(3,383)	(271)	(3,654)	(3,707)	(291)	(3,998)
Operating income before restructuring, impairment of property, plant and equipment and intangibles, gains and losses on disposals, and litigation	5,864	593	6,457	5,509	597	6,106	5,217	512	5,729
Impairment of property, plant and equipment and intangibles	(1,554)		(1,554)	(58)		(58)	(1,162)	(1)	(1,163)
Operating income	3,801	593	4,394	5,314	597	5,911	4,318	510	4,828
Financial expenses	(313)	(22)	(335)	(326)	(3)	(329)	(450)	(5)	(455)
Financial income	89	14	103	179	11	190	374	1	375
Income tax expense	(516)	(166)	(682)	(518)	(169)	(687)	(660)	(140)	(800)
Share of profit/loss of associates <sup>(1)</sup>	809	3	812	621	(24)	597	459	(8)	451
<b>Net income</b>	<b>3,870</b>	<b>422</b>	<b>4,292</b>	<b>5,270</b>	<b>412</b>	<b>5,682</b>	<b>4,041</b>	<b>358</b>	<b>4,399</b>
Attributable to minority interests	441		441	419		419	392	1	393
<b>Attributable to equity holders of the Company</b>	<b>3,429</b>	<b>422</b>	<b>3,851</b>	<b>4,851</b>	<b>412</b>	<b>5,263</b>	<b>3,649</b>	<b>357</b>	<b>4,006</b>

<sup>(1)</sup> Financial information for associates is included in the Pharmaceuticals segment, except for associates specifically involved in the Vaccines business.

Inter-segment transactions are not material. Transfer prices between segments are determined on an arm's length basis.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008****Assets and liabilities by segment**

Assets and liabilities by segment are as follows:

( million)	December 31, 2008			December 31, 2007			December 31, 2006		
	Pharma- ceuticals	Vaccines	Sanofi- aventis consolidated	Pharma- ceuticals	Vaccines	Sanofi- aventis consolidated	Pharma- ceuticals	Vaccines	Sanofi- aventis consolidated
Investments in associates <sup>(1)</sup>	2,028	431	<b>2,459</b>	2,022	471	<b>2,493</b>	2,132	505	<b>2,637</b>
Segmental assets	55,358	6,518	<b>61,876</b>	58,524	5,734	<b>64,258</b>	64,072	5,999	<b>70,071</b>
Unallocated assets <sup>(2)</sup>			<b>7,652</b>			<b>5,163</b>			<b>5,055</b>
<b>Total assets</b>	<b>57,386</b>	<b>6,949</b>	<b>71,987</b>	<b>60,546</b>	<b>6,205</b>	<b>71,914</b>	<b>66,204</b>	<b>6,504</b>	<b>77,763</b>
Acquisitions of property, plant and equipment and intangible assets	1,192	414	<b>1,606</b>	1,214	396	<b>1,610</b>	1,185	269	<b>1,454</b>
Segmental liabilities	13,856	1,078	<b>14,934</b>	13,073	965	<b>14,038</b>	14,421	994	<b>15,415</b>
Unallocated liabilities <sup>(3)</sup>			<b>11,982</b>			<b>13,157</b>			<b>16,528</b>
<b>Total liabilities</b>	<b>13,856</b>	<b>1,078</b>	<b>26,916</b>	<b>13,073</b>	<b>965</b>	<b>27,195</b>	<b>14,421</b>	<b>994</b>	<b>31,943</b>

(1) Financial information for associates is included in the Pharmaceuticals segment, except for associates specifically involved in the Vaccines business.

(2) Unallocated assets mainly comprise:

- Deferred tax assets of 2,920 million at December 31, 2008 ( 2,912 million at December 31, 2007, 3,492 million at December 31, 2006); and
- Cash and cash equivalents of 4,226 million at December 31, 2008 ( 1,711 million at December 31, 2007, 1,153 million at December 31, 2006).

(3) Unallocated liabilities mainly comprise:

- Deferred tax liabilities of 5,668 million at December 31, 2008 ( 6,935 million at December 31, 2007, 9,246 million at December 31, 2006); and
- 6,006 million of debt at December 31, 2008 ( 5,941 million at December 31, 2007, 6,944 million at December 31, 2006).

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008****D.35.2. Information by geographical segment**

Information by geographical segment for the year ended December 31, 2008 is as follows:

<i>( million)</i>	<b>Total</b>	<b>Europe</b>	<b>United States</b>	<b>Other countries</b>	<b>Unallocated costs <sup>(1)</sup></b>
Net sales	<b>27,568</b>	12,096	8,609	6,863	
Operating income before restructuring, impairment of property, plant and equipment and intangibles, gains and losses on disposals, and litigation <sup>(2)</sup>	<b>6,457</b>	5,001	4,718	2,454	(5,716)
Acquisitions of property, plant and equipment and intangible assets	<b>1,606</b>	1,062	237	307	
Total assets	<b>71,987</b>	35,826	23,395	12,766	
<i>Of which non-current assets other than deferred tax assets <sup>(3)</sup></i>	<b>53,664</b>	24,262	20,517	8,885	

<sup>(1)</sup> Unallocated costs consist mainly of fundamental research and worldwide development of pharmaceutical molecules, and part of the cost of support functions.<sup>(2)</sup> After amortization of intangible assets ( 3,483 million).<sup>(3)</sup> Includes goodwill of 28,163 million and intangible assets of 15,260 million.

Information by geographical segment for the year ended December 31, 2007 is as follows:

<i>( million)</i>	<b>Total</b>	<b>Europe</b>	<b>United States</b>	<b>Other countries</b>	<b>Unallocated costs <sup>(1)</sup></b>
Net sales	<b>28,052</b>	12,184	9,474	6,394	
Operating income before restructuring, impairment of property, plant and equipment and intangibles, gains and losses on disposals, and litigation <sup>(2)</sup>	<b>6,106</b>	4,742	4,952	2,173	(5,761)
Acquisitions of property, plant and equipment and intangible assets	<b>1,610</b>	1,178	316	116	
Total assets	<b>71,914</b>	35,356	23,744	12,814	
<i>Of which non-current assets other than deferred tax assets <sup>(3)</sup></i>	<b>56,449</b>	25,912	21,129	9,408	

<sup>(1)</sup> Unallocated costs consist mainly of fundamental research and worldwide development of pharmaceutical molecules, and part of the cost of support functions.<sup>(2)</sup> After amortization of intangible assets ( 3,654 million).<sup>(3)</sup> Includes goodwill of 27,199 million and intangible assets of 19,182 million.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

Information by geographical segment for the year ended December 31, 2006 is as follows:

( million)	Total	Europe	United States	Other countries	Unallocated costs <sup>(1)</sup>
Net sales	28,373	12,219	9,966	6,188	
Operating income before restructuring, impairment of property, plant and equipment and intangibles, gains and losses on disposals, and litigation <sup>(2)</sup>	5,729	4,603	4,560	2,082	(5,516)
Acquisitions of property, plant and equipment and intangible assets	1,454	1,072	246	136	
Total assets	77,763	35,742	28,808	13,213	
<i>Of which non-current assets other than deferred tax assets <sup>(3)</sup></i>	<b>62,111</b>	<b>26,734</b>	<b>25,436</b>	<b>9,941</b>	

(1) Unallocated costs consist mainly of fundamental research and worldwide development of pharmaceutical molecules, and part of the cost of support functions.

(2) After amortization of intangible assets ( 3,998 million).

(3) Includes goodwill of 28,472 million and intangible assets of 23,738 million.

**E. PRINCIPAL ACCOUNTANTS FEES AND SERVICES**

PricewaterhouseCoopers Audit and Ernst & Young Audit served as independent auditors of sanofi-aventis, for the year ended December 31, 2008 and for all other reporting periods covered by this annual report on Form 20-F. The table below shows fees paid to these firms and member firms of their networks by sanofi-aventis and other consolidated companies in the years ended December 31, 2008 and 2007:

( million)	Ernst & Young				PricewaterhouseCoopers			
	2008	%	2007	%	2008	%	2007	%
	Amount		Amount		Amount		Amount	
<b>Audit</b>								
<b>Audit opinion, review of statutory and consolidated financial statements <sup>(1)</sup></b>	<b>11.7</b>	<b>94%</b>	<b>12.3</b>	<b>99%</b>	<b>12.2</b>	<b>99%</b>	<b>12.7</b>	<b>99%</b>
- of which sanofi-aventis	4.1		4.2		4.1		4.2	
- of which consolidated subsidiaries	7.6		8.1		8.1		8.5	
<b>Other audit-related services <sup>(2)</sup></b>	<b>0.7</b>	<b>6%</b>	<b>0.2</b>	<b>1%</b>	<b>0.1</b>	<b>1%</b>	<b>0.1</b>	<b>1%</b>
- of which sanofi-aventis	0.7		0.2		0.1		0.1	
- of which consolidated subsidiaries	0.7		0.2		0.1		0.1	
<b>Sub-total</b>	<b>12.4</b>	<b>100%</b>	<b>12.5</b>	<b>100%</b>	<b>12.3</b>	<b>100%</b>	<b>12.8</b>	<b>100%</b>
<b>Non-audit services</b>								
Tax								
Other								
<b>Sub-total</b>								
<b>TOTAL</b>	<b>12.4</b>	<b>100%</b>	<b>12.5</b>	<b>100%</b>	<b>12.3</b>	<b>100%</b>	<b>12.8</b>	<b>100%</b>

- (1) Professional services rendered for the audit and review of the consolidated financial statements of sanofi-aventis, statutory audits of the financial statements of sanofi-aventis and its subsidiaries, compliance with local regulations, and review of documents filed with the AMF and the SEC (including services normally provided by independent experts of the audit firms in connection with the audit).
- (2) Services that are normally performed by the independent accountants, ancillary to audit services.

**Audit Committee Pre-approval and Procedures**

The Group Audit Committee has adopted a policy and established certain procedures for the pre-approval of audit and other permitted audit-related services, and for the pre-approval of permitted non-audit services to be provided by the independent auditors. In 2008, the Audit Committee established a budget breaking down permitted audit-related services and non-audit services, and the related fees to be paid.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008****F. LIST OF PRINCIPAL COMPANIES INCLUDED IN THE CONSOLIDATION FOR THE YEAR ENDED DECEMBER 31, 2008****F.1. Principal fully-consolidated companies**

The principal companies in the Group's areas of operations and business segments are:

		<b>Financial interest %</b>
<i>Europe</i>		
Sanofi-Aventis Deutschland GmbH	Germany	100
Hoechst GmbH	Germany	100
Winthrop Arzneimittel GmbH	Germany	100
Sanofi-Aventis GesmbH / Bristol-Myers Squibb GesmbH OHG <sup>(1)</sup>	Austria	51
Sanofi-Aventis GmbH	Austria	100
Sanofi-Aventis Belgium	Belgium	100
Sanofi-Aventis Denmark A/S	Denmark	100
Sanofi Winthrop BMS partnership (JV DK) <sup>(1)</sup>	Denmark	51
Sanofi-Aventis SA	Spain	100
Sanofi Winthrop BMS partnership <sup>(1)</sup>	Finland	51
Sanofi-Aventis Finland OY	Finland	100
Sanofi-Aventis Europe S.A.S.	France	100
Sanofi-Aventis Participations S.A.S.	France	100
Sanofi-Aventis Amérique du Nord S.N.C.	France	100
Sanofi Pasteur Holding S.A.	France	100
Aventis Pharma S.A.	France	100
Sanofi Pasteur S.A.	France	100
Aventis Agriculture S.A.	France	100
Francopia S.A.R.L.	France	100
Winthrop Médicaments S.A.	France	100
Sanofi Chimie S.A.	France	100
Sanofi Participations S.A.S.	France	100
Sanofi Pharma Bristol-Myers Squibb S.N.C. <sup>(1)</sup>	France	51
Sanofi-Aventis S.A.	France	100
Sanofi-Aventis France S.A.	France	100
Sanofi-Aventis Groupe S.A.	France	100
Sanofi-Aventis Recherche et Développement S.A.	France	100
Sanofi Winthrop Industrie S.A.	France	100
Sanofi-Aventis Greece	Greece	100
Chinoin Pharmaceutical and Chemical Works Co Ltd	Hungary	100
Sanofi-Aventis ZRT	Hungary	100
Cahir Insurance Ltd	Ireland	100
Carraig Insurance Ltd	Ireland	100
Sanofi-Aventis Ireland Ltd	Ireland	100
Sanofi-Aventis Spa	Italy	100

## Edgar Filing: SANOFI-AVENTIS - Form 20-F

Sanofi-Aventis AS	Norway	100
Sanofi Winthrop BMS partnership ANS <sup>(1)</sup>	Norway	51
Sanofi-Aventis Netherland BV	Netherlands	100
Sanofi Winthrop BMS VOF <sup>(1)</sup>	Netherlands	51
Sanofi-Aventis Sp Zoo	Poland	100
Winthrop Farmaceutica Portugal Lda	Portugal	100
Sanofi-Aventis Produtos Farmaceuticos SA	Portugal	100
Sanofi Winthrop BMS AEIE <sup>(1)</sup>	Portugal	51
Sanofi-Aventis sro	Czech Republic	100
Aventis Pharma UK Ltd	United Kingdom	100

<sup>(1)</sup> Partnership with Bristol-Myers Squibb (see Note C.1.).

F-107

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

		<b>Financial interest %</b>
<i>Europe</i>		
Sanofi Pasteur Holding Limited	United Kingdom	100
Sanofi-Synthélabo Ltd	United Kingdom	100
Sanofi-Synthélabo UK Ltd	United Kingdom	100
Winthrop Pharmaceuticals UK Ltd	United Kingdom	100
Fisons Limited	United Kingdom	100
May and Baker Limited	United Kingdom	100
Aventis Pharma ZAO	Russia	100
Sanofi-aventis Pharma Slovakia s.r.o	Slovakia	100
Sanofi-Aventis AB	Sweden	100
Sanofi SA-AG	Switzerland	100
Sanofi-Aventis (Suisse) SA	Switzerland	100
Sanofi-Synthélabo CIS & Eastern countries SA	Switzerland	100
Sanofi-Aventis Ilaclari Ltd Sirketi	Turkey	100
Winthrop Ilac AS	Turkey	100
Sanofi-Synthélabo Ilac AS	Turkey	100
Sanofi-Synthélabo BMS ADI Ortakligi partnership <sup>(1)</sup>	Turkey	51
Sanofi-aventis Ukraine LLC	Ukraine	100

(1) Partnership with Bristol-Myers Squibb (see Note C.1.).

		<b>Financial interest %</b>
<i>United States</i>		
Armour Pharmaceuticals C.	United States	100
Aventis Inc.	United States	100
Aventisub Inc.	United States	100
Aventis Holdings Inc.	United States	100
Aventis Pharmaceuticals Inc.	United States	100
Carderm Capital L.P.	United States	100
Sanofi-Aventis US Inc.	United States	100
Sanofi-Aventis US LLC.	United States	100
Sanofi Pasteur Biologics Co.	United States	100
Sanofi Pasteur Inc.	United States	100
Sanofi-Synthélabo Inc.	United States	100
Vaxserve Inc.	United States	100

		<b>Financial interest %</b>
<i>Other Countries</i>		
Sanofi-Aventis South Africa (Pty) Ltd	South Africa	100
Winthrop Pharmaceuticals (Pty) Ltd	South Africa	100
Pharmachoice	South Africa	100
Winthrop Pharma Saïdal	Algeria	70
Sanofi-Aventis Algérie	Algeria	100
Aventis Pharma (Argentina) S.A.	Argentina	100
Sanofi-Aventis Australia Pty Limited	Australia	100



Edgar Filing: SANOFI-AVENTIS - Form 20-F

Symbion CP Holdings Pty Ltd	Australia	100
MCP Operations Pty Ltd	Australia	100
Bullivant s Natural Health Products (International) Pty Ltd	Australia	100
Bullivant s Natural Health Products Pty Ltd	Australia	100
Cenovis Pty Ltd	Australia	100
MCP Direct Pty Ltd	Australia	100

F-108

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008**

		<b>Financial interest %</b>
<i>Other Countries</i>		
Carlson Health Pty Ltd	Australia	100
Sanofi-Aventis Farmaceutica Ltda	Brazil	100
Sanofi Pasteur Ltd	Canada	100
Sanofi-Aventis Canada Inc.	Canada	100
Sanofi-Aventis de Chili SA	Chile	100
Sanofi-aventis Pharma Beijing (China)	China	100
Hangzhou Sanofi-aventis Minsheng Pharmaceuticals Co Ltd	China	98
Shenzhen Sanofi pasteur Biological Products Co Ltd	China	100
Winthrop Pharmaceuticals de Colombie SA	Colombia	100
Sanofi-Aventis de Colombia SA	Colombia	100
Sanofi-Aventis Korea Co Ltd	Korea	91
Sanofi-aventis Gulf F.Z.E	United Arab Emirates	100
Sanofi-Aventis SAE Egypt	Egypt	100
Sanofi-Aventis del Ecuador SA	Ecuador	100
Sanofi-aventis de Guatemala	Guatemala	100
Sanofi-Aventis Hong Kong Limited	Hong Kong	100
Sanofi-Synthélabo (India) Ltd	India	100
Aventis Pharma Limited (India)	India	50.1
PT Sanofi-Aventis Indonesia	Indonesia	100
PT Aventis Pharma (Indonesia)	Indonesia	75
Sanofi-Aventis K.K.	Japan	100
Sanofi-Aventis Meiji Pharmaceuticals Co Ltd	Japan	51
Winthrop Pharmaceutical Japan Co Ltd	Japan	100
Sanofi-Aventis Yamanouchi Pharma. K.K.	Japan	51
Winthrop Pharmaceuticals SDN-BHD	Malaysia	100
Sanofi-Aventis SDN-BHD	Malaysia	100
Maphar	Morocco	81
Sanofi-Aventis (Morocco)	Morocco	100
Sanofi-Aventis de Mexico SA de CV	Mexico	100
Sanofi-Aventis Winthrop SA de CV	Mexico	100
Winthrop Pharmaceuticals de Mexico SA de CV	Mexico	100
Symbion Consumer Products (NZ) Ltd	New Zealand	100
Sanofi-Aventis Pakistan Limited	Pakistan	53
Sanofi-Aventis de Panama SA	Panama	100
Sanofi-Aventis del Peru SA	Peru	100
Sanofi-Aventis Philippines Inc.	Philippines	100
Sanofi-Aventis de la Rep Dominicana	Dominican Republic	100
Aventis Pharma Manufacturing	Singapore	100
Sanofi-Aventis Singapore Pte Ltd	Singapore	100
Sanofi-Aventis Taiwan Co Ltd	Taiwan	100
Sanofi-Synthélabo (Thailand) Ltd	Thailand	100
Sanofi-Aventis Thailand Ltd	Thailand	100
Sanofi Aventis Pharma Tunisie	Tunisia	100
Winthrop Pharma Tunisie	Tunisia	100
Sanofi-Aventis de Venezuela SA	Venezuela	100
Sanofi-Synthélabo Vietnam	Vietnam	70
Sanofi-Aventis Vietnam	Vietnam	100



**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Year ended December 31, 2008****F.2. Principal associates**

		<b>Financial interest %</b>
InfraServ Höchst	Germany	30
Bristol-Myers Squibb / Sanofi Canada Partnership	Canada	49.9
Bristol-Myers Squibb / Sanofi Pharmaceuticals Holding Partnership	United States	49.9
Bristol-Myers Squibb / Sanofi Pharmaceuticals Partnership	United States	49.9
Bristol-Myers Squibb / Sanofi Pharmaceuticals Partnership Puerto Rico	United States	49.9
Bristol-Myers Squibb / Sanofi-Synthelabo Partnership	United States	49.9
Bristol-Myers Squibb / Sanofi-Synthelabo Puerto Rico Partnership	United States	49.9
Sanofi Pasteur MSD SNC	France	50
Société Financière des Laboratoires de Cosmétologie Yves Rocher	France	39
Zentiva	Czech Republic	24.9
Merial	United Kingdom	50

F-110